



## CASE STUDY: Startup Medical Device Company

### **Client:**

Medlogics Device Corporation, founded in 2004, is a biotech startup focused on the development of an effusive stent. The founder of the company left his position as President of an established biotech firm, Bioheart. Medlogics is backed by strong VC funding and is testing its stent internationally.

### **Challenges:**

The client is a startup and has limited resources to devote to the clinical study process. The personnel in the company are best suited to product development, design testing, clinical monitoring and interpreting results; not setting up and running the clinical study, particularly from a data collection standpoint.

### **How We Helped:**

- Configured Clinical Data Management System (Oracle Clinical) based on specifications created by client
- Designed and implemented the data management plan and edit check specification
- Implemented CDMS verification logic for study data entry
- Managed the clinical data collection, data entry, and validation process
- Enabled the Medlogics R&D team to focus its limited resources on high value added activities in the refinement of the product
- Allowed the Medlogics management to focus its energies on running the company, not on clinical trial management