THE POWER OF INTEGRATED EVIDENCE GENERATION PLANS IN MODERN BIOPHARMA

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Introduction

The Integrated Evidence Generation Plan (IEGP) is a strategic framework that identifies evidence gaps and outlines approaches to address them, supporting successful product development and commercialization.[1] This IEGP framework is derived in large part from the Target Product Profile (TPP) and Target Value Proposition (TVP) as well as the competitive landscape. A well-constructed IEGP not only addresses the needs and expectations of internal stakeholders across biopharma functions and geographies but also lays the groundwork for clear, compelling communication with regulators, payers, healthcare providers, and patients.[2]

IEGPs are carefully crafted by cross-functional teams responsible for driving the success of each therapeutic asset. These plans are typically initiated during the clinical development stage, with early input from key functions such as Clinical, Statistical, Regulatory, Commercial, and Medical Affairs. While the overall framework and core objectives remain consistent, evolving regulatory expectations and payer evidence requirements can introduce new demands and data sources over time shaping how IEGPs are designed and executed.

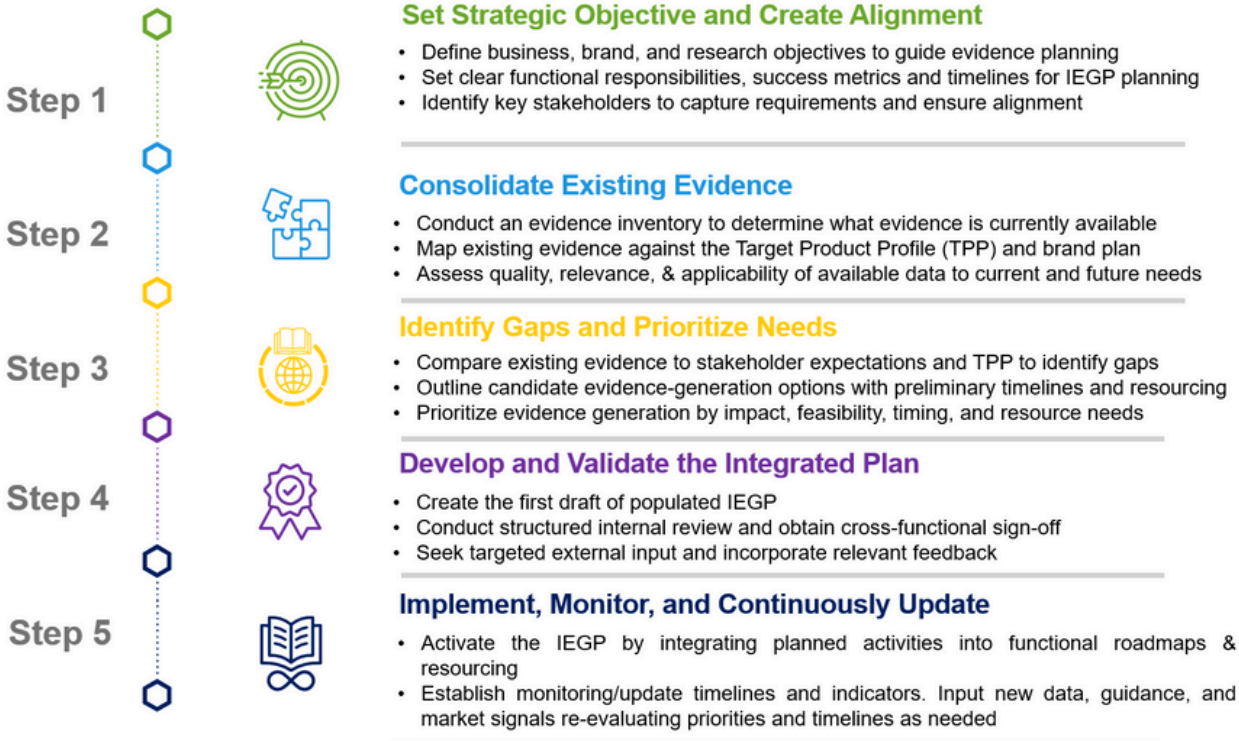
While placebo-controlled trials remain the gold standard for New Drug Applications (NDA), both the United States Food and Drug Administration (FDA) and European Medicines Agency (EMA) now accept submission packages that include Real-World Evidence (RWE).[3] The increasing prevalence of rare conditions defined by genetic or biological markers has further accelerated the adoption of innovative study designs. These include interventional approaches such as single arm trials supported by external control groups, as well as observational studies aimed at characterizing the natural course of disease, evaluating comparative effectiveness in routine clinical practice, or assessing the broader impact on patients and society.[4]

