



Optimizing Integrated Evidence Generation Planning: How HEOR & RWE Leadership Can Drive Better Outcomes

May 18, 2026

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- 2 HEOR & RWE leadership: overcoming common IEGP challenges
- 3 Best practices & digital solutions



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Delivering on the promise of IEGPs

Introductions



Jonathan Kowalski

Executive Vice President, Global Head
Strategic Advisory Services, HEOR
Lumanity

Jonathan works across Lumanity's HEOR, RWE, COA, market access, medical, and commercial consulting capabilities to help pharma and biotech clients solve their most complex evidence and access challenges. He advises on U.S. Medicare drug price negotiations, Joint Clinical Assessment strategy and submissions, and global HTA engagement, and supports fully integrated launch readiness through integrated evidence generation planning.



Chris Pashos

Head, Real World Evidence
argenx

Chris works collaboratively across argenx and with external partners to ensure evidence is generated to support internal decision making across the development and commercialization lifecycle, and to meet regulatory, HTA/payer, clinician and patient evidentiary requirements. He has demonstrated leadership in academia, consulting and global life sciences companies and previously served as President of ISPOR.



Meena Venkatachalam

Global Head of RWE Consulting
Lumanity

Meena leads the development of pragmatic evidence strategies that support regulatory, payer, and HTA needs. Her experience spans IEGP, RWE study design, and data source strategy, with a strong focus on generating evidence that is decision-relevant for reimbursement and market access.

With expertise across both RWE and HEOR, she brings the cross-functional perspective needed to build effective IEGPs – ensuring evidence plans connect clinical development with value demonstration and access strategy.

Achieving patient access through integrated evidence generation planning (IEGP)

What?

- Provides a single, comprehensive view of internal and external evidence and research
- Links evidence to shared objectives and key strategic decisions
- Tracks evidence gaps and the plan to address them (data sources, endpoints, timing)
- Aligns evidence generation with dissemination/publication plans
- Supports an asset end-to-end: development, launch, and ongoing lifecycle value generation

When?

As early as possible in the life cycle (~phase I/II POC): annually after strategic alignment, but prior to business planning

Who?

Multi-stakeholder, global, and regional integration and alignment

How?

- Establish a cross-functional working team and governance
- Collect key inputs from stakeholders (e.g., strategic plans, TPPs, landscape analyses, regulatory & commercial timings)
- Compile evidence/insights materials (SCPs, publication plans, patient pathways)
- Gather external intelligence (competitor and market insights)
- Conduct stakeholder interviews and/or cross-functional workshops to align on priorities and gaps

