



## Integrated Safety Services

### **Engineered For Success: Integrating Safety into All We Deliver**

Patient safety is of paramount importance and at the very core of how United BioSource Corporation (UBC) operates. Never before has the characterization of safety events, identification of possible signals and the context of those findings related to your product been more important to regulators, manufacturer and payers. Appropriately anticipating your product's safety profile and designing effective evaluations into your planning impacts the quality of your submission and product approval and commercialization.

### **New Standards of Evidence of Safety**

UBC is a strong contributor to the conceptual, operational and reporting approaches around product and device safety. We help our customers solve complex design issues around the approach to product safety evaluation and support them through the implementation of these programs globally. The depth of our leadership team and breadth of products we have helped commercialize enables us to offer critical insight into program design and delivery across a wide range of product, market or regulatory conditions.

### **Flexible Delivery of Safety Solutions**

Customers require safety solutions that fit their development and commercialization operating models. Many UBC customers need full-service safety and pharmacovigilance solutions for all products, all geographies and across all active protocols. Others need targeted solutions to solve distinct needs or priorities. UBC deploys safety solutions in three distinct delivery models: consulting, full-service and functional/vertically-integrated. UBC offers unique operating models that enable predictability of spend, decreased cost-basis for safety case processing operations and robust reporting to keep critical information in the hands of the people that need it.

In support of ensuring the safety of your product, UBC provides safety case processing and regulatory reporting globally with experience in North America, Eastern and Western Europe, Asia, the Pacific Rim and Latin America. UBC supports our customers through a broad range of safety services for drugs, biologics, devices and vaccines.

### **Highly Credentialed Resources Providing Solutions**

UBC establishes safety teams that combine industry-leading epidemiologists, experienced industry physicians, pharmacists and safety scientists. UBC's experience can support program design, case processing, regulatory requirements, fully integrated safety department solutions and safety medical writing.

### **Safety is an Ongoing Discipline through Development Planning**

Robust safety characterization is present in most development, commercial or life cycle management initiatives. UBC works with our customers to create safety plans that span development milestones, protocols, populations and indications. Working with customers to identify safety and pharmacovigilance plans that transcend individual protocols is an important way to communicate product safety attributes in a broader context, to a larger base of stakeholders. UBC engineers safety plans that connect through the entire suite of clinical initiatives.

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



## **Partnering in Product Safety is Never “One Size Fits All”**

UBC is always flexible. The products, sponsors and manufacturers we support are as diverse as the solutions we implement. UBC can act as a fully-integrated safety organization for customers who have made a decision that safety is either a non-core competency or have chosen a partnering strategy that enables them to better manage their fixed costs and associated resources. UBC has other models where we act as a functional service provider (FSP) responsible for a particular aspect of the safety and/or pharmacovigilance needs for our customers. Whether integrated into a full-service, global clinical trial, or as a consultancy involved with signal detection and evaluation, UBC operates a flexible delivery model to offer our customers the right balance.

## **Enhancing Safety Process through Technology**

UBC deploys technologies to accelerate decision making and proactively manage safety events. UBC customizes the systems we deploy to best meet the workflow and alert requirements of our customers. We utilize a variety of technologies, both industry standard products as well as internally developed platforms. Additionally, our team is well-versed in all standard safety reporting systems and is capable of remote data entry into your safety system if that is your preferred method of entry and review.

For clinical trials or registries, Safety Managers are intimately involved in CRF design and identification of ‘triggers’ for immediate safety attention. SAE forms submitted from investigative sites are immediately imaged and routed to the safety team. Client notification can be accomplished through paperless systems of email links to the event data posted on a secure portal. UBC operates an industry standard commercial safety database for pre-marketing and post-marketing safety surveillance. In post-marketing safety programs, similar systems and workflows are used, incorporating global call centers, local affiliates and data collection systems.

UBC computer applications provide safety personnel with global access to AE/SAE forms completed in our systems across all patients. We enable our customers the ability to view data details as well as look for potential patterns in the safety data.

UBC helps our customers be proactive, move quickly and have better visibility over key safety data needs.