An IEGP helps pharmaceutical companies navigate this evolving landscape by providing an integrated and consolidated approach to evidence generation planning. It identifies evidence gaps, prioritizes studies, and leverages all available data types to build a cohesive strategy. By doing so, it enables companies to more effectively demonstrate the value of their therapies, supporting better decision making for regulators, payers, and healthcare providers.

When are IEGPs implemented?

Ideally, an IEGP is initiated two to three years before the anticipated market launch to establish a robust and integrated evidence foundation, recognizing that evidence generation requires significant lead time. This early planning ensures that data needs across geographies and stakeholder groups are identified and addressed well before regulatory submission and market entry.[1,2] An IEGP can also be implemented when a product is newly acquired or reprioritized, when late-stage assets enter new indications, or when changes in the competitive or regulatory environment create new evidence requirements.[1]

Steps to IEGP Implementation



IEGP Components

IEGP are drug- and condition-specific, requiring tailored evidence to meet regulatory and reimbursement needs. Plans can be created by product or franchise depending on strategic priorities.[1] These plans support the TPP and fulfill the TVP. The key components of an IEGP can be found in **Figure 1**. An IEGP typically incorporates evidence and data from clinical trials, comparative studies, real-world evidence studies, economic analyses, and systematic reviews. IEGPs should be updated regularly or at key milestones to reflect internal priorities, new data, and external environmental changes.

Figure 1. Key Components of an IEGP

Benefits of Implementation

The implementation of an IEGP offers multiple strategic benefits by fostering cross-functional organization and brand alignment, enabling long-term planning and ensuring that each activity supports the product's strategic objectives. It improves evidence generation efficiency by allowing early identification of evidence gaps and supporting a prioritized approach to data generation that maximizes value and impact. Consolidating evidence efforts eliminates redundancies, reduces unnecessary duplication, and creates a centralized repository of data that promotes integration and transparency. An IEGP also strengthens stakeholder alignment by anticipating and addressing the diverse needs of regulators, payers, healthcare providers, and internal teams through a coordinated and consistent narrative. Together, these advantages increase the impact of evidence generation activities by building a compelling value story that supports regulatory approvals, payer negotiations, clinical adoption, and guideline inclusion, ultimately driving product differentiation and market success.

