Fortrea

Why literature reviews should be a key part of your evidence-generation strategy

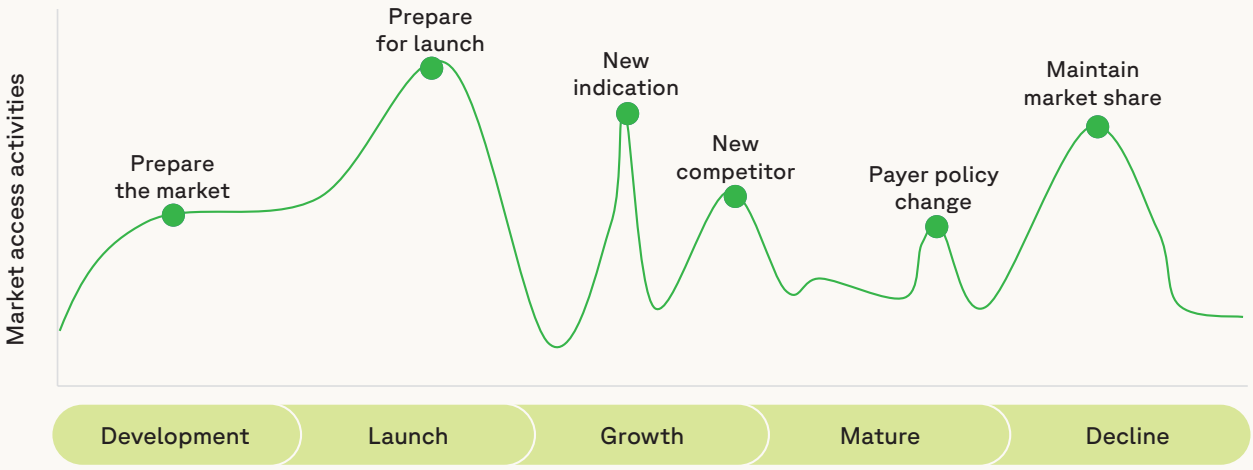
While efficacy, safety and quality of a product are necessary to secure regulatory approval, these pillars alone are not sufficient to achieve market access success. To achieve uptake of a new product, a developer is challenged to differentiate from competitors while taking account of an evolving reimbursement landscape, with consideration that payers and other key stakeholders demand convincing information to support the value of a product and justify its price, compared with current standard of care or emerging therapies.

In the era of decision making that is evidence based, literature reviews offer a cost-efficient approach to appraise the currently published literature to gather evidence, address potential data gaps and support downstream market access activities. For example, systematic literature reviews are a key component of Health Technology Assessment (HTA) submissions around the world for many HTA agencies and are mandated to provide a comprehensive, high-quality appraisal of published evidence. Literature reviews are, therefore, an important element of developing well-informed market access and health economics and outcomes research (HEOR) evidence-generation strategies.

Why perform a literature review across a product's lifecycle?

Preparation of a comprehensive literature review at an early stage builds the required evidence platform for a product. Further, literature reviews may also serve as a means to tackle data gaps at various stages of product development and commercialization.

Successful market access is predicated on having the right evidence at the right time



Build the evidence platform for a product

- Etiology and epidemiology of a disease
- Humanistic and economic burden of a disease
- Treatment guidelines/patterns in clinical practice
- Clinical effectiveness of comparators
- Resource use, cost and utility estimates with comparators
- Information on potential real-world use of a product
- Emerging treatments in a specific therapeutic area

Contribute to mandatory requirements for reimbursement authorities

Provide inputs necessary for other key research efforts, such as:

- Pharmacoeconomic modeling
- Mixed/indirect treatment comparisons

Inform the need for ongoing literature surveillance

- Product life cycle management
- Differentiate a product in a crowded market where real-world evidence may uniquely distinguish from existing products

Provide information to address a research question (e.g., identification of relevant outcome assessments)

Identify critical gaps in publicly available data

Start early: building a compelling value story for a new product

At Fortrea, we know planning for market access starts *early* and involves a variety of experts to research and communicate the evidence required to build a compelling value story for a new product. The compilation of evidence from literature review outputs—in combination with other evidence-generation activities—help to build the foundation for the value proposition of a product and, in turn, support an effective market access strategy. Highlighted below are the types of literature reviews that we most frequently conduct; ad-hoc, targeted (or focused) and systematic literature reviews. While not all-encompassing to every type of review, the list illustrates the range of methodologies that are available and how each may be employed to achieve a specific evidence objective.