## **Safety Endpoints**

UBC oversees endpoint processing for thousands of events. Our UBC eJudicate™ technology streamlines the adjudication process, allowing the busy key opinion leader adjudicators an easy method to provide review and findings. By simply going to a secure website, the adjudicator can complete a worksheet and submit. This system allows for easy tracking of adjudication findings, comparison between adjudicators and sponsor access.

## **Safety Consulting**

UBC has the depth of experience to assist clients as they venture into new therapeutic or product areas. Our team routinely assists clients with SOP development/review, training on safety device, drug and biologic regulations, and mentoring sponsor safety teams to function independently.

## **Data Safety Monitoring Services**

Understanding the relevance, relatedness and potential drug-induced events associated with a key endpoint in a clinical program is a critical aspect to many clinical investigations. UBC helps our customers understand what data elements to review, the frequency of review, adaptive design considerations and the analysis and reporting of key findings of critical safety data.

## **UBC's Experience at Work for You**

### *Serious Adverse Events (from Clinical Trials)*

Process Phase II-IV clinical trial ICSRs across therapeutic areas and regions, from receipt to regulatory reporting

### *Spontaneous Reports*

Develop processes and conduct all post-marketing reporting requirements, from intake to literature review to regulatory reporting

### *Product Complaints*

Accurately report and document product complaints

### *Signal Detection (and Evaluation)*

Conducted > 100 in-depth evaluations (2006-2009)

### *PSUR/PADER Aggregate Reports*

> 150 reports (2006-2009)

### *Literature Reviews*

> 200 products (2006-2009)

## **UBC's Pharmacovigilance Services**

### *Case Processing*

- Spontaneous or clinical trial adverse events
- Cases from observational studies and registries
- Serious or non-serious cases
- Remote processing in the client's database or UBC's ARGUS™ database
- Experience with ARGUS™, ARISg™, AERS™, Clintrace™, BaseCon
- Complete or partial processing including: case receipt and evaluation, data entry, quality control, coding, narrative, causality assessment, labeling, medical evaluation, follow-up requests and tracking, reporting to authorities and other stakeholders
- Legacy case entry

### *Safety Writing*

- Periodic Safety Update Reports (PSURs), addendum reports and summary bridging reports
- Annual Safety Reports, Development Safety Update Reports (DSURs)
- Risk Management Plans
- Quality control and consistency check of all safety documents
- Safety sections of the CTD and the investigator brochure
- Expert statements
- Risk or signal analysis documents
- Responses to competent authorities

## **UBC's Pharmacovigilance Services (cont.)**

### *Project/Study-Driven Safety Activities*

- Endpoint adjudication processes
- Development of Risk Management Plans, including Safety Specifications, Pharmacovigilance Plans, as well as Risk Minimization Action Plans (RiskMAPs) and Risk Evaluation and Mitigation Strategies (REMS)
- Preparation of safety study specific documentation (SAE form, safety management plan)

### *Integrated Safety Services (your customized internal safety department at UBC)*

- Database setup (products, reporting rules, users) and documentation
- Process and workflow definition, SOP preparation
- Communication with third parties (clinical CROs) and preparation of safety data management documents
- Registration for safety reporting to authorities (Eudravigilance)
- Training of investigators, CRAs, sponsor/MAH staff
- Signal detection and evaluation
- Reporting to authorities (E2B, CIOMS, MedWatch)
- Reporting compliance monitoring
- Monthly status reports

### *Consulting Activities*

- Literature search activities
- Training activities (investigators, CRAs, sales representatives, general staff)
- Safety data exchange agreements
- Safety systems due diligence
- SOPs and detailed description of pharmacovigilance system
- Safety surveillance post REMS and/or EU-RMP implementation

### *Technical solutions*

- Safety document tracking logistics and data management
- Project portal for document exchange and key performance indicators monitoring

*For more information about UBC's safety and risk management services, call us in the U.S. at +1 215 591 2880 or in the E.U. at +44 (0) 208 834 0100. Or email us at [info@unitedbiosource.com](mailto:info@unitedbiosource.com).*