

Know and manage the risk-benefit profiles of your products.

## Minimize Risk, Maximize Success

Your success depends on knowing the potential risks associated with your product and managing those risks throughout its life cycle. We'll work with you each step of the way so you can maximize patient safety and preserve access to your treatment.

## Assess Risks and Benefits

We help you define and understand potential risks associated with your drug and identify populations of special concern through rigorous epidemiologic investigation. To put risks and benefits in perspective, we evaluate utilization and safety patterns of therapies and rigorously assess patient and physician preferences for treatment as they trade off risks and benefits. These analyses and deliverables can guide your clinical development programs, regulatory submissions, and post-approval strategies.

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

- Training your in-house team on benefit-risk assessment using leading frameworks and methods
- Leading your team in a benefit-risk assessment for a product or therapy area
- Literature review and synthesis
- Discrete choice experiments and other stated-preference studies
- Studies to evaluate risk in real-world settings



## Develop and Implement Tools

Once you have a robust assessment of your product's risks and benefits, we bring knowledge of the clinical context to help you determine the most appropriate strategies to manage a potential risk. A response may include a formal Risk Evaluation and Mitigation Strategy (REMS) or European Risk Management Plan (EU-RMP) that specifies tools ranging from education programs to performance-linked access systems. Whatever the strategy, you'll have a variety of experts helping you develop and review your plan.

Contact Us:  
[info@rtihs.org](mailto:info@rtihs.org)  
[www.rtihs.org](http://www.rtihs.org)

## Key Technical Staff

### Elizabeth Andrews, PhD

Vice President,  
Pharmacoepidemiology and  
Risk Management  
eandrews@rti.org

### Susana Perez-Gutthann, MD, PhD

Vice President and Global  
Head, Epidemiology  
sperez@rti.org

### Kenneth Rothman, DrPH

Distinguished Fellow and  
Vice President,  
Epidemiology Research  
krothman@rti.org

## Evaluate and Modify the Program

Ongoing evaluation of risk management plans provides you with real-world evidence on how well the program elements are working to modify behavior of health care professionals and patients, while maintaining risks at an acceptable level. You can use this evidence to modify your programs when needed, and in some cases eliminate them altogether.

To evaluate your plan, we implement state-of-the-art methods and tools, such as:

- Cognitive evaluation of educational materials
- Surveys of prescriber and patient knowledge, attitudes, and practices
- Prescription compliance studies using claims database and prescribing data
- Medical chart abstractions
- Studies of adherence to prescribing regimens
- Patient registries and real-time safety studies

## Rely On Our Technical Team

You can depend on our thought leaders to advise you on the best methodologies, study designs, and analytic strategies to meet your risk management needs. You'll have access to established leaders in the fields of epidemiology, survey research, medicine, psychometrics, and biostatistics. 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, among others.

When you partner with us, you can be confident that your programs will comply with current regulations and submission guidelines. We routinely work with ICH, FDA, and EMA and stay abreast of industry developments through our relationships with academic institutions and professional societies.

## See How We've Helped Others

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