ALKEMI

Rest in Peace, GVD

The case for building a living evidence and access discipline

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Rest in Peace, GVD: The case for building a living evidence and access discipline reflects an effort by Alkemi in collaboration with pharmaceutical and life sciences industry experts. The information presented is an aggregated synthesis of perspectives from senior leaders and is intended for research and educational purposes only.

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Executive Summary

The traditional GVD is failing its primary purpose.

Designed to carry a product's clinical and economic value story from global teams to local affiliates, the GVD often arrives late and reflects headquarters' assumptions more than local market realities.

Exhibit 1: Why the traditional GVD model falls short

01 Delivered too late to guide local planning

02 Static, one-way global-to-local communication

03 Built on assumptions rather than local realities

04 Limited affiliate capacity to adapt and activate

05 Little capture of market learning or best practices

The effort and intention behind the GVD remain well-placed. Global teams build robust value foundations, yet the resulting product, a large, static document flowing in one direction, often fails to deliver on its promise.

Access environments are becoming more complex, and the commercial consequences of poor global to local collaboration continue to grow. Local pricing and reimbursement outcomes increasingly influence global commercial success, making stronger collaboration more important than ever.

The future of the GVD is a living evidence and access discipline that connects global strategy with local execution and continuously captures market learning.

This paper presents the case for moving from static deliverables to a multi-way information exchange that strengthens local execution, captures market learning, and improves access outcomes.

Prepared by
Alkemi

The Problem: Why the GVD Model Is Broken

SUCCESS REQUIRES MORE THAN A DOCUMENT

Note: In this paper, "GVD" is used as shorthand for global value deliverables, including payer value propositions (PVPs), global economic models, and value communication tools.

The GVD was built on a reasonable assumption: that a comprehensive, globally consistent evidence package would give local affiliates what they need to engage payers.

Despite the strategic intent, the original linear logic of "one global value story, locally adapted" is missing the mark in today's access environment. In February 2026, Alkemi CEO Betsy Lahue, MPH, moderated "The GVD Is Dead, Now What?" at the ACCESS Forum. The interactive session included senior HEOR & market access leaders from pharmaceutical, biotech, and medtech companies to diagnose this problem.

The consensus was clear: (1) the current approach is broken; (2) organizational silos create challenges; (3) both global and local affiliate leaders desire solutions. Over the next six months, our group of collaborators piloted new formats and tools to guide local preparation, adapt evidence, capture real-time tactics, and share emerging insights across markets.

Exhibit 2: The shift from the original assumption to today's reality

THE ORIGINAL ASSUMPTION	TODAY'S REALITY
One global value story	Value narrative must fit local context
Comprehensive evidence package	Unique requirements, scenarios by HTA
Affiliates adapt dossier locally →	Expertise goes beyond submission
Effective payer engagement	Engagement with multiple stakeholders
Local access leader drives success	Cross-functional execution required

We learned that payers don't experience global strategy; they experience local execution. An Italian payer wants to know how the new product performs against the therapies she's currently covering, in patients who look like her population, at a price that fits her budget. Unfortunately, a GVD frequently answers questions that local payers are not asking and omits the level of detail required for the country-level assessment.

Regulatory, medical, payer, and policy environments continue to increase in complexity. Leaders shared that access success requires multi-year coordination cycles, deep insights on the treatment landscape, engagement across functions, and collaboration with external stakeholders.

> "The best global dossier in the world is worthless if the affiliate team is too stretched to read it, let alone adopt it."
>
> – Global Value & Access Lead,
> Large Pharmaceutical Company

Finally, we heard how industry restructurings over the past few years reduced the number of experienced associates in both global and local roles. Even when global teams deliver robust materials, affiliates may lack resources or bandwidth to adapt and deploy them.

The first wave of Europe's Joint Clinical Assessment (JCA) process demonstrated the importance of early global-local coordination. While JCA may reduce duplicative literature reviews, it does not simplify local pricing and reimbursement decisions. National Health Technology Assessment (HTA) bodies still evaluate the evidence in the context of country-specific comparators, treatment pathways, affordability thresholds, and decision frameworks, increasing the premium on locally tailored evidence and value narratives.

