



United BioSource Corporation (UBC) is a global scientific and medical affairs organization that partners with life science companies to develop and commercialize their products. We bring together scientific experts, research professionals and new technologies to generate authoritative, real-world evidence of product effectiveness, safety and value.

UBC Service	Description
Peri- & Post-Approval Clinical Development	<ul style="list-style-type: none"> ▪ UBC designs and implements Phase IIIb/IV studies that deliver authoritative evidence of product effectiveness, safety and value. ▪ We specialize in the design and implementation of observational programs that streamline and reduce the burden for health care professionals who may be unaccustomed to participating in clinical research. ▪ We are leaders in helping clients balance the complex demands associated with protecting patient safety, building evidence to support product use, demonstrating product value and maximizing commercial potential during the crucial years between launch and loss of exclusivity.
Phase II & III Clinical Development	<ul style="list-style-type: none"> ▪ UBC designs and implements Phase II and III studies that deliver authoritative evidence of product efficacy and safety. ▪ Our experts have the experience necessary to plan and implement product development programs to meet regulatory requirements throughout the world. ▪ We provide comprehensive support for submissions of New Drug Applications (NDAs), Biologic License Applications (BLAs) or Pre-market Approval Applications (PMAs).
Risk Evaluation & Mitigation Strategies (REMS) Design & Implementation	<ul style="list-style-type: none"> ▪ UBC is a recognized industry leader in the design and management of REMS. We have participated in consulting, planning and full-scale management of more REMS programs than any other service provider. ▪ We understand the rationale behind regulators' approaches to risk management and have deep experience negotiating critical aspects of the plans with authorities and implementing agreed plans in partnership with clients. ▪ Our experts are active participants in the development of regulatory guidances and are well positioned to understand risk assessment and minimization priorities established by regulatory authorities such as the FDA and the EMEA.
Product & Disease Registries	<ul style="list-style-type: none"> ▪ UBC is an industry leader in the design and implementation of disease and product registries. ▪ We have experience designing and implementing registries that serve the needs of patients, health care professionals, health authorities and manufacturers during every phase of the product life cycle. ▪ Our epidemiologically-based approach to registry design and execution supports collection of data that illustrate real-world use of products by patients and health care professionals.
Pregnancy Exposure Registries	<ul style="list-style-type: none"> ▪ UBC is an industry leader in the design and implementation of pregnancy exposure registries. ▪ We design and implement stand-alone pregnancy registries that use a variety of reporting and communications methods. We collect and process pregnancy exposure reports and can blend this information with spontaneous adverse event reports to provide a comprehensive information resource. ▪ We design and implement registries in conjunction with one or more clinical trials and are capable of following up on live births.
Global Pharmacovigilance & Safety Monitoring Solutions	<ul style="list-style-type: none"> ▪ UBC provides global pharmacovigilance and product safety monitoring support by collecting, assessing and reporting safety information for clinical trials and spontaneous reports of adverse events. ▪ Our safety team provides comprehensive product safety solutions that include the management of case processing and writing periodic safety update reports (PSURs). Our advanced technologies allow us to work with diverse manufacturers and to customize our solutions.
Risk Communication	<ul style="list-style-type: none"> ▪ UBC is an industry leader in developing materials to help communicate product risk information to health care professionals and patients. ▪ We develop and test risk communications aids such as medical guides, patient package inserts and prescriber/physician materials.
Study Design & Protocol Development	<ul style="list-style-type: none"> ▪ UBC has extensive experience developing and implementing study designs and protocols. ▪ We deploy teams of physicians, epidemiologists, biostatisticians, health outcomes experts, economists, former principal investigators, key opinion leaders and other research scientists to develop study protocols for randomized clinical trials, large streamlined studies and registries. ▪ We routinely manage the process of obtaining protocol approvals, protocol amendments and informed consent forms from independent review boards and ethics committees.
Patient Recruitment	<ul style="list-style-type: none"> ▪ UBC helps study sponsors recruit appropriate patients for clinical research. We work to ensure each study site is active, engaged, aware and highly organized. Our recruitment programs focus on site-centric models that are driven by customized patient recruitment tools.

