



Phase I-III Clinical Research

**For clinical studies,
from early development
through product
approval, UBC offers
unique expertise to plan,
manage and complete
clinical research on
your compound.**



United BioSource Corporation

Evidence Matters.™

Capabilities Matter

Since 1976, we have focused on clinical development. Our global experience extends across all therapeutic categories, and shapes the solutions we offer – services to help design and implement clinical trials and development activities that support your strategic needs. Our clinical development services have supported trials on hundreds of prescription and over-the-counter medications, enrolled over 365,000 patients in clinical trials, and managed over 82,000 study sites.

OUR EARLY CLINICAL EVIDENCE-BASED CAPABILITIES INCLUDE:

- Phase I-IV clinical trial management
- Protocol, ICF & CRF development
- Project management
- Interactive voice response system (IVRS)
- Site selection & qualification
- Site training and support
- Clinical monitoring
- Medical monitoring
- Quality assurance
- Regulatory audits
- Data management
- Statistical services
- Medical writing
- Central pharmacy services
- Outcomes tool design – patient reported & health economics
- Strategic consulting
- Electronic data capture (EDC) and management
- Web-based study reports
- Patient diaries
- Patient enrollment
- Patient registries

Experience Matters

Client satisfaction –
Over 90% of clients
have placed additional
programs with UBC.

Choosing a proven outsourcing partner with therapeutic experience is a critical component to your compound's success. UBC's well trained, multi-functional teams of project managers, medical writers, CRAs, data managers and regulatory experts are empowered, engaged and have personal ownership in every study they perform. Our senior management is involved at a "hands-on" level to ensure accurate and timely completion of your study. We excel at project management by strictly adhering to project parameters and issuing change orders only when mandated by the client. UBC's unique and proactive processes provide clients with the right information at the right time to make the right decision.

From extensive field experience in placing, managing and monitoring studies in virtually all therapeutic categories, to cost efficient projects delivered on time and on budget, it's all part of what makes UBC an informed choice.

THERAPEUTIC EXPERIENCE:

- Allergy/Asthma
- Analgesia/Pain Assessment
- Cardiovascular
- Central Nervous System
- Dermatology
- Gastroenterology
- Infectious Disease
- Metabolic Studies
- Oncology
- Psychology
- Rheumatology
- Sexual Dysfunction
- Urology



Expertise Matters

UBC's scientists, researchers and project managers have developed and implemented proof-of-concept studies to demonstrate efficacy, safety, tolerability and commercial viability. UBC's ability to provide credible sites that are capable of meeting tight enrollment timelines, set us apart from other contract research organizations.

UBC can help transition your compound from clinical development to commercialization by designing and conducting either structured or more simplified studies with larger study databases that can validate and, in some cases, develop additional product claims. Our international reach into Eastern and Western Europe and Latin America allows us to offer unique sites to a client. Our processes for managing studies provide high quality data to support your submission requirements.

UBC's strong presence in other countries is vital when conducting global studies. Knowledge of the local regulations, experience with local physicians and tenured staff are all part of the expertise that UBC brings to clients.

The ability to identify Key Opinion Leaders (KOLs) and having an extensive investigator database can mean the difference between meeting a study's timelines and having your competitor beat you to market.

“Hands-on” senior management, experienced project leaders and proactive CRAs – all focused on serving our clients.

OUR STRENGTHS INCLUDE:

- Nearly 30 years in drug development services
- Global research & expertise
- Comprehensive therapeutic experience
- Project & budget management
- Low staff turnover – less than 8%
- Tenured staff focused on client service

GLOBAL EXPERIENCE, FLEXIBILITY AND PERFORMANCE THAT EXCEEDS EXPECTATIONS

UBC managed a Phase II, 6 week hospital and out-patient based oncology study in seven countries providing a full drug development plan including a Drug Development Board and Data Management Committee.

UBC enrolled 250 sites for a Phase IIIb study in approximately two months, boasting a 96% enrollment rate. 2,224 patients were enrolled, exceeding the target of 2000. 90,959 CRFs were received, imaged, reviewed and data entered.

Technology Matters

UBC offers user-friendly, scalable data collection technology that is compliant with key regulatory guidelines and conventions.

We are on the forefront of developing and integrating advanced data collection and clinical study management technology to improve reliability and efficiency, reduce errors, ensure process consistency, and provide cost and time savings.

DATA MANAGEMENT INNOVATIVE AND USER FRIENDLY:

- Electronic data capture (EDC)
- Interactive voice response system (IVRS)
- Imaging/scanning
- Real time fax input
- Web-based training
- Web-based data collection
- SAS programming
- Oracle clinical capabilities
- Web-based study management reports
- Web-based collections & management



Proven technologies that are continually enhanced through real world experience to effectively evaluate compounds in clinical development.



People Matter

Our clients share a common goal – a goal articulated in their mission and implicit in the products they create: to help people live healthier, longer and more productive lives.

At UBC, it is our mission to help companies achieve this goal. Our product support provides the pharmaceutical, biotechnology, medical device and diagnostics industries with the rigorous, scientific evidence necessary to demonstrate the clinical benefits, safety and economic value of their products worldwide.

Our goal is to build long-term relationships with clients by earning their trust on each program, pre-approval or peri-approval, that we conduct.

Client service is more than a catch phrase. It is an integral part of the culture and commitment at UBC.

Capabilities

KEY SERVICES

- Phase I-IV clinical trial management
- Physician education studies
- Safety studies
- Risk management programs
- Pediatric studies
- Ethnic studies
- Epidemiology
- Women's health
- Medical devices

SPECIALTY SERVICES

- Phase I management & supervision
- KOL/advisory board identification & management
- Protocol & CRF design
- Project management
- Investigator identification & recruitment
- Site contract & investigator compensation management
- Medical monitoring
- Data management
- Statistical analysis
- IND consultation
- Clinical monitoring
- Regulatory document collection & tracking
- DSMB management
- Report writing
- Quality assurance

Credible evidence will help provide clients with the efficacy, safety and patient reported outcomes they require and patients the confidence in the investigational and commercial products they need.

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