

Epidemiology: REMS/Risk Minimization Surveys

- *Scientific rigor*
- *Operational excellence*
- *Unparalleled experience*

Focus on Safety

The EMEA and FDA (under the new authority of the Food and Drug Administration Amendments Act of 2007) are mandating risk minimization (RM) plans and risk evaluation and mitigation strategies (REMS) to manage risks and assure safety for many new and established drugs and biologics. Sponsoring companies are further required to evaluate the effectiveness of those plans in managing risks. Some of these evaluations must rely on collection of data directly from physicians, nurses, pharmacists, and patients using surveys. As with other epidemiology study types, evaluation surveys must use scientifically sound and reliable methods in design, execution, and analysis.

Benefit from Our Experience in Evaluating Risk Minimization (RM) Plans

At RTI-HS, we have provided extensive risk management consultation to more than 35 major pharmaceutical companies in support of more than 40 products. We have worked with clients on all aspects of RM plans including design and implementation

of programs and developing and testing of educational materials.

When you collaborate with RTI-HS, you gain the experienced insights of an integrated team of thought leaders in risk management, pharmacoepidemiology, survey research, psychometrics, pharmacovigilance, biostatistics, and health communication. Additionally, you leverage our experience and infrastructure to quickly and efficiently field evaluation surveys. We can help you successfully execute your RM plan because we understand:

- The key issues regulators expect a program to address
- How to develop and test reliable survey instruments
- Methodologies to collect the highest quality data from patients and healthcare providers
- Methods for supplementing survey data with other information, such as chart abstraction
- How to analyze and interpret data from evaluation programs
- How to report the results of an RM plan evaluation to regulatory authorities.

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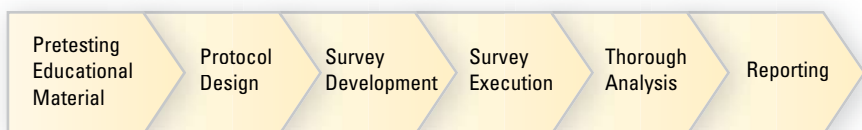
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A Systematic Approach to REMS Evaluation Programs



We have developed a systematic approach to REMS and RM evaluations that provides meaningful and actionable data. Our clients can use this information to update and

refine their RM programs so that patients receive the benefits of treatments and risks are minimized.

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Step 1. Pretesting of Educational Material

We always recommend rigorous pre-testing of the risk communication program to maximize its likelihood of success. Our health communications experts can help design materials and test them in the target population for content, appropriateness of reading level format, and dissemination route.

Step 2: Protocol Design

As we design the study protocol for the post-approval evaluation study, we consider the unique characteristics of the product, prescribers and patients who will use it, and the concerns of regulators. Key considerations include distribution, method of administration, frequency of use, population sampling methods, and methods to identify and minimize bias. We consider appropriate modes of collecting data including use of claims data, chart reviews, or prospective surveys.

Step 3: Survey Development

We develop instruments that measure the key elements of an RM plan, including receipt of educational materials, understanding of product safety and appropriate use, attitudes about safety messages, and actions taken to minimize risk. Instruments are evaluated using advanced cognitive testing processes that RTI has developed.

Step 4: Survey Execution

We recommend appropriate survey methods based on the unique characteristics of the population being surveyed, with a focus on limiting the potential for bias. Our survey experience includes Web surveys, paper, EDC, tablet, chart abstraction, and in-person and telephone interviewing. We offer a central IRB experienced in reviewing observational studies and survey research. Our IRB understands the need to expedite approval when timelines are short due to regulatory requirements.

Step 5: Analysis

In analyzing survey data we evaluate the potential for bias based on characteristics of responders vs. nonresponders. We apply advanced methods such as root cause analysis if performance of the program is less than ideal.

Step 6: Reporting

We author reports that provide results, synthesis, and interpretation in a format that can be submitted directly to regulatory agencies. Typically our reports include recommendations on refining the RM plan, and frequently our senior leaders offer consultation on communication strategies for regulatory submissions.

See How We've Helped Others

Patient Follow-up Survey Assessing Compliance with a Drug Indicated for IBS Risk Management Program

As part of a risk management plan, we conducted a study to measure how well physicians and patients follow the risk management program requirements for prescribing a drug indicated for IBS and to determine how well patients comprehended the information provided to them. Over 4,000 patients enrolled in the study, and the retention rate across multiple follow-up questionnaires was over 95%. As a result of our work, the study sponsor was able to demonstrate high compliance with the risk management program. Results were published in *Alimentary Pharmacology and Therapeutics*, 2006;24(5):869-878.

Health Care Provider Survey to Evaluate the Risk Management Education Program

As part of the risk management program for an antidepressant, we evaluated physicians' and pharmacists' knowledge of educational materials. The objective of this online study was to measure postintervention knowledge of screening methods to identify patients at high risk of suicidality; counseling and monitoring practices for these patients; and prescribing practices for high-risk patients.

Risk Management Drug Utilization and Treatment Practice Pattern Studies in European Countries

As part of an EMEA requirement for a product approved for a range of indications in pediatric and adult patients, we evaluated product utilization and treatment patterns. The study included a cross-sectional survey of physicians and a systematic review of patients' chart data during a 12-month period. We surveyed 500 physicians from 10 specialties in Germany, Spain, France, Italy, and the UK in order to provide context for safety reports in the EU.

Let RTI-HS Help You

To learn more about our capabilities, please visit us online at www.rti.org, email us at

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