THE STAKES ARE HIGHER

Ex-US markets comprise over 50% of projected lifecycle revenue in many global pharmaceutical companies, while US revenue may dominate in others. Policies such as Most Favored Nation (MFN) pricing mean that price concessions in Germany, France, or Japan can directly influence US pricing.

That changes how companies should invest in global value and access. **It is no longer acceptable to resource the US launch heavily, distribute a GVD to affiliates, and hope for the best.** Early, strategic collaboration with affiliates has become a critical commercial strategy to improve local access outcomes, protect global pricing, maximize lifecycle value, and reduce commercial risk.

AFFILIATES AND GLOBAL TEAMS VIEW THE PROBLEM DIFFERENTLY

Brainstorming sessions with HEOR and access leaders illuminated a structural bias. The old axiom "where you sit determines what you see" is both literally and figuratively true. When queried about the biggest challenge for access success, responses depended on the geographic focus of the role (see **Exhibit 3**).

From the global perspective, misalignment was number one. But affiliates cited local environment complexity as their top challenge. Affiliates must navigate an increasingly volatile external landscape including shifting HTA requirements, tightening payer budgets, and accelerating competitive dynamics.

Notably, "gaps in resourcing at local, global or asset level" was the number two challenge regardless of perspective.

Given the need for market-level focus on in-line assets (today's revenue), it is understandable that global HEOR and access leads (who are focused on preparing pipeline assets for launch) perceive "misalignment."

The difference reflects the realities of their respective roles. Inadequate communication was identified as a major cause of both the misalignment and the poorly understood local requirements. And all leaders shared a concern about having limited resources given a complex and ever-evolving health policy environment.

Thus, regardless of the perspective, a gap in communication contributes to suboptimal access outcomes. Our next question, naturally, was: Are you ready to make a change to enable access success?

Exhibit 3: Global and affiliate teams define the problem differently

GLOBAL	VS.	AFFILIATE
Largest challenge **Misalignment across global, regional, and local teams**		*Largest challenge* **Increasing complexity and unpredictability in local environments**
#2 challenge **Gaps in resourcing** at local, global, or asset level		

PRECISELY WHY THE GVD FAILS

Exhibit 4: Four structural failures of the traditional GVD deliverable

Uni-directional communication

Global HEOR "owns" the global dossier, global access "owns" the value proposition and the information flows to the markets.

The GVD goes stale at launch

Affiliates need current intelligence during active payer negotiations but the GVD update is scheduled annually.

One-size-fits-all support model

GVDs are a perfect starting place for a highly experienced local access team (think UK) while other affiliates may need more guidance.

No capture of real-world best practices

Insights on value positioning and tactics that worked in early markets are not documented to inform the next wave of countries.

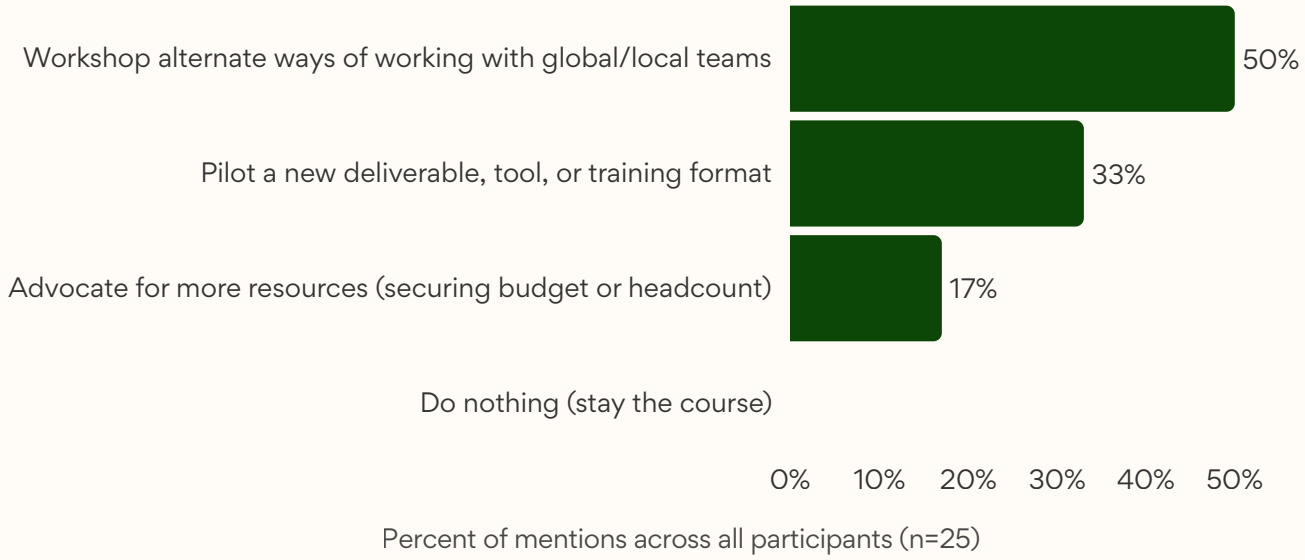
None of this means the GVD should disappear. But it does mean that the work system and assumptions must change fundamentally for global HEOR and access teams to succeed in their mission of enabling access.

