Pharmacovigilance
Risk Management
Signal Detection and Management

United BioSource Corporation (UBC) provides technology and services that encompass safety/pharmacovigilance, risk management, signal detection, and assessment – as a comprehensive integrated program, or as stand-alone, targeted solutions.

The comprehensive technology-enabled solutions and expertise offered by UBC can help you characterize safety events, identify possible signals, and understand their context efficiently and confidently. The management of the safety of products requires extensive medical and regulatory knowledge and expertise. Interconnection between key documents is critical to smooth product development and approval, and consistent post-marketing safety management.
Pharmacovigilance Operations
More than 100 pharmacovigilance professionals, located in Europe and in the United States
Global Solutions - Global Processes - Multicultural Team

Case Processing
• Case processing: spontaneous sources, clinical trials, observational studies, and registries
• Remote processing in client’s database or UBC’s ARGUS™ database
• Experience with ARGUS™, ARISg™, AERS™, Clintrace™, BaseCon®
• Complete or partial processing
• Legacy case entry and electronic data migration

Safety and Medical Writing
• Benefit Risk Assessment
• PSURs, PBRERs, DSURs, PADERs
• Risk Management Plans
• Safety sections of the CTD and investigator brochure
• Expert statements
• Risk or signal analysis documents
• Update, harmonization of SPCs
• SOP preparation and update
• Responses to competent authorities

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Integrated Safety Services: a flexible customized solution for your business
• Database setup and documentation
• Process workflow definition
• SOP preparation
• Pharmacovigilance system master file setup and maintenance
• Registration for safety reporting to authorities (Eudravigilance, FDA)
• xEVMPD registration and maintenance
• QPPV
• Training of investigators, CRAs, sponsor/MAH staff
• Complete system administration and coordination

Project Management
• Project managers with pharmacovigilance experience
• Monthly report and Key Performance Indicators
• Effective communication
• Operational plans and documentation

Technology Solutions
• Argus hosting
• Electronic Data Migration

Additional Activities
• Literature screening for safety information (case reports, signals)
• Training (investigators, CRAs, sales representatives, general staff)
• Safety data exchange agreements
• Medical monitoring
• Endpoint adjudication services
• “Rescue” of failed safety programs

Signal Detection and Management
Well-designed signaling and data mining systems, medical experts in signal detection, validation, prioritization and assessment

Signal Detection, Prioritization
• Sorting methods
• Imputation screening methods
• Signal evaluation and case series characterization
• Qualitative detection on individual case data

Statistical Analysis in Large Adverse Event Databases
• Periodic monitoring of large databases of spontaneous adverse event reports
• Patterns of disproportionately reported drug/event combinations
• WHO Vigibase, FDA AERS, Vaccine data, Client data
• Full spectrum of software and/or services designed to suit client-specific needs
• Integration with case review process

Active Surveillance
• Rapid analysis of large electronic healthcare databases (UK Clinical Practice Research Database, IMS Germany Database, US Insurance, and electronic medical record databases)
• Signal detection for targeted health outcomes of interest
• Signal refinement for rapid triage and prioritization of potential signals
• Disease characteristics
• Exposed population characteristics
• Comparator/Drug class characteristics
• Incidence rate of an outcome of interest
• Full spectrum of active surveillance software and/or services designed to suit client-specific needs

Quality and Compliance
• Regulatory reporting compliance monitoring
• Regulatory safety intelligence activities
• Regulatory inspection support
• Safety systems due diligence
• System and department audits

Web-based software especially designed for drug safety scientists and epidemiologists, SAFETYWORKS® enables rapid analysis of large healthcare databases via a user-friendly point-and-click interface

Signal Validation, Prioritization and Assessment:
• UBC or Client signal detection systems outputs
• Review of all data sets: individual reports, literature, data mining outputs
• Tracking and analysis according to FDA regulations and EMA GVP Module IX and CIOMS VIII
• More than 15 Safety Physicians and experts
• Routine or ad-hoc support
• Signal validation
• Signal analysis and prioritization
• Signal assessment
• Signal tracking and documentation

Web-based software to monitor large adverse event databases, to identify drug/event combinations being reported more frequently than expected compared to other drugs in the database

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Risk Management

International industry-leading expertise in Europe and America to enhance patient safety and manage the benefit-risk profile

UBC is able to provide you with a global range of complete risk management activities to support your product during the peri and postapproval period: from the initial drafting of a risk management plan, through implementation and monitoring of effectiveness. UBC is experienced at providing pragmatic solutions to enhance patient safety, maximize efficacy, and ensure that patient access to medicines is not compromised. UBC’s risk management teams can:

• Provide strategic input into risk management and risk minimization approaches
• Partner, support, and advise in your discussions with Regulatory Agencies, in the EU and the US
• Produce regulatory acceptable risk management documents
• Design and conduct peri and postapproval risk management programs including:
  • Post Authorization Safety and Efficacy Studies (PASS/PAES)
  • Exposure and disease registries
• Risk minimization activities including
  • Patient and healthcare professional communication programs
  • Risk Evaluation and Mitigation Strategies (REMS)
  • Elements to Assure Safe Use (ETASU)
  • Monitoring the effectiveness of risk minimization activities
  • Physician, patient, and Knowledge, Attitude and Behavior surveys
  • Off-label use monitoring

For more information about UBC’s comprehensive services, call us in the U.S. at 1.866.458.1096, in the E.U. at +44 (0) 20 8834 0100, or email us at contact@ubc.com.