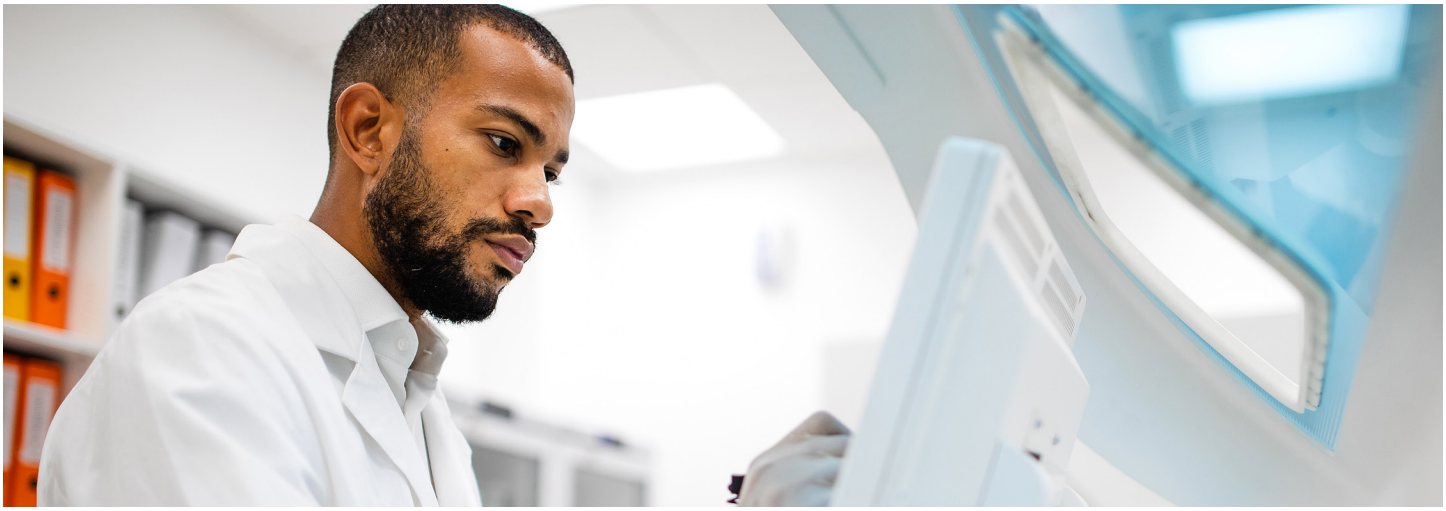
POST-MARKET CASE STUDY: MEDPACE RESCUES STUDY MANAGEMENT FOR OBSERVATIONAL STUDY OF PACEMAKER AND CARDIAC RESYNCHRONIZATION THERAPY DEVICES



BACKGROUND

A large medical device company no longer had enough internal resources to continue to conduct this comprehensive, five year, US-based post-market observational study of pacemaker and cardiac resynchronization therapy devices. In the second year of the study, this sponsor company contracted with Medpace Medical Device to take over clinical trial management.

CHALLENGES

At the time Medpace took over this project, some of the sites were unaware the research study was still ongoing and there were a large number of protocol deviations, a high number of open data queries, poor patient compliance and a high patient attrition rate. The sponsor company was experiencing turnover on their study team so the study lost momentum and lacked continuity.

SOLUTION

Medpace seamlessly transferred site and data management responsibilities for this logistically complex research study which included 140 centers and 3,000 patients in the United States. Working closely with the sponsor, we developed a site-specific transition plan tailored to the needs of each site and dedicated site resources to work closely with the sites to help them understand and adhere to the protocol. We also held coordinator meetings to facilitate open discussions regarding common issues faced at the sites, which proved to be effective in collectively resolving issues and keeping the sites engaged. Medpace focused on data integrity and reviewed very close to 100 percent of data in real time to provide timely feedback to the sites and to proactively address questions.

RESULT:

After Medpace stepped in to get the study back on track, protocol deviations decreased 40% and data query issues also fell by more than 40% after the first year.

DECREASED PROTOCOL DEVIATIONS BY **40%**

REDUCED DATA QUERY ISSUES BY MORE THAN **40%** AFTER THE FIRST YEAR

REDUCED 1,200 OUTSTANDING DATA QUERIES BY **75%** WITHIN THE FIRST THREE MONTHS

PATIENT FOLLOW-UP COMPLIANCE IMPROVED BY **7%**

ACCELERATED DATA ENTRY AND REVIEW TIMELINES — NEARLY **100%** OF ALL DATA WAS REVIEWED IN REAL TIME

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

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