



Patient Outcomes Matter

Meeting Your Health Outcomes Needs

United BioSource Corporation's (UBC) 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 new patient-reported outcomes (PRO) measures, 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.

We supply evidence-based solutions to health outcomes challenges by providing:

- PRO instrument development and validation
- PRO measure selection and clinical study design
- Analysis and interpretation of HRQL and PRO data
- PRO and regulatory claims strategies and support
- Health outcomes research agenda development
- Health outcomes dissemination planning
- Health outcomes strategic and scientific consulting

Moving into the Electronic Age with ePROs

UBC has strong electronic data capture and electronic patient-reported outcomes (ePROs) capabilities and can develop or adapt PROs to be completed via the Web, interactive voice response (IVR) systems, handheld devices such as personal digital assistants (PDA) and tablet PCs.

UBC employs an array of leading-edge electronic data capture technologies that are:

- Efficient, reliable and secure
- 21 CFR Part 11 compliant
- User-friendly
- Scalable to large studies
- Easily adapted to allow process improvements
- Designed to ensure maximum utility for study sponsors and ease of use by end users

We have more than 150 employees dedicated to electronic-based PRO and patient diary solutions. Since 1995 we have worked with more than 100 sponsors to solve their ePRO needs and help make their critical implementation decisions (e.g., EDC, IVR, PDA, paper). UBC routinely provides strategic regulatory consulting and advice to pharmaceutical clients on how to appropriately adapt PROs to e-mode, as regulatory agencies such as the FDA increasingly require additional validation evidence before accepting an ePRO.

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

Our services include:

Planning & Strategy Development

Strategic Consulting

- Identify key patient-reported outcomes (PROs)
- Develop dissemination plans
- Participate on advisory boards
- Develop research programs and portfolios
- Consult on PRO regulatory claims

Background Briefing Papers

- Conduct literature reviews and synthesis
- Review and critique PRO measures
- Review and critique methodologies
- Provide up-to-date information on regulatory requirements for PRO data

Scientific Consulting

- Develop new instruments
- Select instruments to meet specific measurement goals
- Design studies
- Provide statistical consultation
- Solve analytical problems
- Interpret endpoints of clinical trials
- Critique scientific quality of published or unpublished documents, research instruments or analytical methods
- Develop new methodologies to evaluate treatment outcomes

Position Papers

- Develop position papers and manuscripts addressing standards of evidence for labeling and promotional claims
- Interpret outcomes data
- Communicate new outcomes research methodologies

Evaluating Patient Outcomes

Clinical Trial Design

- Design clinical trial and other studies
- Select instruments, observation intervals and data collection methods
- Conduct statistical analyses
- Train investigators and site staff
- Prepare reports, presentations and manuscripts

Health Preference Assessment

- Derive utility estimates
- Develop and test preference assessment methods

Instrument Development and Evaluation

- Develop new measures to evaluate treatment outcomes
- Provide psychometric assessment of new or existing measures
- Item response theory analysis
- Structural equation modeling

Statistical Analysis

- Develop and implement statistical analysis plans for clinical trials and prospective studies

Integrated Translation Services and Cultural Adaptation

- Provide full-scale linguistic and cultural translation
- Evaluate evidence on translation performance

Communicating Patient Outcomes

Dissemination

- Author abstracts
- Develop presentations
- Prepare manuscripts for publication
- Define audience-appropriate methods to communicate findings to scientists, clinicians, decision-makers and consumers

Training and Education

Provide seminars, workshops and training sessions on health outcomes research methods and topics:

- Meeting customer needs
- Quantifying health and economic consequences of disease
- Integrating outcomes studies with product development

For more information about UBC's scientific consulting and communications services, call us in the U.S. at +1 301 654 9729 or in the E.U. at +44 (0) 207 299 4550. Or email us at analytics@unitedbiosource.com.