

Case Study 1: IDE Clinical Study Management

Situation (Discuss)

The client was interested in obtaining clinical monitoring support for a multi-center IDE clinical trial for an anti-obesity device that was being prepared for regulatory submission. The study was already in progress when Magellan first became involved and the client otherwise had a well-staffed internal support team.

Business Recommendation (Design)

Magellan recommended a project team that would both supplement and compliment the client's own internal organization in three important ways: 1) by providing support to study investigators in navigating the IRB process at their respective study centers, 2) by providing locally based surgical case coverage for implants during the clinical trial, and 3) by offering clinical monitoring support at several study sites that could be managed more efficiently and cost effectively by Magellan personnel located in close proximity to study centers.

Magellan Team (Deploy)

The Magellan team was lead by a Clinical Research Manager who also acted as the team's Project Manager. In addition to overseeing the development and management of the clinical field staff, the Clinical Research Manager provided support for and served as a liaison between the client and the study investigator throughout the IRB approval process. The clinical field staff consisted of a team of five Clinical Specialists who provided surgical case coverage, as well as a team of three Clinical Monitors. The entire Magellan field staff was geographically dispersed in order to maximize responsiveness to both the client and study investigators, and to minimize costs. The project management team also included an Executive Sponsor who assisted with project management oversight and ensured quality and consistency throughout the project.

Results (Deliver)

The project produced the following key outcomes for the client:

- A more efficient IRB approval process that required less hand-holding by both the client and the study investigators
- Improved communication with the field, including both client and Magellan personnel
- Superior field support and surgical case coverage
- Reduced travel for clinical monitoring, resulting in more efficient management of both time and expense

Business Impact

Magellan was able to assist the client in completing the clinical study and submitting a PMA application to the FDA in a timely manner. By providing clinical field support during the clinical study Magellan was able to ensure greater clinical consistency throughout the clinical trial and free up internal client resources that were instead available to focus on preparing for the product launch. Most importantly, Magellan was able to provide this higher level of clinical support more efficiently and cost-effectively than the client would have been able to do on its own.

Competencies Demonstrated

Clinical Research (Clinical Monitoring, IRB Process Management, Investigator Training, Surgical Case Coverage)

Go Further™

Magellan Medical Technology Consultants