



# Integrated Evidence Generation Planning

From strategy to execution

## Introduction



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Integrated Evidence Generation Planning (IEGP) has moved from best practice to business necessity. As regulatory expectations evolve, payer scrutiny intensifies, and patient-centricity becomes embedded in development and commercialization strategies, organizations can no longer afford fragmented approaches to evidence planning.

Lumanity's previous thought leadership publications established why IEGP matters and highlighted the risk of delayed or misaligned evidence planning, from reimbursement failure to lost commercial potential. This paper focuses on the next frontier: **how organizations operationalize IEGP in practice**

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# Lumantity's four complementary engagement models within our Evidence Navigator™ umbrella meet clients where they are

Organizations that successfully operationalize IEGP share several common characteristics. They view IEGP as:

- An opportunity to rethink evidence strategy rather than reinforce the status quo
- A continuous process that requires regular touch points
- A cross-functional responsibility, not a single-team deliverable
- A living evidence roadmap rather than a static plan

However, achieving this level of IEGP optimization in practice is challenging. While most companies recognize the importance of IEGP, they differ widely in when IEGP is leveraged (eg, in phase 1, phase 2, phase 3), in internal subject matter expertise and involvement (eg, regulatory, HEOR, market access, patient-centered outcomes, real-world evidence, medical strategy, and commercial), and in available resources.

As a result, organizations vary significantly in their ability to translate best-practice principles into consistent execution.

To meet clients where they are, Lumantity has developed 4 complementary engagement models within our Evidence Navigator umbrella:

**Compass** – Lumantity-led strategic thinking

**Guide** – Client-led strategy with expert navigation

**Hub** – Lumantity's digital IEGP platform

**Pilot** – End-to-end execution support

These engagement models reflect the real-world landscape that Lumantity encounters through IEGP: organizations face distinct challenges, levels of maturity, and resource constraints that require flexible, tailored approaches to successfully operationalize IEGP.



Figure 1

# Evidence Generation Formula



Across all 4 levels of Evidence Navigator engagement models, the core IEGP process remains consistent:

- 1. Assess the current evidence base:** Review and evaluate existing evidence to understand its strengths, gaps, and relevance to the asset strategy; this creates a shared factual foundation for the next steps.
- 2. Strategic alignment and definition of the desired future evidence base:** Align stakeholders on the overarching asset strategy, then define the future evidence needed to support it. As a cross functional team, assess and prioritize evidence gaps to focus on the most critical needs.
- 3. Develop solutions and an evidence-generation roadmap:** For each prioritized gap, identify feasible solutions and create a coordinated, cross functional plan to generate the required evidence.

Figure 2



Source: Lumanity analysis

# 1. Evidence Navigator Compass

Evidence Navigator Compass is Lumanity's strategy-led engagement model that is designed to provide end-to-end leadership across the full IEGP process. It combines Lumanity's deep subject matter expertise with structured client cross-functional alignment to help organizations define strategy, identify evidence gaps, and build actionable, future-ready evidence roadmaps.

This approach is designed for organizations that require comprehensive strategic support and an external perspective across regulatory, HEOR, market access, patient-centered outcomes, real-world evidence, medical strategy, and commercial planning.

## Roles and Responsibilities: Lumanity Leads, Clients Partner

Under Evidence Navigator Compass, Lumanity assumes primary responsibility for driving the IEGP process, while client teams contribute critical asset knowledge; provide strategic input; and validate Lumanity's proposed evidence-gap identification, prioritization, and study solutions.

Aligned to the 3 core phases of IEGP, Lumanity leads the development of all required planning materials:

- **Phase 1: Assess the current evidence landscape:** Lumanity conducts an in depth review of the existing evidence base; benchmarks competitor evidence-generation strategies; and evaluates clinical, regulatory, payer, patient, and commercial evidence. This assessment is framed against the asset's overarching strategy to ensure relevance and strategic fit. The outcome is a clear, strategy aligned baseline of where the asset evidence stands today.
- **Phase 2: Define the desired future evidence state and identify gaps:** Building on the agreed upon asset strategy, Lumanity develops a future

focused evidence framework that anticipates regulatory, payer, and market access challenges, while reflecting the needs of key stakeholders (eg, regulators, healthcare professionals, policymakers, patient advocacy groups, and patients). The existing evidence is mapped against this strategy driven desired state to identify gaps. These gaps are then pressure tested through structured discussions with client teams and external experts to validate assumptions and bring additional unmet evidence needs to the surface.

