FACT SHEET

Risk Management & REMS

Maximize product performance by managing risk before, during, and after launch with the industry's most comprehensive global suite of solutions available.

UBC's unparalleled team of advisors will guide you in meeting regulatory requirements across a broad range of therapeutic areas and for a wide range of serious risks.

PHASE II	PHASE III	PHASE IV
• Evaluate the epidemiology of the underlying disease and proposed treatment population • Begin the safety specifications of the RMP	• Start pharmacovigilance plan • Determine how the product might be used or misused in the post-approval arena, the risks that may upset the benefit/risk balance, and the unique benefits of the product • Evaluate the need for risk minimization • Create a risk minimization plan • Design and prepare a Risk Evaluation and Mitigation Strategy (REMS) • Develop educational tools for all stakeholders, as required	• Monitor product safety • Implement REMS and other risk mitigation strategies • Evaluate the effectiveness of risk mitigation activities • Design and implement studies to meet post-marketing regulatory requirements • Create a risk minimization plan • Design and prepare a Risk Evaluation and Mitigation Strategy (REMS) • Develop educational tools for all stakeholders, as required

Our Expertise

STRATEGIC CONSULTING

Multidisciplinary consultants providing strategic recommendations and solutions.

- Regulatory authority negotiations
- Need for risk minimization
- Options to maximize benefit and minimize risk
- Program modifications and revisions

REMS & RMPS

Robust risk management and risk minimization plans that meet regulatory requirements and ensure prescriber and patient accountability.

- Post-Authorization Safety Studies (PASS)
- Safety reports and manuscripts for regulatory product marketing and medical communications
- Risk Evaluation and Mitigation Strategies (REMS) and Risk Management Plans (RMPs)
- Knowledge, Attitude, and Behavior (KAB) surveys

PHARMACOVIGILANCE & SAFETY MONITORING

We offer global safety services to support your pharmacological and risk management needs.

- Complete PV systems setup, case processing, and reporting
- Signal detection and evaluation
- Literature screening
- Ad-hoc support and consulting
- Case processing for clinical trials and post-marketing reports
- Safety writing, such as periodic reports

SOFTWARE FOR SAFETY & RISK MANAGEMENT

Our automated, user-friendly, analytical tools offer scalable, cost-effective, transparent, and reproducible results to help you decide whether additional studies may be required and how they should be designed.

REGISTRIES & OBSERVATIONAL STUDIES

Our epidemiological approach to registries and other noninterventional studies focuses on collecting relevant data to understand and guide real-world use of biopharmaceuticals and devices throughout the product life cycle, either as an ad hoc study or in an automated database.

- Product and disease registries
- Pregnancy exposure registries
- Prospective and retrospective observational studies
- Large simple studies and pragmatic trials

RETROSPECTIVE CHART REVIEW STUDIES

Specializes in identifying, designing, and analyzing tailored chart review studies to inform regulatory and payer decision-making.

- Case-control studies
- Cohort studies
- Natural history studies
- Drug utilization studies

COMMUNICATIONS

We develop materials to help communicate product benefit and risk information to healthcare professionals and patients. We develop and test a diverse range of risk communication aids.

- Medication guides and patient information leaflets
- Prescriber and patient brochures
- Prescriber or patient checklists
- Patient diaries
- Patient alert cards
- Educational videos

UBC has developed, implemented, and/or evaluated more risk management programs than any other provider, including more than 15 rare diseases

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UBC
Patients First. Powered by Evidence.

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