



# Epidemiology: Literature Reviews

Summarize scientific knowledge into a concise report

## Understand Complex Clinical and Safety Issues

Evidence-based decision-making is critical in today's health care environment. Our epidemiology literature review services help you understand both the content and the methodological quality of studies so you can evaluate the body of published knowledge related to your particular health care question. This enables you and your colleagues to make better plans for drug development, to plan for the eventual use of the product and to place potential safety signals into appropriate context. These types of reviews are often required for regulatory submissions, such as orphan drug applications, pharmacovigilance and risk management plans required by FDA, EMEA and other regulatory agencies.

For a particular disease state, we perform literature reviews that examine:

- Measures of disease frequency
- Risk factors
- Burden-of-illness
- Treatment patterns

Literature reviews are also conducted to examine drugs that may be of interest, including an analysis of:

- Safety
- Effectiveness
- Populations at particular risk
- Utilization and persistence

They can also guide your clinical trial and survey designs and/or provide compelling evidence for new research areas to explore.

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### Literature Searches Tailored to Your Needs

We customize your literature reviews to match the level of complexity that you require. The three standard levels we offer are described below:

	Restricted	Targeted	Comprehensive
Description	An overview of literature in a particular area of interest using a restricted, agreed upon number of articles	Critical review of a targeted topic of interest; review is exhaustive within a narrowed scope	Comprehensive review of literature in a particular disease area, drug or drug class
Example	Brief disease backgrounder for use in planning clinical development programs	Incidence of adverse events among a patient population or those taking a certain drug	Review of all information (prevalence, symptoms, health care utilization, etc.) related to a certain illness
References	Primary references and/or review articles	Mainly primary references, with some review articles	Mainly primary references, some review articles
Typical Timelines*	1-2 Months	1-4 Months	4-9+ Months

\*Timelines will vary due, in part, to number of conditions/diseases, countries of interests, breadth of current literature, translations requirements, etc.

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## *RTI Health Solutions Key Thought Leaders*

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## **A Methodology You Can Depend On**

We have a consistent process by which all literature searches are conducted in a scientifically rigorous and efficient manner.

First, we collaborate with you to develop the study plan, which includes defining:

- Specific objectives
- Scope of the review (e.g., targeted, comprehensive)
- Inclusion/exclusion criteria (e.g., geography, patient population)
- Database and data sources (including both peer-reviewed journals and “gray” literature such as unpublished manuscripts)
- Deliverables and timelines

Once the plan is defined, the literature search is conducted and the process fully documented. The reviewer then systematically abstracts information from the included articles to capture key elements of the study. To conclude, the findings are summarized in a final report.

## **Meta-Analysis Services**

While systematic literature reviews are qualitative in nature, meta-analyses are quantitative. Often a comprehensive literature review is accompanied by a meta-analysis. Utilizing the latest techniques, our epidemiologists and biostatisticians perform meta-analyses to pool and analyze the research results of separate but similar studies. Meta-analyses are particularly helpful for better understanding the safety and efficacy differences between two or more drugs when head-to-head trials are not conducted.

## **See How We’ve Helped Others**

1. To assist a client in understanding four different events that had been reported through spontaneous adverse experience reports and published case reports, we conducted focused reviews of four conditions (one common, three relatively rare). Senior epidemiologists with experience in the relevant therapeutic areas summarized the key published information in summary reports. Extracts of these reports were included in the company’s response to regulatory agencies.
2. Patients who receive an organ transplant are surviving longer than in the past due to improved procedures and therapies. We conducted a literature review on the risks of selected outcomes in transplant patients to better understand the background rates of those outcomes in clinical trials of new drugs. Results of the study were presented at an international conference.

## **Rely on Our Thought Leaders**

With our diverse and distinguished international team of epidemiologists, physicians, safety experts and biostatisticians, we offer a comprehensive range of literature review and meta-analysis options for your epidemiological, safety, and risk management needs. Our scientists participate in and have access to the scientists and resources of the RTI-UNC Evidence-Based Practice Center.

## **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.