

EVIDENCE GENERATION: IDENTIFYING AND ADDRESSING GAPS TO MEET THE CLINICAL AND EDUCATIONAL NEEDS OF STAKEHOLDERS

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ABSTRACT

Objectives: To provide a clear framework that enables a thorough situational and behavioral analysis to be conducted to identify evidence gaps in the clinical development plan that may become a barrier to effective product use by health-care professionals. To understand the range of options available to address these key evidence gaps, and how to effectively and efficiently implement a compelling evidence-generation plan early in a product's development that will support all key stakeholders' educational needs throughout its life cycle.

Challenge/problem: Situation analyses and their subsequent interpretation are often conducted in an inconsistent manner and do not always take into account deep insights into the behavioral and cultural environment of health-care professionals and their patients. This can leave vital gaps in a product's evidence base. Coupled with this, evidence-generation planning is often highly reactive. As a result, medical plans are not always grounded in the right evidence to address key stakeholder needs through the life cycle and may lack a consistent thread from medical strategy through to communication tactics.

Solution: To develop a framework for comprehensive and robust evidence platform generation, with its translation into actions that drive positive behavioral change in health care through engaging and creative multichannel delivery.

Outcome: A medical plan that ensures valuable evidence is anticipated, in place, and linked to a clear end goal of positive behavioral change in patient care.

Benefits: Starting a formal evidence-generation and communication process early in development (i.e. Phase 2) ensures that the necessary information is available to make pricing, reimbursement, and product-positioning decisions at the time of launch.

INTRODUCTION

- To be successful, a formal evidence-generation process needs to start early in development to ensure that the necessary information and data are at hand to effectively support a product through all key lifecycle milestones ahead
- Based on our extensive experience, the process we recommend ensures delivery of a robust evidence-generation plan as part of the medical plan for a product; the development of a parallel risk-management strategy is an integral component of this process
- Through this, we evaluate the most appropriate and efficient solutions to fill evidence gaps and identify the optimal mix of communication strategies and tactics to drive the medical plan through the internal cross-functional team and out to external stakeholders in order to encourage positive behavioral change in health care
- The key stages of this framework are:



INSIGHT

- Insight identifies the need for additional evidence that is increasingly necessary to meet new requirements for registration and access; the process can also identify gaps within the medical plan and allow for the prioritization of evidence-generation activities based on realistic assumptions of timing and resources
- Market access barriers, safety concerns, drug development costs, and the expectations of health-care professionals (HCPs) and patients are all increasing; in order to effectively address these issues, the insight-gathering stage must go far beyond simply the product and competitor profiles, and should also incorporate deep insights into the behavioral and cultural environment of HCPs and their patients
- There should be careful evaluation of health and social trends; customer journeys; the attitudes, behaviors, and motivations of both patients and HCPs; market dynamics and competitor profiles; and key differentiators and product data (Figure 1)
- Using a cross-functional team to identify areas for potential insight development, which may lead to the identification of evidence required to support the key medical objectives, is critical to the process
- Once insights are captured through analysis and extensive cross-functional evaluation, it is time to develop your evidence-generation strategy (Figure 2)

Figure 1. Factors to consider when gathering insight to generate a robust evidence base and identify gaps within the overall medical plan

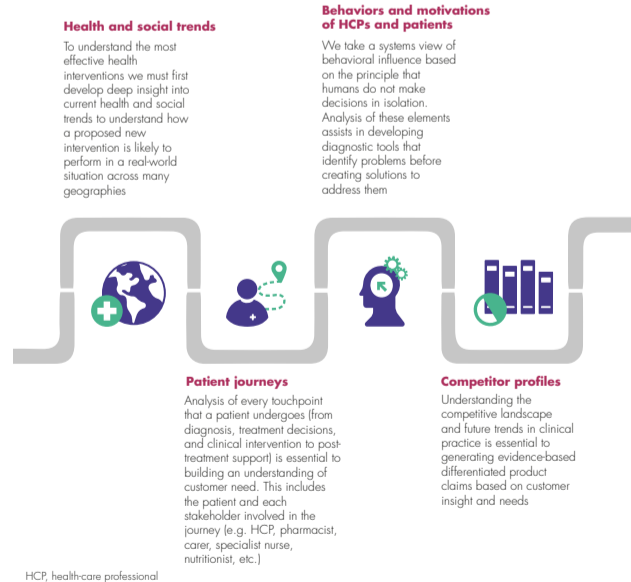
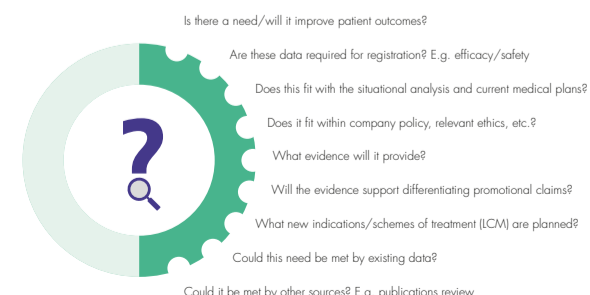