	Ad-hoc literature review	Targeted or focused literature review	Systematic literature review
Definition and purpose	Succinct search to efficiently address a research question without concern for scope or critical appraisal of the results	Informative review of literature on a specific topic, whether to guide a strategy, help identify trends or provide an understanding for what is known about a particular field; common to use a pre-defined search protocol and a semi-systematic approach to identify relevant articles of interest	Comprehensive collection, study and synthesis of all available information on a topic that ensures rigor and minimization of bias in the identification of relevant literature; this type of review is considered the '*gold standard*' for evidence assessment
Strategy	No pre-defined search protocol, one reviewer	Pre-defined search protocol, one reviewer	Pre-defined search protocol (including inclusion and exclusion criteria), two reviewers
Reproducible search	No	Yes	Yes
Databases searched	At least one database	One or more databases, depending on scope	Multiple databases, likely to also include registries, grey literature and unpublished data
Advantages	• Quick intelligence gathering • Minimal effort to conduct	• Informative review on a specific topic area • Transparent and reproducible • Potential to be time and cost sensitive	• Comprehensive overview of a topic area • Objective, transparent process with minimal bias • Identify potential gaps and areas for new research • Can be used as a basis for independent or mixed treatment comparisons
Disadvantages	• Not transparent, reproducible or comprehensive • Selection, information and/or confounding bias • Quality appraisal of output not feasible	• Not comprehensive • Selection, information and/or confounding bias • Quality appraisal of output not feasible	• Time- and cost-intensive process • Difficult to address questions not covered in the review
Phase of development	Any phase	Any phase	• Any phase • Often required for pricing and reimbursement submissions, including HTA
Time to complete	<1 month	~1 to 4 months, depending on scope and research question(s)	~5 to 8 months, depending on scope and research question(s)
Guidelines to follow	None	Elements from Cochrane Handbook for Systematic Reviews of Interventions, PICO(TS) framework and PRISMA checklist may be employed but are not required	• Cochrane Handbook for Systematic Reviews of Interventions • Country-specific HTA guidance • PICO(TS), PEO, SPIDER and COSMIN question frameworks • GRADE quality framework • PROSPERO protocol registration • PRISMA, MOOSE and AMSTAR checklists
Activities output can support	• Value proposition development • Burden of illness/disease-state insights • Emerging topic identification • Endpoint identification (e.g., outcome assessments, resource use, costs)	• Value proposition development • Evidence gap analysis • Global value dossier development • Market access strategy planning • Communication planning • Literature review surveillance	• HTA development • Pharmacoeconomic modeling • Comparative evidence activities (e.g., feasibility assessment; mixed/indirect treatment comparison; classical and network meta-analysis)

AMSTAR, Assessing the Methodological Quality of Systematic Reviews; **COSMIN**, Consensus-based Standards for the Selection of Health Measurement Instruments; **GRADE**, Grading of Recommendations, Assessment, Development, and Evaluations; **HTA**, Health Technology Assessment; **MOOSE**, Meta-Analyses and Systematic Reviews of Observational Studies; **PEO**, Population, Exposure, Outcome(s); **PICO(TS)**, Patient/Problem, Intervention, Comparison, Outcome(s), Timeframe, Study design; **PRISMA**, Preferred Reporting Items for Systematic Reviews and Meta-Analysis; **PROSPERO**, International Prospective Register of Systematic Reviews; **SPIDER**, Sample, Phenomenon of Interest, Design, Evaluation, Research Type.

What are the fundamental questions when planning a literature review?

When considering what type of review would best address the evidence objective, we recommend considering:

- What are the **evidence gaps** and which **specific research questions** are to be addressed?
- What is the **primary intended use** of the findings?
- Who is the **intended audience(s)**?
- How will **sensitivity** and **specificity** be effectively addressed during protocol design?
- What **established guidelines or guidance are expected to be followed** during execution of the literature review?
- Is there intention to **publish the outputs** of the literature search?
- What is the **relevance of the search and output to other work streams** (e.g., global value dossier development, pharmacoeconomic modeling, market access planning, regulatory commitments, post-marketing commitments and differentiation)?

Why choose Fortrea as your partner for literature reviews?

At Fortrea, we understand literature review strategy and how to advise for a best approach given a client's circumstance, weighing the pros and cons of different methodologies. We have in-house, end-to-end capabilities to conduct literature reviews in addition to the planning and execution of associated market access and HEOR activities that a literature review output may lend support to (e.g., dossiers, meta-analyses, models, publication writing). As our consulting team includes experts in market access, HEOR and the related activities that require literature reviews, our clients benefit from efficiencies of parallel and integrated work streams. In addition to an abundance of ad-hoc literature reviews, our expert teams are executing—on average—25 to 30 targeted or systematic literature reviews per year. For many of these engagements, the findings from literature reviews are being used in downstream market access activities including, but not limited to, establishing burden of illness, evidence gap analysis, creation of value messages and development of various dossiers. Our team also performs 10 to 15 meta-analyses per year, many of which support commercial-in-confidence reimbursement submissions.

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