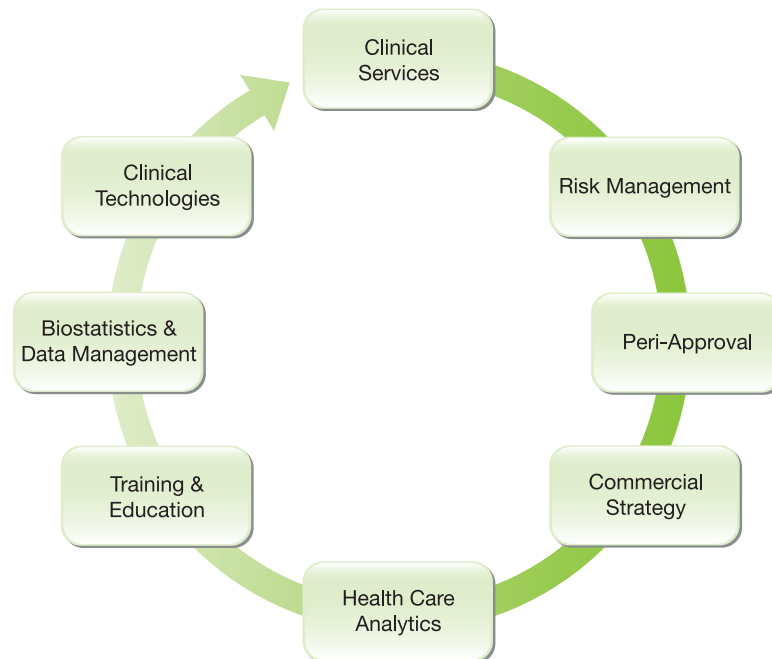


The Right Evidence at the Right Time

United BioSource Corporation (UBC) is the Leader in Comprehensive Risk Evaluation & Mitigation Strategies

- UBC ensures your product gets to the right patients, under the right conditions at the right time
- UBC's level of investment in risk management infrastructure and resources rewards our customers with custom technological and operational solutions, not replicated by other service organizations

Organization:



UBC played a key role in the design, implementation and/or evaluation of 8 of the 16 FDA-‘deemed’ REMS products.

The Right People

- A dedicated Safety, Epidemiology, Registries and Risk Management team with unparalleled Risk Management experience
- 1,400+ employees located in 30 offices in over 20 countries
- 30% hold advanced science degrees
- 10% with doctorate-level
- 2,000+ peer-reviewed publications

The Right Experience and Expertise

Risk Management Strategy

- > 50 US RiskMAPs/REMS programs
- 14 US Pharmacovigilance plans
- 22 EU RMPs
- FDA Advisory Committee preparation
- Key industry advisors for FDA, EMEA and Health Canada negotiations

Risk Management Intervention

Design & Implementation

- 13 programs with elements to assure safe use
- 33 Knowledge Attitudes and Behaviors (KAB) Surveys for 24 products
- 11 REMS programs with communication plans

Risk Management Educational Tools for Multiple Stakeholders

- Low literacy PPIs or Med Guides for > 70 products
- Device or product instructions for 5 brands
- 15 low-literacy patient brief summaries for DTC ads
- HCP-specific tools for prescribers, nurses, pharmacists, home health, hospitals
- Develop qualitative testing protocol and screeners
- Conduct quantitative testing of educational tools
- Handle subject recruitment, moderate interviews, manage subject honoraria and final report with key findings

Assembling Your Risk Management Team

Risk Management & Epidemiology

27 epidemiologists and risk management experts

Medical & Scientific Expertise

45 PhD/MDs who connect REMS goals to the product and market

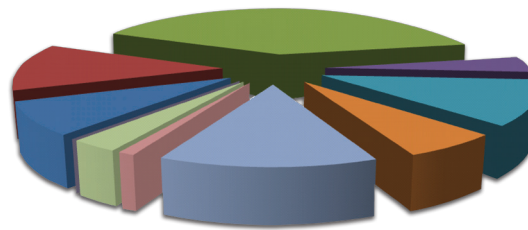
Program Delivery

32 Project Managers, 200 Call Center/Fulfillment staff, 25 Medical Communications staff

Technology & Infrastructure

21 CFR part 11 validated systems supporting REMS Programs

Risk Management Activity by Therapeutic Area



■ 8%	Anti-infective
■ 13%	Cardiovascular
■ 40%	CNS
■ 4%	Dermatology
■ 11%	Endocrinology/Metabolism
■ 6%	GI
■ 14%	Hematology/Oncology
■ 1%	Immunology
■ 3%	Respiratory/Pulmonary

For more information about UBC's peri- and post-approval study and registry 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 riskmanagement@unitedbiosource.com.