Lumanity

Integrated Evidence Generation Planning

A strategic imperative for biopharma innovation

Introduction

GP Carlo
Managing Consultant

GP is a Managing Consultant at Lumanity. He has over 3 decades of industry experience across a number of pharma and biotech, and he has led or been a part of IEGP teams for much of it.

GP Carlo's experience spans most therapeutic areas, including rare diseases and vaccines.

Integrated Evidence Generation Planning (IEGP) is recognized as a strategic necessity for biopharmaceutical organizations. As the complexity of therapies and the expectations of regulators, payers, and patients continue to rise, the importance of doing it and doing it well increases. Missed data, misaligned priorities, and delayed launches can cost companies millions of dollars, slow patient access, and erode trust. This white paper presents best-practice considerations for IEGP that are enriched with real world case studies illustrating the consequences of both success and failure in evidence planning.

The case studies are anonymized, real examples from my 30 years in industry, mainly on the pharma/biotech side and sprinkled with a few years in consulting.

01

What is IEGP?

It may be easier to start with what IEGP is not. It is not a planning template with a chapter per function that is dutifully filled in periodically (we have seen this, as we are sure you have). The value of the "integrated" part of IEGP comes from engaging, understanding, and aligning the cross-functional team. IEGP should be embarked upon with as much diligence as the in-market teams' brand plan, the difference is the cadence. Some structure and process should be in place that allows that "integrated" element to happen at least at every stage-gate, but there may be other times when it is called upon (eg, a major competitor readout). Some IEGP elements benefit from more "integration" than others. From brainstorming on the "what if" or "what could be," we have found that franchise/ medical leads from other disciplines can enrich the process by adding value through "relationship thinking," but sadly it is rarely done. A particularly memorable experience was leading an IEGP pilot process in gastroenterology. We had agreed to include an internal Medical Affairs leader from the oncology field to observe our sessions. During the very first working meeting, she linked a patient unmet need to an endpoint we had not considered—one that was relevant in cancer patients with similar disease manifestations. It was a humbling moment, as our team believed we had a thorough understanding of our therapeutic area. Ultimately, we incorporated her suggestion, which added significant value to the asset. Of course, the devil, as they say, is in the details.

If we distil IEGP into 4 basic steps, it is essentially:

Figure 1
Evidence Generation Formula

Source: Lumanity analysis.

02

Make sure every function is at the table

Breaking Down Silos:

IEGP requires the active involvement of teams across Medical Affairs, Clinical Development, HEOR/RWE, Market Access, Regulatory, Commercial, and (increasingly) Communications and Patient Advocacy, among others. Each group contributes distinct perspectives, and excluding any of them can lead to gaps that weaken the overall evidence plan. It is important to view IEGP as an investment of both time and resources.

Case Study 1: The Dreaded Miss

One experience that we all dread will happen to us on a pipeline team is that an important piece of data is identified after phase 2 and before phase 3. The reason for the dread is that most companies will not risk their asset by changing their phase 3 to accommodate something not tested or proven in phase 2. This leaves us to repeat phase 2, taking the risk and continuing or looking for a parallel data source. This has most often revolved around not having identified a payer's need early enough to expose reimbursement risk.

One example that shaped my early career (in the respiratory therapeutic area) was not having enough of a patient subgroup in phase 2; the decision was made to continue despite the risk (assumed worst case: payers would only reimburse that population). What happened? Payers asked for all the data in that subgroup population, deemed it insufficient, and did not reimburse the product.