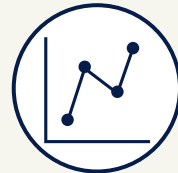
Key principles for activating an IEGP



Collaborative



Strategic



Insight-led



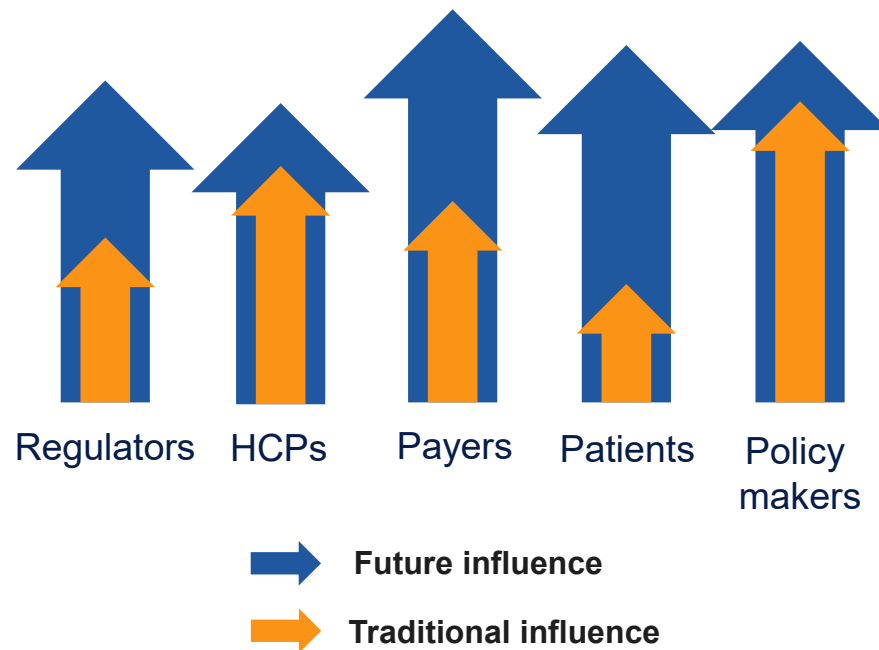
Geographic representation



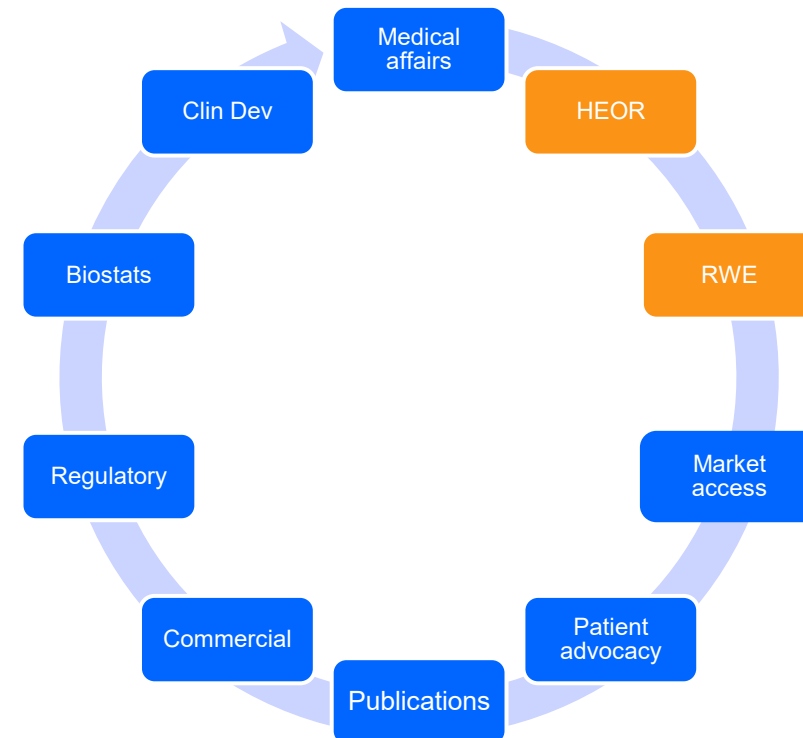
Living document

Effective IEGPs support patient access through the dual aim of optimal internal evidence planning/execution & the right evidence at the right time to inform external stakeholder decisions

Increasing evidence demands across all external stakeholders to achieve commercial success

