Case Study

Global Cardiovascular Medical Device Rescue Trial

IQVIA™ MedTech's rescue team resolves backlogs and gets study timelines back on track

Situation

A global cardiovascular medical device company approached IQVIA MedTech to rescue a clinical trial in progress in nearly 20 countries. The clinical operations team was not happy with its current contract research organization (CRO) and made the decision to transition mid-study. IQVIA was selected to deliver project management, clinical monitoring, document management, vendor management and regulatory services. The sponsor turned to IQVIA MedTech because of our proven expertise in medical device clinical development and particular experience with cardiovascular medical devices.

Challenges

Like all rescue studies, the primary challenge is making a smooth transition for the sponsor and study sites. IQVIA MedTech was jumping into an unknown study where monitoring had been put on hold for nearly a year.

The study was evaluating safety and efficacy of surgery versus a cardiac stent in a select population and planned to enroll more than 2,000 patients at more than 125 medical centers in nearly 20 countries from regions including the U.S., Europe, Asia Pacific, Canada and Latin America. When IQVIA MedTech stepped in, all countries and sites were active. IQVIA MedTech assembled a team to quickly assess the situation and develop a plan to expedite protocol amendment approvals and complete site transitions and country authorizations.

Solution

The IQVIA MedTech team began working immediately to mend relationships with investigators and sites, sending CRAs to visit every site to evaluate its status, begin building relationships and address concerns related to the backlog of data. This task was completed within five months – one month earlier than originally planned.

IQVIA MedTech and the sponsor established strong communication and solid timelines to get the study back on schedule. In an effort to stay within budget, IQVIA MedTech recommended a risk-based monitoring approach that worked well for this study.

Results

At publication, the study is ongoing and has two more years written in the protocol. All sites are active and the sponsor is pleased with IQVIA MedTech's ability to deliver services on-time and on-budget to meet primary endpoint targets.

- The clinical monitors on the study have a solid understanding of running medical device studies and the specific nuances of a cardiovascular device trial
- IQVIA MedTech appointed an internal group of senior executives across clinical operations to support the larger team, provide superior communication with the sponsor, and address challenges quickly and efficiently
- The sponsor and IQVIA MedTech shared an excellent working relationship, collaborating to make decisions quickly and make a smooth transition for active sites
- The sponsor has chosen to award IQVIA MedTech a number of new projects, including several large global cardiovascular studies, some of which have obtained FDA approval

Contact us today to learn how we can drive your medical device product development forward.

"The dedicated medical device team at IQVIA MedTech worked seamlessly to transition our study and provided excellent communication and customer service. They offered flexibility in everything from timelines and budgets to our many meeting requests. After our experience with a generalist CRO, it was a welcome change working with a veteran medical device project manager who understands the nuances of device trials."

— Global Project Manager, Cardiovascular Medical Device Company

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