

## Minimize Risk and Maximize Success: Therapeutic Risk Management

*Know and manage  
your products'  
risk-benefit profile*

### Minimize Risk, Maximize Success

Successful regulatory approval and commercialization of pharmaceutical products requires a robust risk management strategy. Our risk management strategies help you reduce risks to patients by investigating the patient population epidemiology, the drugs or therapy's effects and usage under real-life conditions. We work with you to design, monitor and evaluate the best risk-minimization program for patients and healthcare practitioners. With an integrated approach to Risk Management Plans (RMPs) including Risk Minimization Action Plans (RiskMAPs), Risk Evaluation and Mitigation Strategy (REMS) and EU Risk Management Plans (EU-RMPs), we help our clients meet regulatory requirements. For example, we help develop RMPs, we conduct database studies, literature reviews, prospective observational studies and physician and patient surveys and we develop and evaluate risk communication strategies.

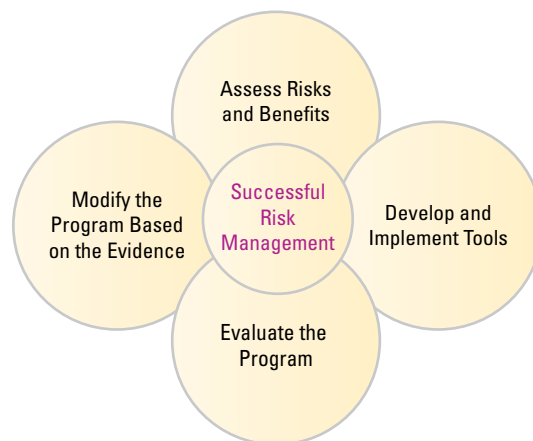
### Assess Risks and Benefits

We help you define and understand potential risks associated with a drug through rigorous epidemiologic investigation. We help identify populations of special concern. To put risks and benefits in perspective, we evaluate utilization and safety patterns of other therapies and we rigorously assess patient and physician views on trade-offs between risks and benefits of treatment. You can use our analyses to help guide your development program, regulatory submission and post-approval strategies.

To meet your requirements for risk-benefit assessment, we apply methods that include:

- Retrospective and prospective epidemiologic studies, including database studies

### Successfully Manage Risk with RTI Health Solutions®



- Large safety trials and registries
- Conjoint analysis of risk-benefit trade-offs (preferences)
- Literature syntheses, including sections in RMP documents
- Expert advisory panels
- Population surveys of physicians and patients, including REMS surveys

### Develop and Implement Tools

With a robust assessment of your product's risks and benefits and with knowledge of the clinical context, we help you determine the most appropriate strategies to manage a potential risk. Responses may include a formal RiskMAP, REMS or EU-RMP that specifies tools ranging from education programs to performance-linked access systems. We select and engage stakeholders to help develop and review the plan. A well-conceived plan, with clear goals, objectives and evaluation strategy, has the greatest likelihood of success in minimizing risk while ensuring access to needed therapy for patients. We adapt deliverables according to ICH, FDA and EMEA guidances.

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We stay abreast of developments through our relationship with regulatory agencies, academic institutions and professional societies, so you can be confident that your programs always comply with current regulations and submission guidelines.

## Evaluate and Modify the Program

The goal of an RMP is to reduce risks to patients while preserving access to treatment. Critical to meeting that goal is to implement an ongoing evaluation of the RMP that provides real-world evidence on how well the program elements are working to (1) modify behavior of healthcare professionals and patients and (2) maintain risks at an acceptable level. Effective evaluation of RMPs allows sponsors to modify the programs and in some cases eliminate them altogether.

We provide you with reliable evidence upon which to assess and, when appropriate, amend the program.

To support you, we collect evidence and conduct program evaluations. Our methods include, but are not limited to:

- Cognitive evaluation of educational materials
- Surveys of prescriber and patient knowledge, attitudes and practices
- Prescription compliance studies using claims database and prescribing data
- Studies of adherence to prescribing regimens
- Patient registries and real-time safety studies
- Failure Mode and Effect Analyses (FMEAs)

## Rely On Our Thought Leaders

At RTI-HS, you have access to established leaders in the fields of epidemiology, survey research, medicine, psychometrics and biostatistics. In addition, we partner with recognized academic and regulatory agencies. For example, our staff have faculty appointments with the UNC School of Public Health and School of Pharmacy, the Harvard School of Public Health and Boston University. We also partner with the UNC Center for Education and Research in Therapeutics.

Rely on our thought leaders to advise on the best methodologies, study designs and analytic strategies to meet your risk management needs.

## See How We've Helped Others

1. Our patient-based follow-up study of clinical eligibility, knowledge and behavior of patients and prescribers demonstrated to the sponsor and regulators that a risk management program was extremely effective in guiding physician and patient compliance.
2. We helped our client fulfill risk management program requirements of regulatory agencies for a new medication by conducting a surveillance study of rare outcomes and exposure in the US and Europe.
3. Our literature review and meta-analysis of published information helped our client better understand a safety signal concerning a rare outcome and treatment indications.

## Let RTI-HS Help You

To learn more about our capabilities, please visit us online at [www.rtihs.org](http://www.rtihs.org), email us at [rtihealthsolutions@rti.org](mailto:rtihealthsolutions@rti.org), or call one of our international offices listed on the front.