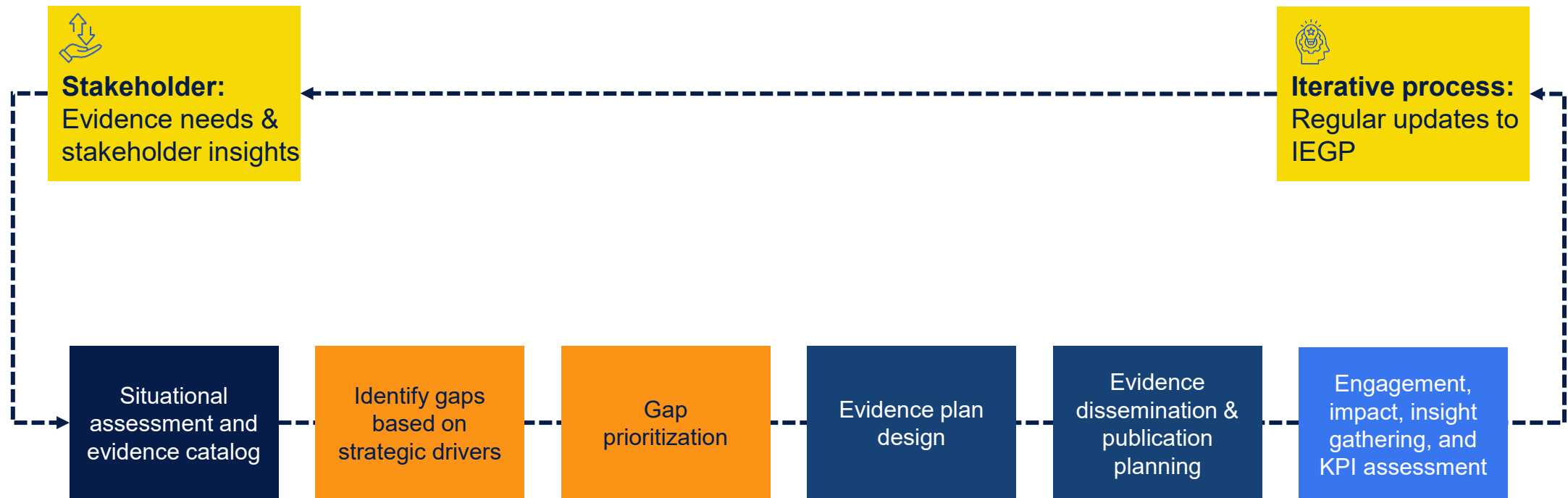


Requires an aligned comprehensive strategy across internal stakeholders



Our IEGP process: Evidence Navigator™

HEOR & RWE leadership is critical in every step of the IEGP process



HEOR = Health Economics and Outcomes Research; IEGP = Integrated Evidence Generation Planning; RWE = Real World Evidence



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HEOR & RWE leadership: overcoming common IEGP challenges

The common pitfalls in IEGP execution that drive inefficiency, commercial risk, and misallocated investment

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Siloed cross-functional planning

Siloed multi-functional planning
Individual functional plans are not aligned, resulting in suboptimal evidence generation

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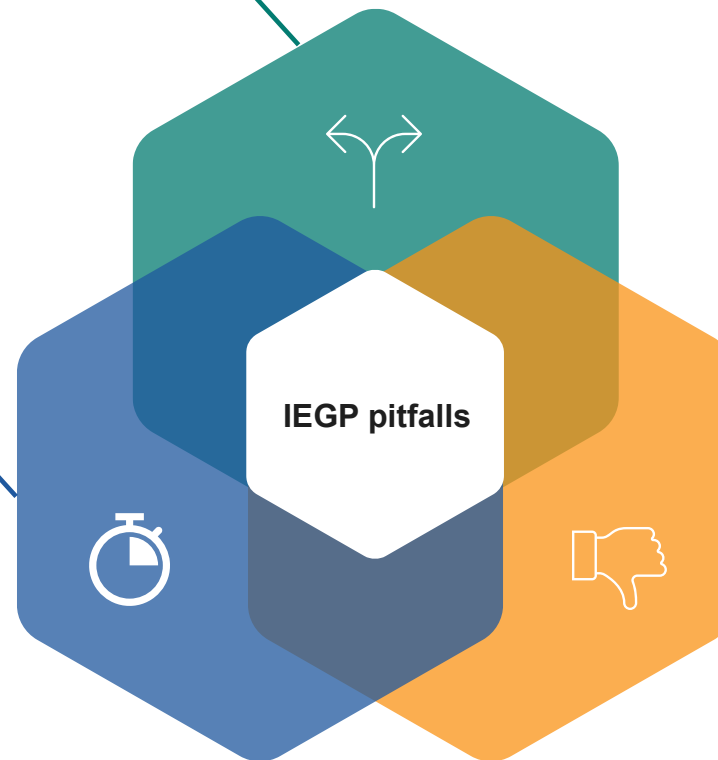
Visibility & usability

Delayed planning and variable execution across assets weaken the strategic value and durability of an IEGP and resulting evidence

2

Global plans lacking regional & local considerations

Failure to account for country-specific requirements creates gaps between global plans and local evidence demands



Overcoming Pitfall 1: HEOR & RWE-led IEGPs ensure payer, HTA, and medical evidence needs are covered - leading to commercial success

Common challenge: IEGPs are often built in functional silos, with HEOR and RWE brought in after major evidence decisions have been made.

