

Support development strategies and regulatory submissions based on expert analysis of published evidence.

### Understand Complex Clinical and Safety Issues

Evidence-based decision making is critical in today's health care environment. Literature reviews help you understand the published evidence related to your research questions—whether the results will be used to inform your drug development and post-approval strategies or place a potential safety signal into the appropriate context. Literature reviews can be a stand-alone project or a component of other larger projects such as regulatory submissions (Orphan Drug Applications, Pediatric Investigation Plans, Environmental Risk Assessments), pharmacovigilance, and risk management plans. They help you understand:

- Burden of illness
- Measures of disease frequency

- Risk factors
- Treatment patterns
- Utilization and persistence
- Drug safety
- Populations at particular risk
- Benefit-risk assessments
- Effectiveness of treatment

Because literature reviews often serve as the foundation for follow-on research and are used for critical decision making, it is imperative that they are done well and with scientific rigor. From defining objectives and preparing the search protocol to conducting the search and reviewing the results, our rigorous, quality-controlled processes consistently ensure high-quality, fully documented, and reliable deliverables.

#### Literature Reviews, Tailored to Meet Your Needs

We customize literature reviews to match the level of complexity 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, with 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, translation requirements, etc.

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## See How We've Helped Others

We helped a company understand and respond to regulatory agencies about adverse events reports. We conducted literature reviews of the conditions, and our senior epidemiologists with experience in the relevant therapeutic areas provided summary reports to the client.

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.

## A Methodology You Can Depend On

We follow a consistent process to conduct all literature reviews in a scientifically rigorous and efficient manner.

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, we conduct the literature review and fully document the process. The reviewer then systematically abstracts information from the included articles to capture key elements of the study. To conclude, we summarize the findings 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.

## 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.