CASE STUDY

Multi-Center Device Trial

Client: Large Multi-National Medical Device Company

SITUATION

A large medical device company contacted Pearl IRB to assist them with a post-marketing surveillance study for an implantable device. The scope of the study was to follow patients post-surgery for ten years tracking outcomes and safety. Pearl staff have noticed a trend of increased post-marketing surveillance studies for implantable devices across the board somewhat driven by pressures from FDA, as well as the market.

SOLUTION

The Pearl IRB Review Board reviewed the study protocol and template informed consent document (ICD).

RESULT

Pearl IRB delivered an initial review in eight (8) business days. Reviews and all follow-up correspondence were performed in a professional and timely fashion. Further, Pearl ReGXP staff has been able to provide expert advice on several regulatory issues and ongoing FDA discussions poised by the sponsor.

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