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Patient Screening & Randomization	<ul style="list-style-type: none">UBC is an industry leader in the development and implementation of phone and web-based screening and randomization systems (IVRS/IWRS) for clinical research. Our technology is scalable, flexible and 21-CRF-Part-11 compliant.Our systems involve the most complex, dynamic and response-adaptive randomization techniques. Our programs are designed and managed by customized teams of information technology professionals, project managers and systems testing experts along with an extensive internal staff of experienced statisticians.
Study Inventory Management	<ul style="list-style-type: none">UBC supports clinical research with robust and reliable inventory management systems. We design and implement complex, predictive, just-in-time, titration and pooled inventory models. Our customized drug return management modules account for inventory to the pill level and complete the inventory management life cycle.Our inventory programs are differentiated by outstanding project management and complex management modules.
Site Selection & Verification Services	<ul style="list-style-type: none">UBC helps sponsors of clinical research in the central nervous system (CNS) rapidly and effectively identify appropriate investigators and sites for their trials. We use our proprietary rater database, <i>RaterHub</i>™ to match our clients' requirements with qualified CNS raters ideally suited to participate in a study.Our CNS site selection and verification services are designed to identify investigators who are likely to contribute effectively to a study.
Study Monitoring	<ul style="list-style-type: none">UBC has a large team of experienced, well trained and highly capable clinical research associates to monitor clinical research throughout the world.We have developed a rigorous platform for training new associates and developing more experienced staff. The <i>UBC Monitoring Academy</i> allows us to provide clients with the highest-quality clinical research associates in the industry.
Investigator Communications & Site Support	<ul style="list-style-type: none">UBC has extensive experience engaging clinical investigators. We design and implement programs to ensure our clients' studies remain top-of-mind.We support our investigator engagement programs with an array of branded materials and ongoing communications.
Data Management	<ul style="list-style-type: none">The <i>UBC Data Coordination Center</i> provides an end-to-end solution for successful data integration and centralized study reporting and monitoring.Our data management platform collects, manages and reports on data from a variety of source inputs including single-keyed, double-keyed, facsimile, telephony, handheld devices and other electronic source formats.In addition to our state-of-the-art data management system, we have established strategic relationships with other marketed electronic data capture (EDC) and electronic patient-reported outcomes (ePRO) platforms.
Data Monitoring Committees	<ul style="list-style-type: none">UBC is a leader in providing administrative, statistical and data management support for Data Monitoring Committees (DMCs). Our DMC services are precise, thorough and rigorous to ensure patient safety.We support members of each DMC with data that are presented effectively, together with critical inferences about relationships, events and signals.
Statistical Support for Adaptive Trials	<ul style="list-style-type: none">UBC designs and implements adaptive clinical trials. We leverage telephone and web technology (IVR/IWR), expert statisticians and partnerships with key opinion leaders to ensure our programs are implemented effectively.UBC is a pioneer in adaptive design and we routinely publish, consult and deliver statistical support as customers seek new ways to increase study quality while simultaneously improving research timelines and reducing costs.
Electronic Common Technical Document (eCTD)	<ul style="list-style-type: none">UBC has unsurpassed experience interfacing with regulatory authorities to negotiate rapid approvals with targeted product labeling and preparing integrated data for eCTD summaries.We help clients advance their New Drug Applications (NDAs) or Market Authorization Applications (MAAs) by providing a dedicated team of medical writers, programmers and statisticians with experience in clinical data submissions.
Regulatory Consulting & Study Quality Metrics	<ul style="list-style-type: none">UBC regulatory strategists help clients assess and navigate the complex regulatory challenges associated with life science product development.We employ a Study Quality Metrics (SQM) strategy to review and monitor key aspects of clinical data on a scheduled basis, throughout the product development process.
Rater/Investigator Training & Endpoint Reliability	<ul style="list-style-type: none">UBC helps clients execute effective clinical research by designing and executing customized training and validated assessment programs for investigators and study site personnel.UBC develops training materials and provides program support to help ensure the quality of clinical trials. We perform analyses at various points during trials and provide in-study management to protect data quality and our client's investment in clinical research.
eLearning Services	<ul style="list-style-type: none">UBC combines an array of study platforms to help streamline a client's training needs. Our eLearning platforms include: <i>Web Study Portal</i>, <i>Learning Zone</i>™ and <i>Webcast Meeting Delivery Services</i>™.eLearning platforms provide an effective alternative or additional learning resource to help sponsors address their global training needs.
Computerized Cognitive Testing Services	<ul style="list-style-type: none">UBC offers <i>The CDR System</i>, a testing service that comprehensively assesses cognitive function. The CDR System covers five major cognitive domains, and the full battery of tests can be completed in approximately 18 minutes. The system is validated and available in almost 60 languages and more than 70 parallel forms.