LEADERS FROM ALL PERSPECTIVES ARE READY TO ACT

The good news: HEOR and access leaders are ready to make a change. When asked what action they were most likely to take within the next six months to enable their market access strategy, 83% of respondents said they plan to workshop new ways of working or pilot a new deliverable, tool, or training format (see **Exhibit 5**).

Exhibit 5: Poll results on near-term market access strategy.

Which action are you most likely to take in the next 6 months to enable your market access strategy? (live poll with n=25 HEOR and access leaders)



Notably, zero respondents selected "do nothing (stay the course)."

Global HEOR and access leaders are not waiting for top-down transformation initiatives. They are seeking practical frameworks and concrete tools.

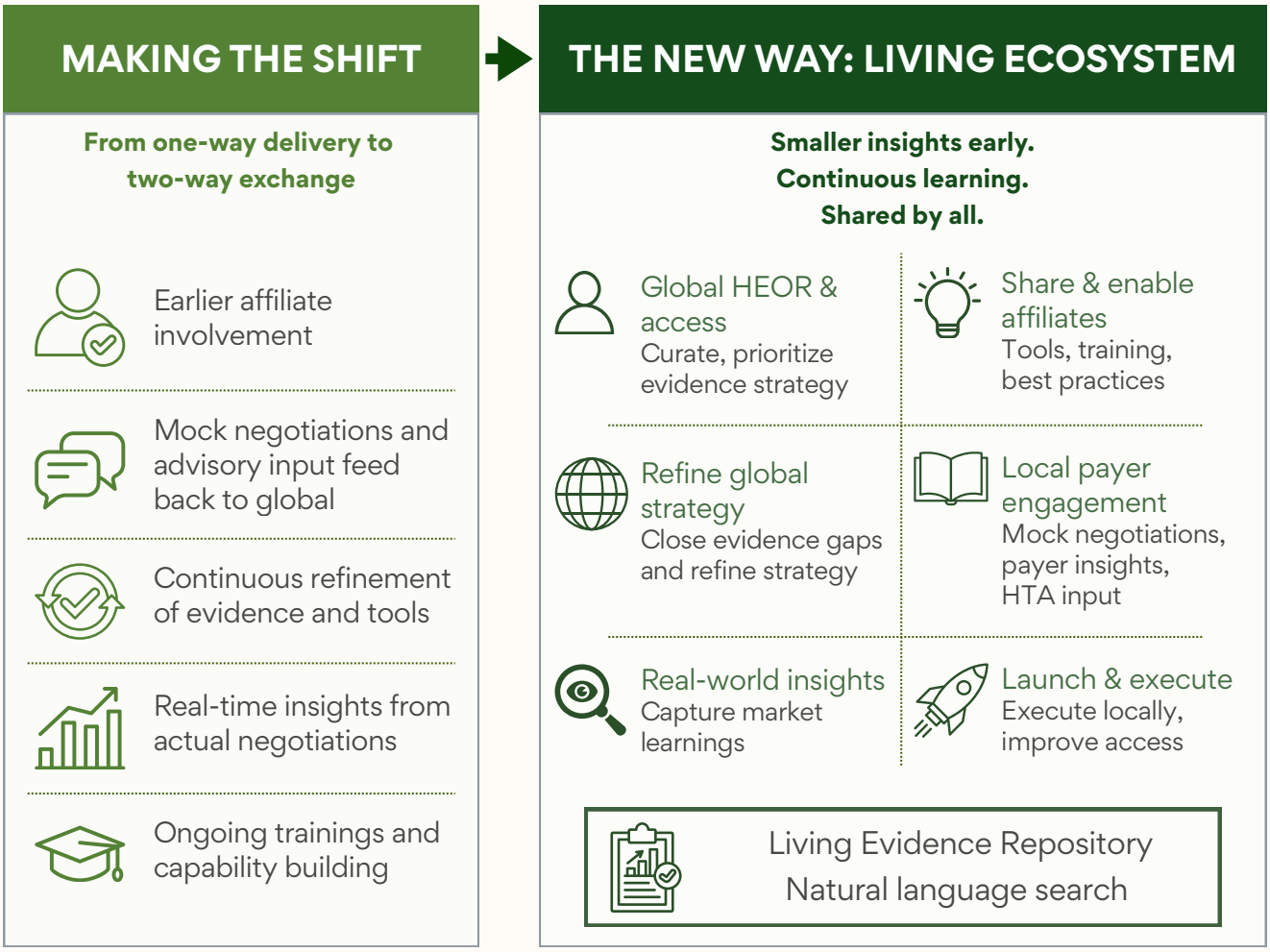
In the next section, we share a conceptual framework and insights on new ways of working to put these ideas into action.

