



## CASE STUDY: Mid-Cap Medical Device Company

### **Client:**

NuVasive, Inc., a medical device company founded in 1997, specializes in the design, research, development and marketing of products to treat spinal disorders. Their goal is to redefine the minimally invasive spine surgery market.

### **Challenges:**

While the client is not a start-up, they are just beginning their venture into clinical trials and have limited resources to devote to the clinical study process. The personnel in the company's clinical research department are best suited to the clinical and regulatory aspect of running clinical studies; not the data management aspect.

### **How We Helped:**

- Analyzed and reconfigured Clinical Data Management System (Medidata Rave) based on specifications created by client
- Managed the data validation process
- Designed and implemented the data management plan and edit check specification
- Facilitated data analysis and designed study outcome reports for the Interim Analysis and Annual Reports used for FDA review
- Trained site coordinators on data management processes and tools; increased quality of data and reduced time spent on data validation
- Worked as a technical liaison with Medidata
- Delivered high quality data within the budget requirements