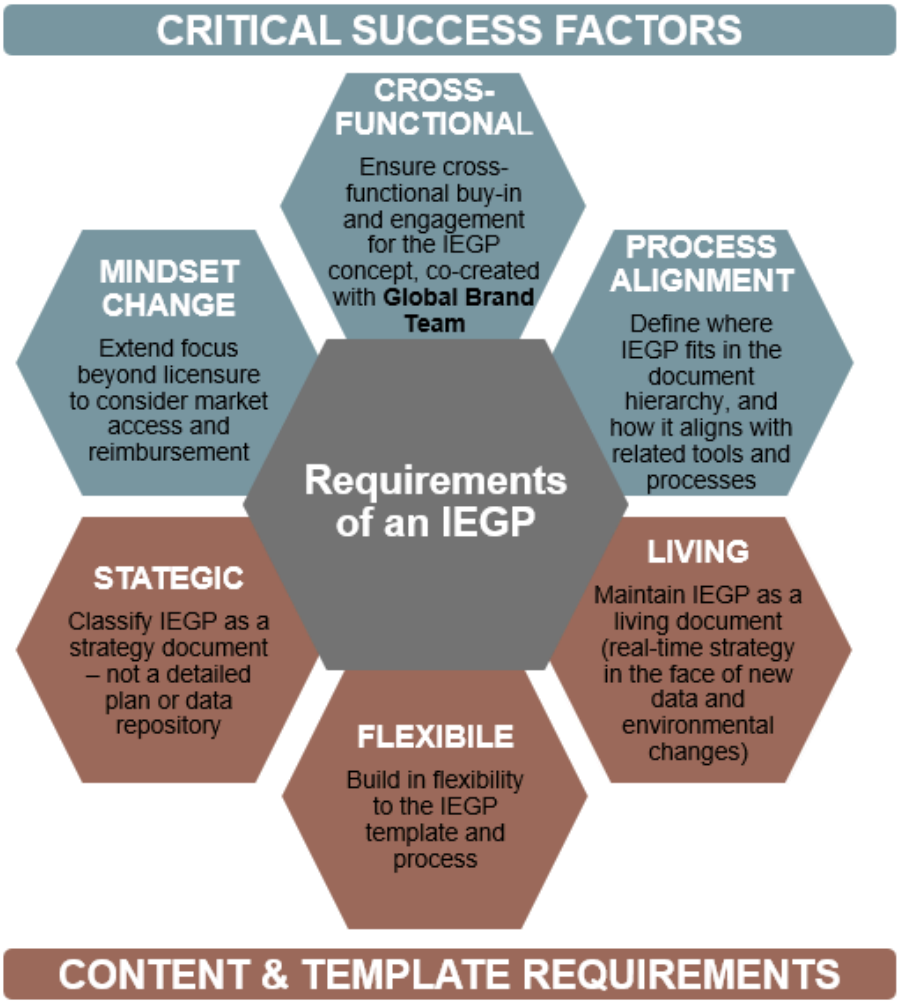
Strategies for Successful IEGPs

Successful implementation of an IEGP depends on balancing scientific rigor, speed, geographic relevance, and life cycle timing. When well executed, the plan coordinates study planning, improves resource efficiency, and supports the development of evidence that meets the needs of multiple stakeholders. Although IEGPs are developed by cross-functional teams that include Regulatory Affairs, Commercial, Market Access, Medical Affairs, RWE, and Health Economics and Outcomes Research (HEOR), the most effective plans have a single accountable owner, often a cross-functional evidence generation expert. This individual ensures collaboration and open discussion so that evidence activities remain aligned with product strategy and stakeholder requirements. Building such collaborations requires time and a willingness to share decision making, build trust, transparency, inclusive perspectives, responsive communication, and recognition of diverse expertise to be able to foster positive relationships.[5,6]

When implementing an IEGP project, six core requirements foster success (See **Figure 2**). IEGPs must be cross-functional. For an IEGP to work, all members of the team must be actively engaged in the planning. This engagement might require a mindset changed to extend their focus beyond their individual considerations to incorporate the needs across the product life cycle. Equally important is process alignment, with a clear understanding of where the IEGP fits within the organizational hierarchy and how it integrates with related tools and processes. Overall, successful deployment must include strategic buy in across the organization and process alignment to ensure long-term success.

The IEGP should be regarded as a strategic document. Despite it being a structured framework, it also must be flexible, allowing for necessary modifications within a dynamic product landscape. This flexibility allows for the IEGP to be a living document that is maintained in real-time, responding to the evolving needs in the face of new data or environmental changes.

Figure 2. Six Core Requirements of the IEGP Project



Conclusion

IEGPs are a strategic framework that consolidates evidence generation and planning for a product or franchise aligning cross-functional priorities and addressing the needs of stakeholders. It enables organizations to generate impactful, timely, and relevant evidence that supports products across their lifecycle. Effective IEGPs strengthen decision-making, accelerate product adoption, and maximize long-term value for patients, healthcare systems, and organizations.

References

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