

Peri-Approval & Post-Approval (IIIb/IV) Solutions

Facilitate patient access to medications or health technologies and support safe and appropriate product use and adherence through the development of real-world evidence to demonstrate effectiveness, safety and value.

Stakeholder-Driven Evidence

Increasingly, regulators, payers, providers and patients require effectiveness and other outcomes data to inform approval, reimbursement and treatment decisions. United BioSource Corporation (UBC) offers strategic, scientifically rigorous studies designed to address stakeholder driven evidence requirements.

UBC is well regarded in the industry for expertise in the development and conduct of registries, large streamlined studies, observational programs and pharmacovigilance. Our ability to develop solutions that communicate value to all key stakeholders is unparalleled in the industry. We have designed and conducted some of the largest and most complex programs, including those that transition from clinical development to peri-approval and post-marketing.

These studies optimize cost and timeline efficiencies and are backed by a highly skilled and experienced team of experts that understand:

- Retrospective and prospective observational studies
- Product, disease and pregnancy exposure registries
- Global market access with strategic evidence planning
- Global pharmacovigilance and patient safety
- Epidemiology and observational study design
- Comparative effectiveness and pragmatic trial design
- Trial simulation
- Health economics, and patient-reported outcomes (PROs and ePROs)

Methods-Driven Operational Principles

Peri- and post-approval programs, such as registries and large streamlined studies, can be large and complex. Achieving the optimal balance between scientific rigor and practicality and feasibility is paramount. UBC offers methods-driven global clinical operations to support strategic development and execution of post-approval programs. UBC experience spans four decades, across all therapeutic areas and includes some of the largest and most complex programs executed.

Technology and Innovation

Technology needs to change and adapt throughout the life of a program, and UBC technologies permit the capture of high quality data as well as efficient and streamlined communications. UBC develops customized, flexible electronic data capture and communications solutions that stand the test of time including our in-house, proprietary systems including eRegistry, IVRS/IWRS and UBC Track/CTMS. Data are aggregated and reports are built and delivered to ensure that quality data are available to inform critical business decisions.



UBC's Comprehensive Solutions

We are a leader in the design and implementation of registries and observational studies to address the needs of patients, healthcare providers, regulatory authorities and manufacturers.

Our epidemiologic approach to registries focuses on collecting relevant data to understand and guide real-world use of biopharmaceuticals and devices, throughout the product lifecycle.

We are specialists in the design and implementation of observational studies, including streamlined programs that aid the understanding of real-world product use, medical practices and treatment patterns.

Product and Disease Registries

We design and implement registries to study and guide the use of biopharmaceuticals and devices and to understand the treatment of diseases and health conditions.

Our registries can address a broad range of issues:

- **Safety** – confirm appropriate product use and estimate incidence of adverse events; provide information to guide and control product use to help minimize risk
- **Regulatory** – address post-marketing commitments; evaluate risk management programs
- **Research** – collect data on real world use for publication and presentation; develop hypotheses for future study; collect resource utilization data for economic evaluations; collect data on off-label use; establish a “stored cohort” for future use
- **Education** – provide data on real world product use and disease treatment to healthcare professionals and payers
- **Practice Modification and Improvement** – document practice patterns and outcomes associated with use of new and mature products; compare actual practices to national/global norms or guidelines
- **Commercial** – understand behavior of early and late adopters; understand product switching; build market intelligence on competitive products

Pregnancy Exposure Registries

We design and implement registries to obtain health information from women who take biopharmaceuticals when they are pregnant and newborns who may have been exposed to these products.

We focus on two types of pregnancy registries:

- Stand-alone programs
- Registries associated with one or more clinical trials

Prospective Observational Studies

Our data collection research study methodologies include:

- Surveys
- Observational prospective and cross-sectional studies
- Time and motion studies
- Disease-specific and multinational resource utilization questionnaires

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