Why it happens

- Clinical & Medical priorities are often prioritized before payer and value evidence needs are fully considered
- HEOR & RWE leadership is viewed as a contributor, not positioned as a co-owner of evidence planning
- Cross-functional governance is too weak to force early alignment on evidence priorities

Why it matters

- Evidence plans don't reflect the realities of payer, HTA, and access decision-making
- Critical payer-relevant evidence gaps are identified too late to address efficiently
- Teams are forced into reactive course correction, creating delay, duplication, and avoidable spend

Role of HEOR & RWE leaders

- Cross-functional governance to elevate roles of HEOR & RWE leadership
- Create formal decision points where HEOR and RWE align on evidence priorities before plans are set
- Use structured planning workshops to ensure payer-relevant questions are addressed from the outset



If HEOR and RWE are not in the room when priorities are set, the IEGP is already at risk of missing what matters most.

Overcoming Pitfall 2: Make the global IEGP market-relevant where access decisions are made

Common Challenge: Global-first IEGPs can miss local evidence requirements, policy shifts, and access timelines, creating misalignment across markets.

Why it happens

- Global consistency is prioritized over local access decision realities
- Teams underestimate how evolving frameworks (e.g., US IRA, EU JCA) shift evidence expectations
- Regional evidence requirements require an IEGP aligned to the asset lifecycle

Why it matters

- Global plans fail to answer the questions that matter in key markets
- Teams face late-stage evidence gaps, market-specific rework, and reduced readiness for HTA and payer engagement
- Investment is diluted across evidence activities that do not translate into local access value

Role of HEOR & RWE leaders

- Bring local & regional perspectives into evidence planning early
- Anticipate market-specific requirements such as PICOs, post-JCA evidence expectations, and shifting access timelines
- Build modular IEGPs that preserve global consistency while allowing market-level adaptation



A global IEGP is only as strong as its relevance in the markets where access decisions are actually made.

Overcoming Pitfall 3: Create a working IEGP - accessible to all stakeholders and built to last

Common Challenge: IEGPs are frequently created late and used inconsistently, turning them into a retrospective exercise instead of a strategic, working plan.

Why it happens

- There is no clear, shared trigger for when IEGP development should begin and be refreshed
- Expectations, ownership, and ways of working vary across teams and assets
- IEGPs are not always designed to be durable through team changes, asset transitions, or evolving evidence needs

Why it matters

- Late planning limits the ability to proactively shape evidence generation
- Inconsistent execution leads to variable quality, uneven investment decisions, and reduced comparability across assets
- Team turnover can weaken continuity

Role of HEOR & RWE leaders

- Define the right timing for IEGP development and updates and embed it into core asset planning milestones
- Standardize processes, templates, and governance to create consistency across assets
- Ensure IEGPs are built as durable strategic documents that can guide decisions over time, even as teams and priorities change



An IEGP delivers the most value when it is developed early, applied consistently throughout the lifecycle, and built to endure beyond the team that created it.



