



## Cutting Study Costs With Effective Enrollment Controls

### **Situation: Costly Enrollment Decisions**

A global medical device company developing a new implantable device was entering a Phase III trial involving more than 50 sites, up to 20 countries, with an enrollment target of hundreds of patients. The urgency of the surgical procedure forced the company to make enrollment decisions under considerable time pressure. Each procedure costs thousands of dollars and included months of follow-up work with each patient.

### **Challenge: Costs Can Easily Multiply**

Every non-evaluable study subject represents unnecessary cost. In the context of clinical research, studies indicate that over-enrollment costs study sponsors an average of \$6,100 per patient. Without effective enrollment controls, that cost burden increases as studies get larger and treatments more expensive.

With effective enrollment controls fewer patients exposed to experimental device which lessens study risks. Study costs are also cut due to fewer total treatments, no extra study data to manage, less inventory and inventory management is required, less monitoring and data entry, lower investigator costs (i.e., labs, medical fees, etc.) and a faster study close date.

### **Solution: IVR Essential in Integrated Study Management**

UBC's IVR technologies carefully track patient enrollment during a clinical trial, assist study managers throughout enrollment and prevent over-enrollment. It automatically prevented new patients from being enrolled after site, country and/or overall enrollment targets were reached. The IVR system relieved study coordinators of the need to be "on-call" to relay critical enrollment data and decisions across multiple time zones. It enabled study coordinators to monitor enrollment progress in real-time, providing an additional layer of oversight to a demanding, fast-paced process.

UBC's use of IVR to randomize and carefully track patient enrollment during a clinical trial can assist study managers in managing enrollment and will stop over-enrollment. In addition to providing real-time trial data, UBC's unique monitoring systems provide automatic enrollment closeout when predetermined demographics are reached.

### UBC At-a-Glance

- 1,000 employees
- 30% of employees hold advanced science degrees
- 10% hold PhDs
- > 90% client retention rates
- < 10% employee turnover
- 2,000+ peer-reviewed publications
- 365,000 patients
- 82,000 study sites
- 3,000 clinical protocols
- 20,000 investigators trained in 60 countries

### Technologies

- Interactive voice response systems (IVRS)
- Interactive web response systems (IWRS)
- Dynamic randomization
- Electronic data capture (EDC)
- Electronic patient diaries
- Adaptive trial design and consulting
- Client portals
- Web-based learning management system
- Searchable databases: MetaHub, RaterHub, Site Database

### U.S. Offices

With corporate headquarters in Bethesda, Maryland, we have U.S. offices located in:

- Blue Bell, PA
- Kansas City, MO
- McLean, VA
- Medford, MA
- Morgantown, WV
- Newtown, PA
- San Francisco, CA
- Wayne, PA

### International Offices

- Brussels, Belgium
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*UBC specializes in offering new and innovative ways to study drugs and devices with an emphasis on science, strategy and execution.*

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