

Quality Analysis for Quality Decisions: Epidemiology

Know risk factors and what they mean for your product and patient safety

Improve the Quality of Your Decisions

Our epidemiology group provides expertise to improve and expedite decision-making. We help you do this during your product's development, launch, and commercialization stages.

Expert advice and results from our studies aid in the understanding and interpretation of data from other sources including:

- Preclinical and early development
- Clinical trials
- Post-approval studies
- Spontaneous reports

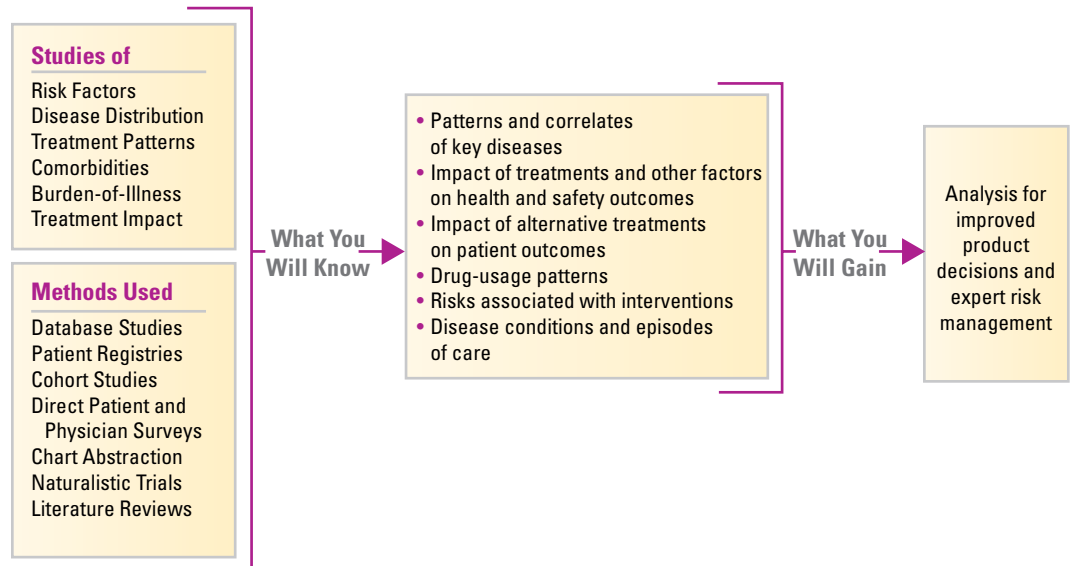
No matter what the study or service, we deliver quality data for quality decisions.

Get Meaningful Data Analysis

We perform studies that yield meaningful data for any stage of your product's lifecycle. To do this, we ask the right questions and apply the right methodologies. Our international team of epidemiologists:

- Conduct disease-burden and prevalence studies
- Design and implement post-approval studies (i.e., post-marketing, safety, and surveillance studies)
- Develop risk management strategies and plans
- Evaluate the effectiveness of risk management strategies
- Help prepare regulatory submissions
- Provide expert advice in scientific advisory boards

RTI-HS studies, methods, and applications provide quality data to help you make quality decisions.



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Rely On Our Thought Leaders

Our epidemiological research and studies appear in leading scientific publications. Academic and government institutions look to our epidemiologists as leading advisors, and we participate on FDA committees. We have academic appointments at the University of North Carolina (UNC) School of Public Health and School of Pharmacy, Boston University, Harvard School of Public

Health, and the University of Dundee. In addition, we partner with the UNC Center for Education and Research on Therapeutics and the European Network of Centers of Excellence in Pharmacoepidemiology and Pharmacovigilance. We are active in a number of professional societies. Our broad range of experience and relationships helps us provide you with better studies for quality decisions.

See How We've Helped Others

1. A client faced methodological challenges in assessing the potential association between a medication and tumor because both drug exposure and the outcome were rare. We were able to collaborate with our client to design a 10-year epidemiologic surveillance study in the US and Europe that will successfully meet our client's patient safety and regulatory requirements.
2. We conducted a study using electronic medical records to evaluate the risk of attempted and completed suicide among adults receiving one of four antidepressants. Results of the study, published in the *BMJ*, helped place patient safety and regulatory concerns into appropriate context [BMJ 2007 Feb 3; 334(7587):242].
3. We conducted a four-country Web-based cohort study, supplemented with in-home validation assessments, to understand the dynamics of smoking cessation and to evaluate possible predictors of successful quit attempts, including weight gain and fear of weight gain. The study provided useful background information to support a product in development. Results were published in *Addiction* [2006; 101(9):1352-61].

Receive Quality Deliverables

We offer various publication strategies and deliverables for each study we conduct. Examples include:

- Strategic and scientific consulting
- Peer-reviewed journal articles
- Presentations at professional meetings
- Posters
- Abstracts
- Study reports

- Study protocols
- Quality-controlled databases
- Statistical tabulations of data
- Epidemiology sections of regulatory and internal documents

Let RTI-HS Help You

To learn more about our capabilities, please visit us online at www.rtihs.org, email us at rtihealthsolutions@rti.org, or call one of our international offices listed on the front.