03

Understand the landscape and how it will evolve

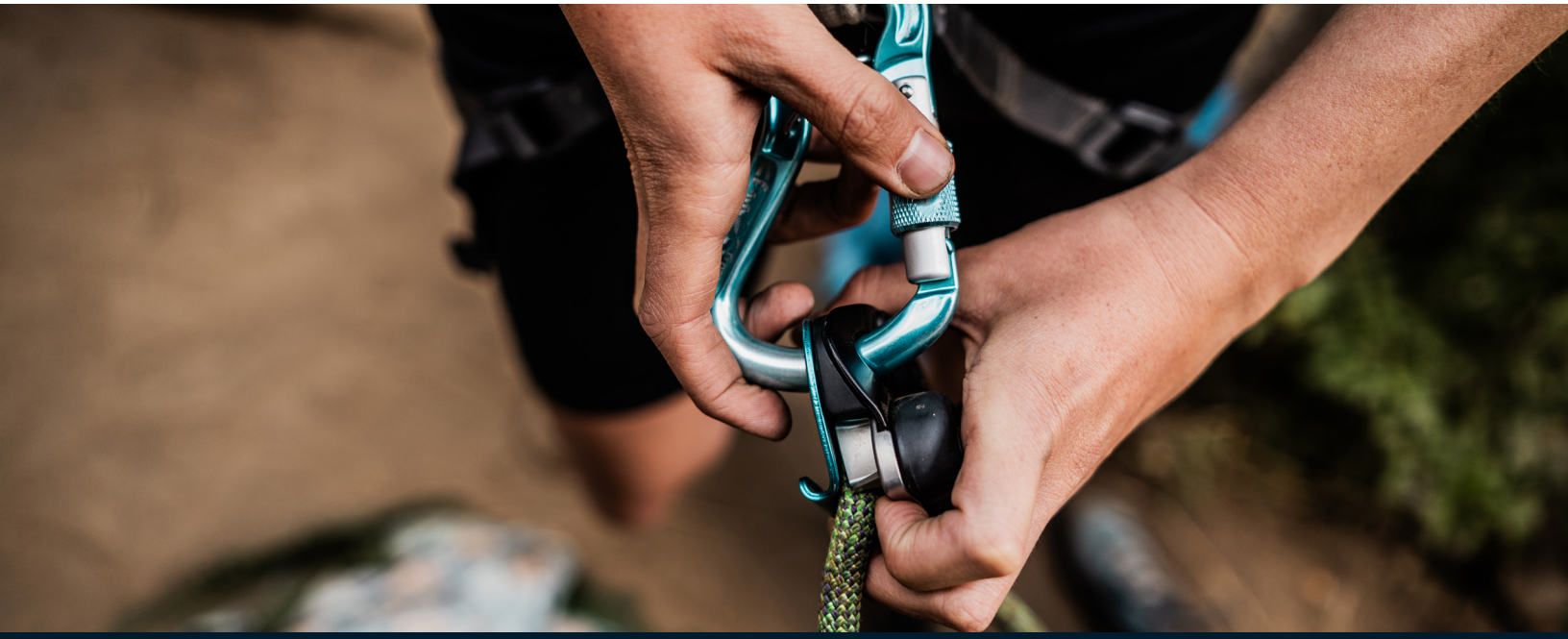
IEGP should be done with the future launch environment in mind rather than focusing solely on today's landscape; overlooking this can be a costly error. We have witnessed products coming onto the market that failed to anticipate changes in the landscape and, as a result, fell significantly short of their potential. When planning for the future, consider the following:

Dynamic evidence drivers:

- **Regulatory evolution:** Understand new FDA and EU HTA requirements for real world evidence and patient-centric endpoints
- **Payer scrutiny:** There is increased demand for comparative-effectiveness data
- **Digital disruption:** AI and real world data sources are reshaping evidence standards
- **Competitive intelligence and competitor rooms:** Track competitor evidence submissions and payer decisions and understand likely positioning and placement/funding on the treatment algorithm
- **Scenario planning:** Model future requirements based on evolving scenarios (eg, regulatory and payer landscapes)

Case Study 2: The Floor

A medicine in a gastrointestinal therapeutic area was in HTA negotiations, and the price was forced below the minimum threshold set by the C-suite because a crucial variable had been omitted from the statistical plan. The Market Access team had flagged this gap during their modeling, but by then it was too late to be incorporated into the pivotal study. Leadership had to decide whether to invest in additional studies and resubmit later or take the risk and continue—a costly delay that could have been avoided if evolving payer needs had been anticipated. The phase 3b study was started to support future HTA submissions after reimbursement failed to be secured in Germany.



04

Identify the future desired state and gaps

A clear and future-focused vision for the asset and/or therapeutic area is crucial; vision statements should serve as a guiding North Star, enabling team members to adapt while ensuring the team always stays aligned with its intended direction. If you have to explain it, it is not a vision. If you are still talking when the elevator doors open, it is not a vision. The most durable visions that we have seen embedded are simple: from X to Y, short, succinct, and aspirational.

Potential Future Evolution (to address gap analyses):

Figure 2 illustrates the evolution of IEGP in pharma, highlighting current practices and a potential future (which some are already excelling in).

Industry is beginning to embed interviews with patients at the beginning and midpoint of clinical studies - Lumanity excels in this space) to monitor progress, detect issues, and understand the patient's journey.

A relatively new development is allowing patients to have more of a say in what we are measuring through the use of personalized endpoints. In essence, the patient tells us what is important to them, and we track that. A lot of diseases are heterogeneous, so having a standardized, one-size-fits-all system excludes things that are important to individual patients. For example, everyone has headache pain in migraine studies and that is the primary measure in those studies, but allowing patients to nominate their most bothersome symptoms, photophobia, or nausea enriches the study and possibly improves data recording too.