- **Phase 3: Prioritize gaps and build the integrated evidence roadmap:** Lumanity facilitates cross-functional prioritization of validated evidence gaps and co-develops solutions to address them. This culminates in an integrated evidence-generation plan that outlines recommended studies, timelines, development phases, estimated costs, and ownership across functions.

The result is a clear, actionable evidence roadmap that aligns stakeholders around a shared evidence strategy and supports informed decision-making across the product life cycle.

Evidence Navigator Compass is best suited for organizations that:

# 1.

**Require in-depth IEGP support**

# 2.

**Need Lumanity subject matter expertise to pressure-test existing evidence strategies**

# 3.

**Want Lumanity expert-led strategic direction**

# 4.

**Have limited internal capacity to lead IEGP independently**

## 2. Evidence Navigator Guide

Evidence Navigator Guide is Lumanity's facilitated IEGP engagement model that is designed for organizations with strong internal leadership that want structured guidance and expert challenge to advance their IEGP. This model enables client teams to lead strategic thinking while Lumanity provides the framework, facilitation, and subject matter expertise needed to ensure rigor, alignment, and integration across functions.

Evidence Navigator Guide is designed for organizations that have internal subject matter expertise across regulatory, HEOR, market access, patient-centered outcomes, real-world evidence, medical strategy, and commercial planning, but benefit from external navigation to bring these perspectives together into a cohesive evidence strategy.

### Roles and Responsibilities: Client Leads, Lumanity Navigates

With the Evidence Navigator Guide, strategic ownership remains with the client. Client teams lead evidence strategy development, while Lumanity guides the process, facilitates cross-functional alignment workshops, and provides expert challenge throughout each phase of IEGP.

Aligned to the 3 core phases of IEGP, Lumanity structures and supports the development of all planning activities:

- **Phase 1: Assess the current evidence landscape:** Lumanity conducts a structured review of the existing evidence base and benchmarks competitor evidence-generation strategies, while explicitly framing the analysis against the asset's overarching strategy. Findings are synthesized and presented during a cross functional **Insights Workshop** that enables internal subject matter experts to develop a shared, strategy aligned understanding of the clinical, regulatory, payer, patient, and commercial evidence landscape.
- **Phase 2: Define the desired future evidence state and identify gaps:** Building on the shared strategic foundation established in phase 1,

Lumanity facilitates a series of cross functional workshops that are designed to extract insights directly from client subject matter experts. Through moderated discussions, client teams confirm alignment with the asset's overarching strategy; define the desired future evidence state; and identify gaps relative to anticipated regulatory, payer, and market access requirements, as well as the needs of key stakeholders.

- **Phase 3: Prioritize gaps and build the integrated evidence roadmap:** Lumanity supports cross-functional prioritization of validated evidence gaps and collaborates with client teams to develop study concepts and solutions. This culminates in an integrated evidence-generation plan that outlines recommended studies, timelines, development phases, estimated costs, and ownership across functions.

The result is a client-owned, externally informed evidence roadmap that is built through structured collaboration and expert navigation and aligns stakeholders around a shared strategy to support confident, integrated decision-making across the product life cycle.



Evidence Navigator Guide is best suited for organizations that:

**1.**

**Have established internal subject matter expertise and strategic leadership**

**2.**

**Want external facilitation and expert challenge to strengthen evidence planning**

**3.**

**Need structured cross-functional alignment**

**4.**

**Prefer a collaborative, client-led approach rather than primarily consultant-led strategy**

## 3. Evidence Navigator™ Hub

Evidence Navigator Hub is Lumanity's digital platform for hosting and managing integrated evidence-generation plans and is designed to transform IEGP from a static deliverable into a living, enterprise-wide system.

Today, the outputs of most IEGP processes live in PowerPoint decks or spreadsheets that quickly become outdated, fragmented, and difficult to maintain. As evidence-generation activities evolve, teams struggle to answer even basic questions, such as:

- What studies are currently underway?
- How are the studies tracking against each of their key milestones?

- Who owns each study?
- How do the planned studies align to our strategic priorities?

This creates inefficiencies, limits transparency, and undermines the long-term value of the IEGP process.

Evidence Navigator Hub addresses this challenge by taking the core elements of IEGP (whether developed through Evidence Navigator Compass or Evidence Navigator Guide) and hosting them in a centralized, online portal that enables continuous visibility, coordination, and governance.

