



Jump Starting an Expanded Access Trial

Situation: Getting Experimental Drug to Cancer Patients

The sponsor's objectives were three-fold:

- Provide access to an experimental drug for patients whose first-line chemotherapy failed
- Evaluate the drug's safety
- Determine how to transition patients from the study drug to the commercial product

Challenge: Combining Expertise in Trials and Technology

To make this program successful, the sponsor needed to find a partner with expertise in expanded access, oncology drugs, technology and Phase IIIb/IV trials.

To meet the challenge, we brought together a lead scientist and experienced project managers – all of whom have many years on the job – to develop a customized plan.

Solution: Using Tested Systems to Speed Up Site Enrollment

We've learned that the easier the process for sites and physicians, the greater the chances of enrolling sites. So we've developed a system that expedites the process.

How? All our communications center personnel have medical training. At project launch, we bring them together with the whole project team to be sure everyone thoroughly understands the protocol.

As a result, our communication center triages calls effectively, determining quickly whether a prospective site has the right patient population.

Further, our clinical trial management system lets our communications center enter data that is visible by the project manager in real-time. So when a sponsor calls for an update, he can quickly learn, as of that minute, how many sites have inquired, enrolled, received CDAs and so forth.

Finally, we streamline the entire regulatory document collection process by:

- Minimizing the number of documents needed
- Keeping the investigator CV to one page
- Having UBC's regulatory team pre-fill critical forms, saving sites considerable time

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
- Budapest, Hungary
- Cologne, Germany
- London, United Kingdom
- Montreal, Canada
- Moscow, Russia
- Prague, Czech Republic
- Sao Paulo, Brazil

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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