Figure 2
Potential Future Evolution of IEGP

Domain	Current State	Potential Future
RWE	Retrospective & prospective analyses leveraging electronic health records, claims, and registry data	■ Expanding use of data sources: Increasing use of data from wearables, genomics, patient-reported outcomes, and non-healthcare datasets (e.g., social care), providing a more holistic view of patient health and treatment effectiveness ■ Broader patient populations: RWE is increasingly used to capture insights from diverse, real world patient groups, including those with comorbidities or who are underrepresented in traditional clinical trials ■ Advancements in methodological approaches applied to RWD sources such as causal inference, data transportability, and surrogacy outcome methods ■ Earlier integration in clinical development: RWE is being used earlier in the clinical development lifecycle to inform Phase 2/3 study designs (e.g., inclusion/exclusion criteria, target populations, endpoints) and to accelerate R&D decision-making
Patient voice	PRO collection PAG surveys	■ Embedded interviews within clinical trials at study entry, mid-point and exit ■ More tailored PRO (FDA validated) analysis and utilization ■ Understanding impact on carergiver and family ■ Utilization of personalized endpoints (e.g., most bothersome symptoms, goals, satisfaction)
Global alignment	Priority country engagement	■ Broader social listening to capture nuance differences that may require validation/mitigation

Source: FDA, US Food and Drug Administration; PAG, patient advocacy group; PRO, patient-reported outcome; RWE, real world evidence.

Case Study 3:
The Comparator (Just in Time)

In Germany, the Federal Joint Committee (G-BA) payers who were reviewing a phase 3 clinical development plan identified that the standard of care for an asset (in the hepatology therapeutic area) should be diet and exercise, and that the company had not considered that as a comparator. They argued that, unless remedied in the protocol, the asset would only secure pricing parity with a basic gym membership. Changing the protocol would have significantly delayed the study. The cross-functional development team reviewed the findings and identified a simple addition to patient recruitment that could mitigate the issue; it required only a modest change and an estimated nominal risk to missing the last patient last visit target. A key learning was that not every adaptation will cost money, nor will it automatically slow development; it is definitely worth finding a solution as a team.

05

Prioritize the impact of gaps and opportunities

When looking at gaps, it is important to not slip into solutions too early. Prioritize the impact of not mitigating for the gap or for not accelerating adoption of a scientifically validated effect.

Data-driven prioritization:

Clinical impact: Patient outcomes and regulatory success

Commercial urgency: Reimbursement and market access risks

Feasibility: Costs, data accessibility, and timelines

Timing: Consider when data are required: can it be delayed until later or does it facilitate other decisions if addressed earlier?

Once you have this information, you will understand the risks and costs of not taking action. This insight will help justify which solutions should be co-created and will support effective prioritization.

Case Study 4:
The Blind Scientist

A company, excited by the novel science of its product, failed to consider patient or commercial perspectives. The Commercial and Medical teams killed the asset's clinical development plan before phase 3, after £40M had been spent, because it was not competitive or patient focused. This underscores the importance of balancing scientific enthusiasm with real world impact and market needs. Proactively involving the cross-functional team early on—and gaining a clear understanding of patient unmet needs, the competitive landscape, and payer requirements—usually helps to avoid this risk. In this case, the team came together to reconsider which patient group would benefit most and redesigned the clinical development plan with the patients' needs at the forefront.

06

Identify solutions that bridge priority gaps

This is one of my bugbears since leaving industry. We cannot emphasize how many IEGP workshops/teams that we have either led or participated in that workshop over, outputs in hand, we would retreat back to our functional comfort zone and secure our budget to deliver against our stated priority gap—pleased a job was done well.

I was genuinely and pleasantly surprised when I joined the Lumanity IEGP Expert Working Group and learned that we bring the cross-functional team together for one additional step—to review the prioritized gaps and present solutions designed to address several of these gaps across functions. Having a team that includes RWE, HEOR, PRO, Patient, Medical, Commercial, and other stakeholders really enables us to develop solutions that save both time and resources. I can't help but smile—and feel a bit frustrated with my younger self—for not having thought of this approach sooner!

07

Global harmonization strategies

Global harmonization strategies in IEGP are essential for aligning evidence needs and activities across regions, functions, and the product life cycle in the pharmaceutical industry. Effective harmonization requires transparent coordination and data sharing among cross-functional teams—including Medical, Regulatory, HEOR, and Commercial—to identify evidence gaps, align priorities, and plan targeted solutions. Standardized frameworks, collaborative workshops, and unified digital platforms help ensure consistency while allowing flexibility for local and regional requirements.