Figure 2. Key questions when initiating the evidence-generation process

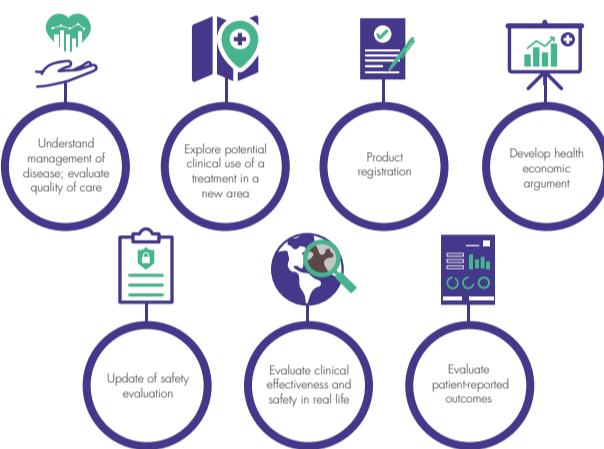


LCM, lifecycle management

STRATEGY

- Developing the medical strategy requires consideration of what types of evidence are needed for specific outcomes (Figure 3) and how, once generated, they will be activated (i.e. how it will be tailored for specific stakeholder personas who will take behavioral action based on their persona throughout the product life cycle)
 - The evidence need that is identified should be clearly linked back to a key medical objective/unmet need for the product
 - The level of evidence required to meet the medical objective should be carefully considered¹
 - The evidence-generation solution that is identified should be designed to represent the most efficient and timely way of generating the data in order to meet this need with a high probability of success

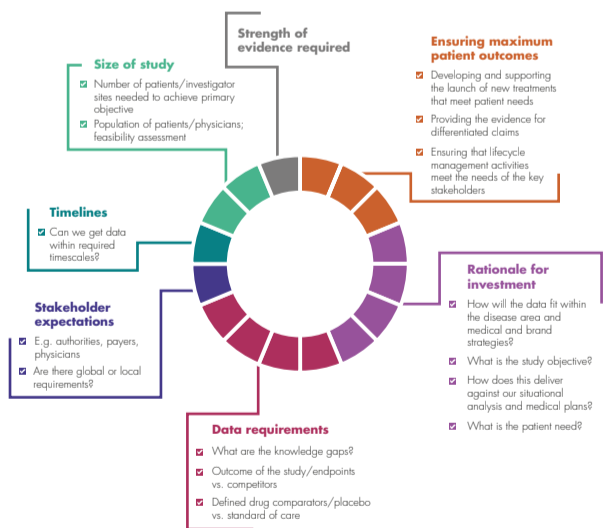
Figure 3. Types of evidence needed to develop a robust medical strategy



EVIDENCE-GENERATION WORKSHOP

- A cross-functional workshop including appropriate experts and international affiliate representation is key to gaining internal alignment regarding the evidence-generation strategy
- During the workshop, the insights gathered are considered and any gaps identified are prioritized
- Potential solutions for the prioritized gaps are discussed, with an emphasis on "thinking outside the box" to identify the most appropriate solution to meet time and budget constraints with a high chance of success
- When considering the evidence needed, a number of factors should be carefully weighed to assess the likelihood of achieving the desired outcome within planned timelines and budget; these factors should be included in a risk and potential mitigation plan (Figure 4)
- Consider:
 - RIGHT EVIDENCE > RIGHT INVESTMENT > RIGHT PATIENTS > RIGHT TIME
- Once the strategy has been developed through determination of the evidence needed and prioritization of identified gaps, it is time to implement your activation phase

Figure 4. Factors to consider when assessing the likelihood of achieving the desired outcome of a strategy



