



Patient Registries & Large Streamlined Trials

Real-World Evidence

An increased emphasis on post-approval product safety and real-world effectiveness are at the core of United BioSource Corporation's (UBC) Patient Registries and Large Streamlined Trials (LST) service offering. Whether done at a regulator's request to fulfill a post-approval requirement or initiated by the sponsor to support the product's commercialization, UBC patient registries and LSTs are designed to balance the need for data with the amount of burden placed upon study investigators, all while demonstrating study value on an ongoing basis.

Research Questions that Appeal to a Wide Range of Stakeholders

While traditionally thought of in the context of patient safety, UBC Patient Registries and LSTs are also designed to maximize value to regulators, patients, providers and payers by incorporating multiple research questions in the areas of:

- Product safety
- Clinical Outcomes
- Pregnancy exposure
- Health-related quality of life
- Treatment satisfaction
- Physician decision making
- Compliance and persistence
- Comparative effectiveness

As registries continue to grow both in terms of size and complexity, UBC recognizes that registries can require a significant budget for their ongoing support and that their value must be maximized and constantly demonstrated. UBC works closely with our internal publication planning team, our sponsors and key KOLs in the field to determine the best uses of registry data, beyond meeting a regulatory need, that will support the brand and further justify the value of registry data.

Study Streamlining Practices

UBC understands that acquiring real-world data relies on real-world investigators who typically have little if any research experience. Based on SOPs specifically designed for these programs, UBC is able to support these investigators in a way that provides a positive research experience and further bolsters the sponsor's reputation in the medical community. As much as possible, UBC streamlines study processes, typically in the following ways:

- Minimizing the upfront paperwork required for site participation
- Offering largely non-negotiable site contracts based on data submitted
- Developing multi-modal study training, allowing sites to choose a training method that works for them
- Focusing on targeted data collection and minimizing extraneous data elements
- Judiciously querying data, typically focusing on critical data elements and safety variables
- Relying on remote site management teams and a 'for cause' approach to site monitoring rather than routine on-site monitoring typically used for a standard clinical trial

UBC accelerates the generation, analysis and communication of real-world evidence.

Custom-Designed Technology

UBC employs its proprietary web-based eRegistry application for data collection and management. The eRegistry has the advantage of being able to accept data via multiple means: directly from patients or physicians via the Web, direct double data entry by UBC staff from paper CRFs, input of survey data by a trained interviewer who is administering a questionnaire directly to a respondent, or directly by patients using IVRS/IWRS. It is built on Microsoft .NET technology and has a quick development time for each registry. It has been designed to:

- Collect data as quickly and cleanly as possible with live data verification
- Provide a simple, easy to use and flexible interface for sites or patients to submit data
- Minimize data collection burden on sites
- Interface with all stakeholders engaged in a registry

UBC has added additional support to maintain and develop our technologies used for registry studies, including our proprietary eRegistry product, our IVRS/IWRS product and our internal UBC Track/CTMS. Our technology services now maintain their own dedicated development teams, responsible for ongoing enhancements to the core product, in addition to teams responsible for registry-specific set-up and maintenance.

Dedicated Professionals Defining the Landscape

To support the Patient Registries and LST service offering, UBC has aggressively sought out and recruited the best and the brightest senior-level talent, with lengthy track records in medicine, epidemiology, FDA employment and/or registry operations. UBC has expanded its capabilities and staff in countries outside of the US to meet the increasing demand for global registries, and for programs initiated in EU and other countries.

UBC is also committed to staying well-informed and ahead of the curve in terms of relevant registry legislation, guidance and best practices. We are known for our presence at key scientific meetings, conferences and advisory board meetings, both as speakers and as audience members seeking the most current information.

Registry and Large Streamlined Trial Experience

UBC's experience in the strategic development and execution of large streamlined trials and registries spans four decades, across most all therapeutic categories, in many countries throughout the world. Collectively, our recent registry and large streamlined study experience includes the enrollment of more than 500,000 patients and management of over 100,000 sites.

