



## CASE STUDY

### Class III Medical Device — Corporate Acquisition & Data Adjudication

**Project Description:** Pivotal study of an implantable device

**Project Objectives:** FDA registration via Premarket Approval (PMA)

**PMI Services:** Clinical site management and monitoring, data management

#### Narrative:

A major medical device company acquired Class III implantable technology undergoing US clinical trials at 16 study sites to support FDA registration. Six hundred evaluable subjects were required. Protocol-specified follow-up for study subjects was 3 years.

Approximately 350 subjects had been enrolled and followed over at least 7 follow-up visits during the first year. Enrollment was on hold, however, pending satisfactory response to FDA questions following an interim progress report.

The objectives of the acquiring company, upon assuming sponsorship of the study, were to:

- Have a smooth transition of documentation and site relationships,
- Maintain study documentation and controls in accordance with generally accepted FDA guidance, and
- Address FDA questions expeditiously so study enrollment could be resumed.

PMI was contracted to transfer and perform limited review of study documentation from the previous sponsor and develop administrative databases to facilitate essential project tracking. PMI was also to provide site management and ongoing monitoring visits, as well as oversight of data management activities performed by the previous sponsor's data management organization.

Soon after initiating work on the project, PMI's client decided that project efficiencies and timelines could be positively impacted by converting data management responsibilities to PMI as well. Resolution of FDA questions was dependent on additional data analysis, so conversion activities had to be completed on a priority basis.

To meet this objective, PMI prepared a new Data Management Plan, developed and validated a new clinical database and imported data from the previous database into the new one. After import, PMI reconciled previously-collected Case Report Forms (CRFs) and Data Clarification Forms (DCFs) versus data line listings in the old and new databases. Additionally, PMI imported critical variable data from an independent reading center. Data inconsistencies and outstanding data were researched and adjudicated.

The entire data conversion program was completed within three months, which gave PMI's client the ability to re-analyze data and return to FDA for further discussion regarding the clinical development program.