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How to: Undertake an Evidence Gap Analysis and Generation Strategy

Linda Murphy, Richard Birnie and Daniel Gladwell

In the seventh installment of our "How to" series, Lumanity's Linda Murphy, Richard Birnie, and Daniel Gladwell explain how conducting an evidence gap analysis and evidence generation strategy can support evidence-based decisions that enhance patient outcomes.



What is an evidence gap analysis and evidence generation strategy, and how to develop it?

Purpose and benefits:

Developing a health economics and outcomes research (HEOR) strategy involves consideration of multiple value elements to optimize reimbursement. Health technology assessment (HTA) bodies require robust evidence to support a technology's value proposition. An evidence gap analysis and evidence generation strategy help a company to compare its evidence base against HTA requirements, identify key areas of uncertainty, and devise solutions. This ensures strong value demonstration by prioritizing and addressing critical gaps.

Framework for implementation:

A structured approach supports the development of a coherent value story, ensuring optimal use of resources and facilitating evidence-based decisions to improve patient outcomes.

1. **Prepare** strategic proprieties for evidence needs, begin by identifying the question or problem that needs to be addressed.
2. **Define** evidence gaps. Align existing evidence to the question and identify gaps.
3. **Design** evidence generation programmes to support prioritized evidence gaps.
4. **Execute** Generate appropriate evidence to fill the gaps.
5. **Review** regularly to refine the strategy as evidence evolves.

Timing:

Develop these strategies early, ideally before a pivotal trial, incorporating cross-functional input to build a robust evidence base. This approach ensures that the right evidence is available at the right time and meets the highest standards.



Overall goal of an evidence gap analysis and evidence generation strategy

Strategic planning:

Insights derived from an evidence gap analysis and evidence generation strategy, crafted with cross-functional collaboration, enables companies to plan effectively, improving the likelihood of reimbursement success. An efficient strategy, developed cross-functionally, guarantees optimal use of resources, supporting evidence-based decisions that enhance patient outcomes.

This guide focused on evidence gap analysis and evidence generation strategy to support global HEOR/ HTA efforts, aligning with our broader Integrated Evidence Generation Planning.

Key activities in developing an evidence gap analysis and evidence generation strategy

An evidence generation strategy connects the desired value proposition to unmet medical needs, pinpointing gaps and outlining research activities to address them.

Step 1:
Prepare (identify the question or problem)

Burden of illness and unmet need:

Assess clinical, economic and humanistic needs, and understand the patient population and disease impact. Review clinical guidelines, current disease management and target population size. Consider how to position the new technology.

Competitive landscape:

Analyze the current and future treatment landscape, reviewing trials to compare technologies, outcomes and feasibility of indirect treatment comparisons. Consider clinical trial endpoints and the feasibility of capturing required evidence outside the trial design.

Market access environment:

Understand clinical and economic assessment needs in key markets, reviewing HTA guidance and past appraisals. Consider early advice to manage uncertainties.

Economic value:

Explore modeling approaches to capture product value. Early modeling helps to explore the economically justifiable price, strengthen evidence, identify key value drivers and supports prioritization of evidence generation activities.

Health service impact:

Assess healthcare service requirements, including changes in patient flow, expertise, diagnosis, administration, monitoring, and education.

Step 2:
Define

Align the existing evidence base to the decision problem, define and prioritize gaps. Incorporate insights from key stakeholders, such as clinical trial experts, biostatisticians, regulatory, pricing, reimbursement, market access, HTA, medical affairs, RWE, PRO teams, health care professionals, patient advocates and local affiliates. This holistic approach fosters alignment and avoids inefficiencies.

Step 3:
Design

Design evidence generation programs to support prioritized evidence gaps. Evidence generation includes a range of activities, for example, targeted literature reviews of epidemiological literature, HTA payer and landscape assessment, systematic reviews of interventions, real-world evidence studies and cost-effectiveness modeling.

Step 4:
Execute

Generate appropriate evidence to fill the gaps and execute in a timely manner.

Step 5:
Review

An evolving disease, market and policy landscape means that evidence generation should be iterative. Regularly update the strategy to ensure the gathered evidence remains relevant, maintaining consensus among stakeholders.

About the authors

Have a question for our authors? Use the links to contact them directly on LinkedIn or by email.



Linda Murphy
Senior Director, Research, HEOR



Richard Birnie
VP Research, HEOR



Daniel Gladwell
SVP & Chief Scientific Officer, HEOR

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