### Turning IEGP Outputs Into an Operational System

Evidence Navigator Hub converts strategic evidence plans into structured, searchable, and continuously updated digital records. Teams can:

- Access updated strategic documents, evidence catalogs, prioritized gaps, and ongoing studies all in a central hub
- View completed, ongoing, and planned evidence-generation activities in one place
- Track ownership, timelines, and dependencies across functions
- Link evidence activities directly to strategic priorities and identified gaps
- Identify duplications, overlaps, or emerging risks
- Maintain a single source of truth for evidence planning

Importantly, Evidence Navigator Hub is designed to integrate with existing internal systems (eg, Egnyte, SharePoint, etc) to allow organizations to connect IEGP outputs with broader development and commercialization infrastructures.

Beyond individual assets, Evidence Navigator Hub also serves as a centralized system across all internal integrated evidence-generation plans to enable portfolio-level visibility. This allows organizations to assess and compare evidence-generation strategies across assets and therapeutic areas, identify synergies, and ensure consistency in planning approaches (capabilities that are difficult to achieve when integrated evidence-generation plans live in disconnected slide decks).

Evidence Navigator Hub is best suited for organizations that:

**1.**

**Want continuous visibility of evidence-generation activities**

**2.**

**Manage complex portfolios or global development programs**

**3.**

**Are pursuing digital transformation of evidence planning**

**4.**

**Want to embed IEGP as a sustainable organizational capability**



## 4. Evidence Navigator Pilot

Evidence Navigator Pilot is Lumanity's execution-focused engagement model that is designed to help organizations operationalize IEGP at scale. This offering provides the governance, coordination, and administrative backbone required to sustain IEGP across assets, functions, and regions.

While many organizations establish IEGP frameworks and templates, it is often challenging to maintain momentum over

time. Competing priorities, fragmented ownership, and limited internal bandwidth can result in delayed inputs, inconsistent outputs, and stalled progress, which undermine the value of the IEGP process.

Evidence Navigator Pilot addresses these challenges by embedding structured coordination and oversight into day-to-day evidence-planning activities.

## Turning IEGP Frameworks Into Sustainable Execution

Lumantia acts as the central program office for IEGP and supports organizations with:

- Development and standardization of IEGP templates and processes
- Planning and coordination of cross-functional workshops
- Stakeholder engagement and follow-up on required inputs
- Collection and organization of evidence-planning materials
- Timeline management and milestone tracking (eg, updating the Evidence Navigator Hub when applicable)
- Governance support to ensure accountability across teams

By centralizing these operational activities, Lumantia removes the administrative burden from internal teams while improving consistency and transparency throughout the IEGP process.

Rather than relying on ad hoc coordination or function-specific ownership, organizations gain a structured operating model that keeps evidence planning on track and aligned across stakeholders.

Evidence Navigator Pilot is best suited for organizations that:

# 1.

**Already have a well-established IEGP framework in place**

# 2.

**Have limited internal bandwidth to coordinate IEGP activities**

# 3.

**Want consistent execution and governance across development programs**

# 4.

**Are looking to institutionalize IEGP as a standard operating practice**



# Final Thought

There is no single “right” way to operationalize IEGP. Many organizations benefit from combining our engagement models, for example pairing Evidence Navigator Compass with Evidence Navigator Hub to establish a strong strategic foundation while enabling long-term visibility and execution across assets and therapeutic areas. Others leverage Evidence Navigator Guide to strengthen internal ownership or Evidence Navigator Pilot to scale planning efforts efficiently. The most effective approaches reflect each organization’s maturity, asset lifecycle stage, available resources, and strategic priorities.

We tailor our approach to fit the corporate cultures and ways of working within each organization, adapting our methods to ensure solutions are embraced, implemented smoothly, and sustained over time.

By offering flexible levels of support, Lumanity enables organizations to transform IEGP from an aspiration into a practical, scalable engine for regulatory success, market access, and meaningful patient impact. Effective IEGP requires adaptability, and that is where Lumanity excels, partnering with organizations to navigate complexity and evolve evidence strategies as needs, landscapes, and ambitions change.

# Ready To Optimize Your Evidence Strategy?

Lumanity's IEGP Working Group is composed of IEGP experts who have decades of experience collaborating with companies of all sizes to operationalize integrated evidence-generation strategies and plans.

Contact us to learn how Lumanity's Evidence Navigator can transform your path to market.

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Lumanity is a leading global strategic partner that engineers breakthrough value to transform lives for biopharmaceutical companies. We combine deep scientific, clinical, medical, regulatory, and commercial expertise with advanced technology and AI-driven tools to guide decisions and execution across the entire medicine value creation journey. With 1200 experts conducting work in over 50 countries, we serve leading pharmaceutical and biotech companies worldwide, integrating strategy, evidence, engagement, and technology to accelerate and optimize access to life-changing medicines.

Contact us to learn more about how Lumanity can support your unique challenge.

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