

Beyond the Data Gap

Is Your Evidence Strategy Answering the Questions That Actually Matter?



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Life sciences organizations have never had access to more data. Clinical trials, real-world evidence, HEOR, patient-generated data, digital health technologies, claims databases, registries, publications, and increasingly sophisticated analytics are continually expanding the evidence landscape.

Yet more data does not always translate to fewer evidence gaps.

Medical Affairs organizations can find themselves generating substantial volumes of evidence while important questions from healthcare professionals, payers, patients, and internal stakeholders remain unanswered. The challenge is no longer simply determining what evidence *can* be generated. It is determining what evidence is worth generating.

That requires a shift in perspective: from *Data Generation* to *Integrated Evidence Planning*.

From Data Generation to Integrated Evidence Planning

Traditional evidence strategies can easily become centered on individual evidence-generation activities: *What study should we conduct? What analysis should we perform? What should we publish next?*

Integrated Evidence Planning takes a broader view.

It brings together what is already known about the asset, what different stakeholders need to understand, what questions are emerging from the external environment, and where meaningful gaps remain. Those needs are considered collectively and prioritized across the product lifecycle before individual evidence-generation activities are selected.

Rather than beginning with *What study should we conduct?*, Integrated Evidence Planning asks:

What do we already know?

What do we still need to understand?

What are our stakeholders asking us?

*Where are the most important evidence gaps?
Which gaps should we prioritize?
What is the best way to address them?*

Only then should the conversation turn to the individual studies, analyses, data sources, or other activities needed to build the evidence.

Not Every Data Gap Is an Evidence Priority

There will always be more questions that *could* be answered than an organization has the resources, or the need, to address. An unanswered question is not automatically an evidence priority.

The value of an evidence plan therefore depends as much on what it does not pursue as on what it does.

Prioritization should consider the scientific or clinical importance of the gap, the stakeholders affected, relevance to the product strategy and patient journey, timing within the lifecycle, and the feasibility of generating meaningful evidence.

It also requires asking a deceptively simple question:

Does new evidence actually need to be generated?

Sometimes the answer will be yes.

Sometimes the answer will be no.

The Evidence May Already Exist

Before investing in additional data generation, organizations should determine whether the information they need already exists somewhere within the evidence ecosystem.

The answer may reside in clinical trial data, an existing publication, real-world evidence, investigator research, a Medical Affairs insight, an HEOR analysis, or information held by another function. The challenge may not be generating additional evidence at all. It may be finding, integrating, interpreting, or communicating what already exists.

This is where the word integrated becomes important.

Clinical Development, Medical Affairs, HEOR, Market Access, Safety, Commercial, and other functions inevitably view evidence through different lenses. Those perspectives are valuable. But when evidence planning occurs independently within functions, organizations risk duplication, competing priorities, and gaps that remain invisible because no one is looking across the entire evidence landscape.

Integration requires more than bringing those functions together for an annual planning meeting. It requires a shared view of existing evidence, known gaps, emerging stakeholder questions, planned activities, and future needs across the product lifecycle.

That shared view allows organizations to identify where stakeholder needs overlap, where a single evidence-generation activity may address multiple gaps, where planned activities are duplicative, and where important questions remain unaddressed.

It also makes dependencies visible. Evidence needed for a future publication, payer discussion, scientific exchange, guideline consideration, or launch may require work to begin months or even years earlier.

Integrated Evidence Planning therefore looks both across the organization and across time.

Evidence Planning Should Be Dynamic

An Integrated Evidence Plan should not be a document created once a year and revisited at the next planning cycle.

The evidence environment continually changes.

New clinical data become available. Competitors publish. Treatment guidelines evolve. Regulatory decisions alter the landscape. Payer expectations shift. Field Medical teams hear new questions from healthcare professionals. Advisory boards identify areas of uncertainty. Real-world experience raises questions that could not have been anticipated during clinical development.

Medical Affairs insights therefore have an important role in keeping the evidence plan relevant.

Evidence → Scientific Exchange → Insight → Evidence Gap → Prioritization → Evidence

An evidence gap identified two years before launch may become less important as new data emerge. A question that initially appeared secondary may become critical as clinical practice evolves. A competitor's publication may close one gap while creating another.

An effective Integrated Evidence Plan is designed to change.

And that means organizations must be willing not only to add activities, but also to challenge those already in the plan:

What should we stop?

What should we combine?

What should we delay?

What no longer addresses an important evidence need?

Removing low-value activity is as much a part of evidence strategy as identifying new opportunities.

From Evidence Generation to Evidence Impact

The final step is determining whether the evidence ultimately accomplished what it was intended to accomplish.

Traditional measures remain useful. Studies completed, abstracts accepted, publications generated, timelines achieved, and data disseminated tell us whether an evidence-generation program was executed successfully.

But they do not necessarily tell us whether the evidence was valuable.

A publication is an output. A completed study is an output. Neither, by itself, demonstrates that an important evidence gap was closed.

Organizations should therefore define the intended value of an evidence activity when it enters the plan, not after the activity has been completed.

Did the evidence address an important scientific uncertainty?

Did it improve understanding of a patient population or treatment pathway?

Did it provide information stakeholders had repeatedly identified as missing?

Did it strengthen the evidence available to healthcare professionals, patients, payers, or other stakeholders?

Did it reveal additional questions that now need to be addressed?

Not every evidence activity will produce an outcome that can be directly measured, and impact should not be reduced to an artificial metric simply because one is easy to count. But the inability to attribute every outcome precisely should not prevent organizations from asking whether the evidence they generated created value.

The question should evolve from:

What did we produce?

to

What did we learn, and what changed because we learned it?

Beyond the Data Gap

The expanding availability of data creates enormous opportunity for Medical Affairs. It also creates a challenge: the ability to generate evidence can easily outpace the organization's ability to determine which evidence matters most.

Integrated Evidence Planning provides the discipline to step back from individual studies and consider the evidence landscape as a whole.

It connects existing evidence with emerging needs, brings stakeholder perspectives and cross-functional expertise into a common plan, prioritizes meaningful gaps, and continuously reassesses those priorities as the environment changes.

Ultimately, the measure of a strong evidence strategy should not be the volume of evidence generated.

The question is not:

How much evidence are we generating?

It is:

Are we generating the evidence that actually matters?

Because in an environment with more data than ever before, the advantage may not be the ability to generate more.

It may be knowing what is worth knowing.