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Scale Management	<ul style="list-style-type: none">UBC manages rating instruments/scales for clinical trials. We identify, select, acquire and translate clinician-rated and patient-reported scales for use in clinical trials. UBC maintains a database of registered, approved and translated instruments.
Health Care Data Capture	<ul style="list-style-type: none">UBC offers customized primary data collection to support health economic evaluations or other studies of economic burden or product value.Our solutions include strategic and scientific consulting (study design, implementation, advisement), retrospective chart reviews (local/one-site or multinational), stand-alone observational prospective studies (randomized clinical trials, non-randomized clinical trials), cross-sectional studies (retrospective, prospective), health economic piggy-back studies, time and motion studies, surveys and multinational resource utilization questionnaires.
Health Outcomes: Scientific, Strategic & Regulatory Outcomes	<ul style="list-style-type: none">UBC scientists are world-recognized leaders in health outcomes research. Our staff provides strategic consultation on health outcomes and regulatory requirements for clinical trials.We have years of experience partnering with biopharmaceutical and medical device manufacturers and other life science companies to design and implement health outcomes strategies that meet regulatory requirements throughout the world.
Electronic Patient-Reported Outcomes	<ul style="list-style-type: none">UBC is a leader in designing and implementing patient-reported outcomes research. We leverage technology to deploy ePROs – patient-reported outcomes data captured electronically.We support our studies with our industry-leading outcomes research scientists, medical professionals and information technology experts. Our solutions are tailored to meet the needs of each study, regulatory requirement or patient need.
Evidence Generation Strategies	<ul style="list-style-type: none">UBC designs and executes comprehensive Evidence Generation Strategies (EGS) to evaluate the market landscape, identify unmet needs, demonstrate product value and establish product positioning. UBC experts identify evidence needs, appropriate audiences and effective means of communicating product information.Our EGS methodology is designed to facilitate payer coverage and reimbursement and to optimize the potential for commercial success.
Coverage, Reimbursement & Access	<ul style="list-style-type: none">UBC experts partner with clients to design and implement strategies designed to ensure that patients have appropriate access to biopharmaceuticals, medical devices and other innovative health technologies.Our scientists are experts in comparative effectiveness research. UBC understands the evolving demands of health care professionals, payers, policymakers, regulators and patients and helps provide real-world evidence to demonstrate the value of health technology.
Medical Communications & Publications Planning	<ul style="list-style-type: none">UBC is an industry leader in medical publications planning and execution. We work with clients to develop and execute strategic evidence communication programs that maximize the potential of research results.Our publications plans are designed and implemented by a large, in-house team of medical writers who have advanced degrees and deep expertise in scientific publishing. Our experts are well versed in good publications practice guidelines, scientific journal and society guidelines, as well as legislative and regulatory mandates.
Publications Planning Software	<ul style="list-style-type: none">UBC developed <i>Datavision</i>TM, the industry's leading publications planning tool. Nearly 40 life science companies and 90 agencies rely on <i>Datavision</i>TM to support publications planning across 530+ products worldwide.In addition to providing a valuable tool for organizing and managing all aspects of publications planning and execution, <i>Datavision</i>TM helps companies build and implement publications plans that are transparent and compliant with good publication practice guidelines and regulatory and legislative mandates.
Independent Grant Management	<ul style="list-style-type: none"><i>Visiontracker</i>TM is a web-enabled software solution designed for the pharmaceutical industry to manage grants and award programs.<i>Visiontracker</i>TM provides a single source of information that allows companies to track their completed grants program across multiple products, therapeutic areas and indications.
Health Economic Evaluations & Modeling	<ul style="list-style-type: none">UBC economists and analysts design and implement health economic analyses using a wide range of techniques and methodologies to quantify the burden of illness, evaluate treatment cost-effectiveness and budgetary impact, and document economic advantage and value.UBC provides strategic support throughout the product life cycle, from early pre-launch planning to launch and post-marketing management, we help clients build economic evidence in support for their products' value messages.
Epidemiology & Database Analytics	<ul style="list-style-type: none">UBC's epidemiology and database analytics team employs an evidence-based approach to understanding disease natural history, clinical treatment patterns, risk assessment, outcomes analysis and risk management planning and response.We specialize in the optimal identification, design and analysis of individual patient databases (medical claims, electronic health records, registries, etc.) and the conduct of focused reviews of available evidence for educated decision-making.
Patient-Reported Outcome (PRO) Instrument Development & Validation	<ul style="list-style-type: none">UBC's health outcomes research staff evaluates the impact of disease, treatment and medical care on health outcomes from the patient's perspective.Combining the disciplines of psychometrics, epidemiology, psychology and other social sciences, UBC researchers develop and validate new patient-reported outcomes (PRO) measures according to scientific and regulatory guidelines, evaluate the measurement qualities of PROs, and design and complete studies to evaluate symptom, health-related quality of life, treatment satisfaction and patient preference outcomes associated with health interventions.