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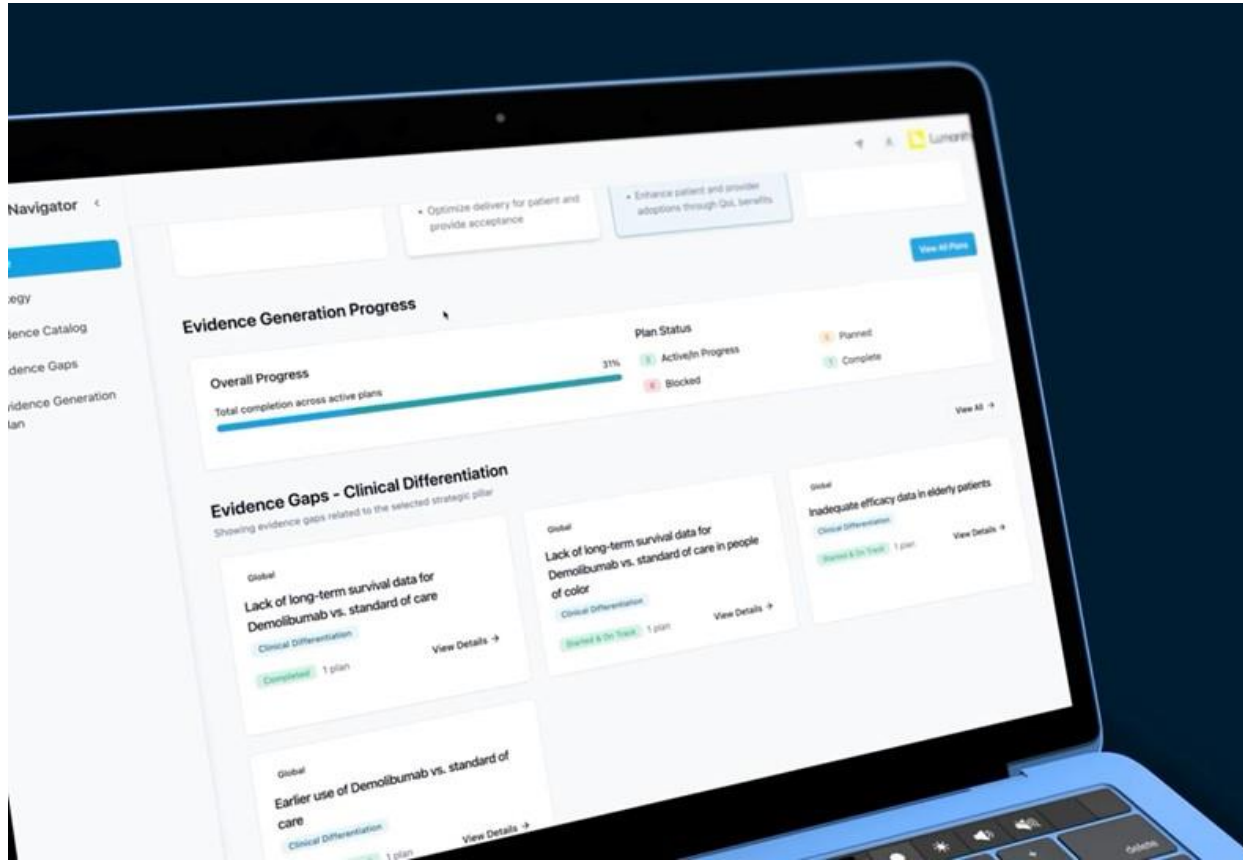
Best practices & digital solutions

Best practices for IEGP delivery to avoid these common pitfalls



Digital IEGP Platforms: The Future Is Now

From static templates to a centralized, AI-enabled hub for IEGP development and execution



- **Centralized hub:** Plan and execute IEGPs while housing all plans, materials, and key decisions in one place
- **Dynamic workspace:** Move beyond static Excel/PPT and recurring version-control issues with always-current content
- **Standardized framework:** Maintain a consistent IEGP process that's easy to update, reuse, and sustain across teams
- **AI-driven evidence catalog:** Improve search, usability, and cross-functional adoption to accelerate alignment and action
- **Enterprise integration:** Connect to internal systems to reduce duplication, strengthen traceability, and speed evidence delivery
- **Real-time dashboards:** Track value messages, available evidence, evidence gaps, the status of planned/ongoing evidence generation activities, and ownership/responsibility for associated research

Thank you

