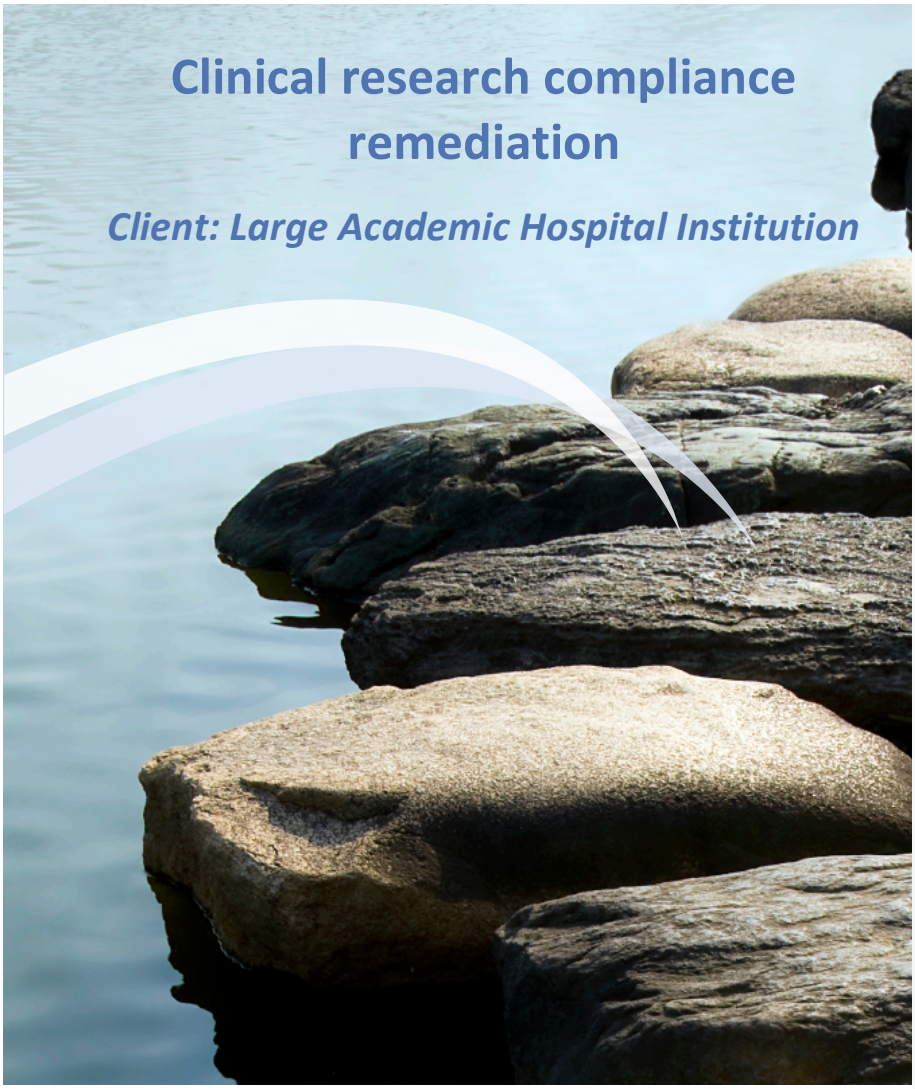
Clinical research compliance remediation

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™

Company Overview

Pearl Pathways is obsessed with accelerating life science product development for our clients. We are an extension of our clients' teams. We partner with the clinical team, in-house regulatory experts, the quality compliance specialists, the quality auditors, and the senior leadership team to get lifesaving 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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