By centralizing evidence repositories and adopting common processes, organizations can minimize duplication, reduce costs, and accelerate evidence generation cycles. However, challenges such as functional and geographic silos, data fragmentation, and varying regulatory expectations must be addressed to achieve true global alignment. Ultimately, global harmonization in IEGP enables pharmaceutical companies to generate robust, high-quality evidence that meets diverse stakeholder needs and supports successful product development and market access worldwide.

Case Study 5: The Missing Continent

The Global team was reluctantly forced to withdraw Japan from clinical development of an asset in their gastroenterology therapeutic area after realizing—too late—that the primary symptom of the target disease was culturally sensitive and rarely discussed openly. Patients in Japan tend to manage this "issue" privately and the unmet need seemed minimal, even invisible, making it hard to justify a benefit. By the time the development team recognized this, it was too late to consider including Japan in phase 2. Japan was dropped from the main development plan, and a parallel phase 2 study was ultimately created to understand the value of the asset in this population, with the goal of reinserting Japan into phase 3.

This example highlights the importance of gathering cultural and regional insights early in global evidence planning. Achieving global alignment and engaging stakeholders early on is essential.

Case Study 6: Manufacturing and Pricing Alignment (In for a Pound – a Good News Story)

A phase 2 asset team (in the hepatology therapeutic area) determined a worst-case scenario for the selling price of their asset that was significantly below their projected cost of goods. This prompted early engagement with the manufacturing team and some challenging feasibility work. The budget was agreed upon, and the 5-year timeline from manufacturing allowed them to convince the leadership team that the asset would be profitable (even in the worst-case scenario). This was seen as a success since there would have been an unacceptable risk to the asset's profit margin without that early (Commercial–Manufacturing) engagement.

08

Measuring IEGP Success

There are many approaches and processes to harmonize IEGP activities and drive efficiencies, as well as ways to measure success. While we are strong advocates for well-defined processes since they help prevent major oversights and improve efficiency, we do see a risk in pursuing efficiency for its own sake.

When we hear of standardized templates for IEGP and that each function completes and then presents as a finished product, we cannot help but feel some pessimism. Although this technically achieves integration by involving multiple functions, it often misses the true spirit of "integration"—the deeper understanding, alignment on shared goals, and co-created solutions. While this approach does help avoid major errors, we are not convinced it fosters real paradigm shifts or encourages innovative solutions.

Like any investment of people, money, or time, it is always worth measuring IEGP success. Some classical IEGP goals (and therefore measurements of success) are seen in the Figure 3.

Figure 3
Measurements of Success

Category	KPI	Example Target
Efficiency	Evidence generation timeline	20% reduction YOY
Quality	Stakeholder acceptance rate	>90%
Cost	Duplicate study reduction	40%
Patient impact	PRO endpoint adoption in labels	All or part of PROs adopted in label

Source: KPI, key performance indicator; PRO, patient-reported outcome; YOY, year over year.

We would advocate for broader approaches to defining success. For example, has your IEGP process uncovered a new endpoint that could make the asset more competitively differentiated or more robust from a payer or HTA perspective? Has it identified a risk and a strategy to mitigate it? Has it revealed a new target population? These are just a few possibilities.

Additionally, as your IEGP highlights gaps, have you developed and scoped solutions that address multiple cross-functional needs, thereby saving both time and resources?

Summary

The future of evidence is integrated:

IEGP transforms evidence from a cost center to a strategic accelerator. The cited case studies illustrate that gaps in evidence planning can lead to costly delays, missed opportunities, and even product termination. By uniting all functions, leveraging technology, and planning with global and patient-centric foresight, organizations can:

1. **Cut evidence costs**
2. **Shorten time-to-evidence**
3. **Boost stakeholder trust** with unified narratives that are validated by real world impact

We are passionate about IEGP and lead our IEGP Expert Working Group at Lumanity with cross-functionally skilled individuals who share the passion and belief that we can make a difference. Do please reach out, as we would love to discuss your IEGP needs.

Contact us to learn more about how our expert Lumanity IEGP team can help you navigate your Integrated Evidence Generation Planning journey: contact@lumanity.com

Lumanity applies incisive thinking and decisive action to cut through complex situations and deliver transformative outcomes to accelerate and optimize access to medical advances. With deep experience in medical, commercial, and regulatory affairs, Lumanity transforms data and information into real-world insights and evidence that powers successful commercialization and empowers patients, providers, payers, and regulators to take timely and decisive action.

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

lumanity.com