UBC has the expertise to design the most effective and efficient programs for you, and the staff to implement programs of all sizes. One of our largest programs involved 45,000 patients and 15,000 sites, while the size of our average program is 2,000 sites and 10,000 patients.

Registry Case Studies

Case Study #1: A Ten-Year Observational Study of the Safety of Device X Compared to Device Y and National Norms

Registry Rationale: FDA mandated as a condition of approval for this device

Specifications:

- Countries: US, Canada
- 54,630 patients
- 1,600 sites

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Operational Challenges:

- Investigator enrolls patient and UBC becomes responsible for all patient communication and yearly questionnaire completion (10 year duration)
- Device requirements

Keys to Success:

- Dedicated call center with customized algorithms
- Streamlined and flexible eRegistry system
- Targeted patient recruitment and retention materials

Case Study #2: A Ten-Year Observational Study of Biologic X in Children with Active Juvenile Idiopathic Arthritis (JIA)

Registry Rationale: FDA and EMEA mandated as a condition of approval for this indication

Specifications:

- Countries: US, Austria, Czech Republic, Denmark, France, Germany, Greece, Italy, Portugal, Slovakia, Spain and Sweden
- 800 patients
- 130 sites

Operational Challenges:

- Complicated patient population and care management
- Limited prescribing
- Transitioning of patient care over a long period
- Sponsor is running study under the IND

Keys to Success:

- Establishing a strong relationship early on with sponsor affiliates
- Global perspective on project management
- Targeted patient recruitment and retention materials
- Long term view of optimal data collection

Case Study #3: A Comparative Safety Study of an Influenza A H1N1 Vaccine in Pregnant Women vs. Non-Vaccinated Pregnant Women

Registry Rationale: EMEA mandated a pregnancy registry of this vaccine, given the recent H1N1 pandemic crisis

Specifications:

- Countries: Italy, the Netherlands, Argentina
- 4,056 patients for 2,434 birth outcomes
- Study in progress, total number of sites to be determined

Operational Challenges:

- Complicated pattern of prenatal care in the Netherlands
- Speed and complexity associated with EMEA requirements
- Extremely research naive investigators
- Lengthy and often non-sequential start-up processes in Italy and Argentina

Keys to Success:

- Expanded project team with expertise in each country of interest
- On the ground resources in each country
- Multiple modes for training
- Supportive approach to sites to enhance patient enrollment

UBC At-a-Glance

- 1,500+ employees
- 30% of employees hold advanced science degrees
- 10% with doctorate-level
- > 90% client retention rates
- < 10% employee turnover
- 1,800+ peer-reviewed publications
- 365,000 patients
- 82,000 study sites
- 3,000 clinical protocols
- 2,500 health outcomes studies
- > 30,000 investigators trained in 70 countries
- 50 languages
- Trials conducted on six continents

UBC's Core Service Areas

- Peri- and Post-Approval Studies & Registries
- Specialty Clinical Solutions
- Value Generation Solutions
- Scientific Consulting & Communications
- Safety & Risk Management
- Clinical Technologies

Technologies

- Interactive Voice & Web Response Systems (IVRS & IWRS)
- Adaptive Randomisation
- Electronic Data Capture (EDC)
- Electronic Patient-Reported Outcomes (ePRO)
- Dynamic Randomisation
- Electronic Patient Diaries
- Adaptive Trial Design & Consulting
- Client Portals
- Virtual Meetings & Web-based Learning
- Searchable Databases: EvidenceHub™, RaterHub™ & Site Databases
- Publication Planning: Datavision™ & Visiontracker™

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UBC is a global medical and scientific affairs organization that partners with life science companies to develop and commercialize their products. For more information, call us in the U.S. at +1 866 458 1096, in the E.U. at +44 (0) 20 8834 0100, or email us at info@unitedbiosource.com.