A New Operating Model: From Deliverable to Discipline

Building a value discipline requires more than replacing one deliverable with another. Delivering a large document is far simpler than building the people, processes, and systems needed to improve access across markets and carry those lessons forward. The role of global HEOR and access should extend beyond producing materials to helping markets use, adapt, and improve them.

So, where do you start?

Exhibit 6: From static documents to a living evidence ecosystem



CAPABILITY AND KNOWLEDGE CAPTURE

The living repository only works if the global team owns the knowledge capture process. This cannot be left to affiliates. Why? Local leads must focus on execution. Affiliates have limited bandwidth and lack cross-market perspective. Our contributors highlighted that global teams must be accountable for updating both the evidence and access insights. We recommend the following elements to embed a new value discipline:

1 ›

Institute a structured affiliate debrief at every major access milestone

For milestones such as establishing a premium price, securing an HTA win, or achieving a premier formulary tier, document: Which value arguments worked? What payer objection caught the team off guard? What local adaptation of the evidence or value story proved most compelling?

2 ›

Calibrate training investment to affiliate sophistication

Consider in-person workshopping and scenario planning pre-launch for less experienced teams; on-demand modular access to global expertise for sophisticated affiliates who can self-direct. One global training module at launch is insufficient.

3 ›

Invest in building affiliate capability over time

Organizations with strong local teams consistently achieve better access outcomes. While it may be tempting for global to swoop in as the “hero,” mature local capabilities are required to sustain access wins. Real-world success provides the most compelling case for local investment. Share “what good looks like” to guide planning and resourcing early in launch planning cycles.

THE NEW WAY IS A LIVING EVIDENCE AND ACCESS DISCIPLINE

Exhibit 7: Four foundational elements of the new value discipline

Early cross-functional insights

Capture local and regional intelligence across HEOR, access, medical, regulatory, commercial, market research and R&D over the portfolio lifecycle.

Collaborative pre-launch planning

Partner with markets to shape external engagement, evidence adaptation, and expert advisory needs.

Market adaptation & execution guides

Equip affiliates to apply global tools locally and navigate anticipated payer and HTA challenges.

Real-world learning capture

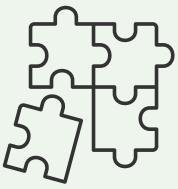
Document negotiation tactics, payer insights, and lessons learned by archetype, and share across markets.

Together, these elements turn the GVD into a living value discipline by connecting global strategy, local execution, and real-world learning across markets.