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Comparative Effectiveness Research (CER) & Health Policy Consultation

- UBC recognizes the critical need to demonstrate value in today's cost constrained environment and has researchers dedicated to understanding the science policy issues that exist in today's health care arena.
- UBC offers leading experts on the use of comparative effectiveness research to improve the practicality and efficiency of comparative clinical studies to address mounting "real-world" evidentiary demands by payers, clinicians and policy makers.

Regulatory & Health Authority Submissions, Dossiers & Health Technology Assessments

- UBC is a global leader with expertise in the development of regulatory and health authority submissions, global value dossiers, and Health Technology Assessments (HTAs) to support evidence-based decision making.
- UBC utilizes extensive experience across a number of therapeutic areas, coupled with capabilities in literature research, economic modeling, risk-assessment and payer coverage research to provide refined and effective submissions.

UBC At-a-Glance

- 1,400+ employees
- 30% of employees hold advanced science degrees
- 10% with doctorate-level
- > 90% client retention rates
- < 10% employee turnover
- 2,000+ 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 Randomization
- Electronic Data Capture (EDC)
- Electronic Patient-Reported Outcomes (ePRO)
- Dynamic Randomization
- Electronic Patient Diaries
- Adaptive Trial Design & Consulting
- Client Portals
- Virtual Meetings & Web-based Learning
- Searchable Databases: MetaHub™, RaterHub™ & Site Databases
- Visiontracker™ & Datavision™

U.S. Offices

- Ann Arbor, MI
- Bethesda, MD (2)
- Blue Bell, PA
- Chantilly, VA
- Glastonbury, CT
- Kansas City, MO
- Langhorne, PA
- Lexington, MA
- McLean, VA
- Morgantown, WV
- Philadelphia, PA
- San Francisco, CA
- Seattle, WA
- Southport, CT
- Wayne, PA

International Offices

- Adelaide, Australia*
- Cologne, Germany*
- Dorval, Quebec, Canada
- Geneva, Switzerland
- Glasgow, United Kingdom*
- Goring-on-Thames, United Kingdom
- Horsham, United Kingdom
- Kiev, Ukraine*
- London, United Kingdom (2)
- Lörrach, Germany
- Moscow, Russia*
- Prague, Czech Republic
- Tokyo, Japan

*Certain locations managed through formal strategic alliances

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) 207 299 4550, or email us at info@unitedbiosource.com.