ACTIVATION

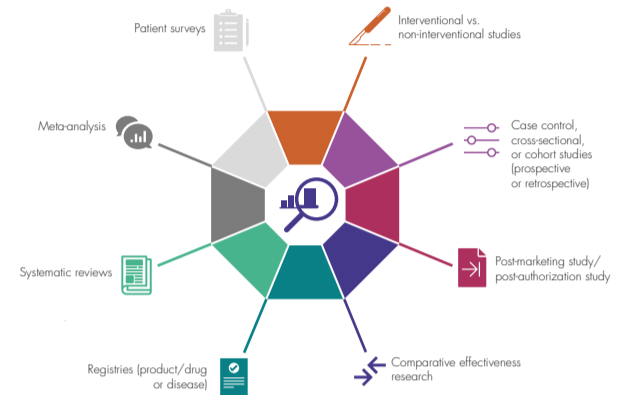
GENERATE YOUR EVIDENCE

- The activation phase involves the implementation of potential evidence-generating solutions (Figure 5) and the communication of the resulting evidence via an engaging, creative, effective, and affective multichannel communications strategy
- The activation plan, together with an associated risk and mitigation plan, should be constantly reviewed to ensure that evidence-generation and communication activities are in line with the medical and brand plans for the product

BENEFITS

- Following this proposed framework for evidence generation alongside the normal medical planning process adds a further dimension to this stage of drug development in terms of insight gathering and behavioral understanding
- This framework ensures that all stakeholder evidence needs are anticipated, met, and linked to a clear end goal of positive behavioral change in patient care

Figure 5. Potential evidence-generating solutions to consider during the activation phase



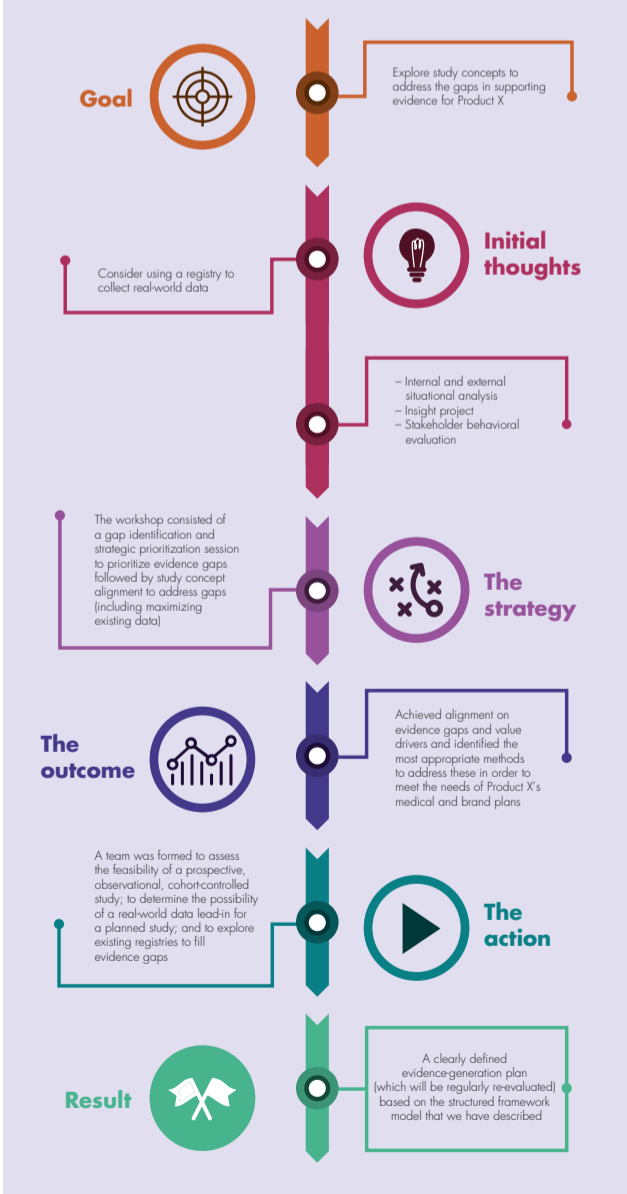
EVALUATION

- The final critical step in the process is to evaluate the impact of the overall medical plan through attitudinal and behavioral measures as well as reach and engagement metrics; these metrics inform ongoing updates to the overall medical plan
 - A useful tool is Moore's pyramid, which details seven levels of educational impact and the methods to assess these²
- The risk and mitigation plan should also be evaluated to determine the accuracy of risk prediction for evidence-generation activities and the success of any defined mitigation strategies implemented when activities have not gone to plan (e.g. additional study sites being opened because the feasibility of trial recruitment was not correctly assessed)

CASE STUDY: THE FRAMEWORK IN ACTION

- A case study utilizing our defined framework to create a successful evidence-generation plan for Product X is presented in Figure 6

Figure 6. Case study utilizing the framework of insight development, strategy, activation, and evaluation to explore study concepts for Product X



REFERENCES

- Centre for Evidence-Based Medicine. Available at: <http://www.cebm.net/index.aspx?o=5653>
- Moore DE et al. J Contin Educ Health Prof 2009;29:1-15