HOW CAN THIS ACTUALLY WORK

We envision a living value repository as a broader value knowledge system that grows richer with each launch, affiliate submission, and payer negotiation. The tools to share insights outside of scheduled updates are available (see **Exhibit 8**).

Exhibit 8: Enablement tools of the living value repository

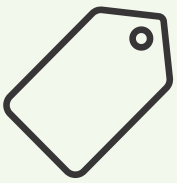


Modular Evidence and Value Architecture

A core global package (clinical evidence, economic models, value messages) structured so affiliates can pull what they need, layer in local payer context, and produce submission-ready materials without excavating a 400-page dossier.

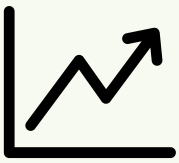
Enabling Search Across the Repository

Any affiliate should be able to ask: "Has another market successfully positioned this product with a similar payer type?" and retrieve relevant examples, supporting materials, and practical guidance. This is achievable today with enterprise search tools and appropriate guardrails.



Value Positioning Libraries Tagged by Market Archetype

The payer objection handles, value messages, and access arguments that worked in Spain should be findable in Brazil before they start from scratch. Tagging by indication, payer type, and market archetype allows the next market to use what earlier markets learned.



Scenario-Linked Pricing Tools

Models that connect evidence and value positioning gaps to HTA outcome scenarios, and those scenarios to revenue implications including MFN and international reference pricing (IRP) spillover. This turns evidence investment decisions from judgment calls into quantified business cases that commercial and executive teams can act on.

Call to Action

Overcoming corporate inertia is not easy. Ask the questions below to start this discussion with HEOR and market access colleagues. The answers can help teams align on what needs to change.

QUESTIONS TO ASK

1

Are we building a value discipline or still shipping documents?

How do we measure the impact of the GVD and other global launch tools? What are the impact metrics we should be capturing?

2

Are learnings and mistakes captured after every launch?

What structured mechanism exists today to share insights? How can affiliate access experiences be shared with global and parallel markets? Will best practices be available to the next wave of markets?

3

Are our global functions aligned early enough to prevent costly late corrections?

What standing meetings or planning forums do we hold to align and challenge assumptions within key global functions before they become embedded in the value strategy?

Summary

The organizations that win on access won't be the ones with the most comprehensive dossiers.

Focusing on creating the same static GVDs with fewer resources is a misguided effort. Access success relies on nuanced, evidence-based value positioning, robust planning, and strong local capability.

HEOR and access must lead this global value discipline. The process starts years before each launch, enables cross-functional inputs, prepares for market-level engagement, and includes built-in feedback loops. As a first step, global HEOR and access leaders can curate a living repository that grows smarter with every local agency interaction, evidence-positioning decision, and access negotiation.

If you have 5 minutes to make your case for change, your key points are:

- Delayed access and local gaps threaten global commercial success
- Implementing a value discipline can mitigate local capability risks
- We have the resources needed to enhance our planning process NOW

We say RIP GVD. Let's build the new value discipline!

P.S. *See Appendix for a few practical tips from our pilots.*

Appendix

Exhibit A1: Practical considerations for a living evidence repository

Governance

- Editorial ownership
- Version control
- Approvals
- Standards oversight

Technology

- Platform (e.g., website, SharePoint)
- Search functionality
- Secure access, sharing
- Enterprise integration
- Scalable / reliable

Enterprise Functions

- IT
- Medical affairs / R&D
- Legal / compliance
- Library information services

Content Management

- Local versions
- References
- Copyright & permissions
- Metadata
- Archival lifecycle management

Practical considerations for implementation

This exhibit provides a high-level overview of key considerations when operationalizing a living evidence repository. Organizations should adapt governance, technology, and content management to their existing structure and resources, while engaging cross-functional stakeholders, including IT, medical, legal, and library information services, early in the planning process. Establishing clear ownership and processes for continuously capturing, curating, and sharing market insights can help sustain collaboration and maximize organizational value.

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* Participation was voluntary and uncompensated. No confidential information was exchanged. Opinions expressed are solely those of contributors and not their current or past employers.

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