Pharma's Commercial Reset

HOW THE INDUSTRY IS REWRITING THE MODEL

September 2026

NUMEROF & Associates

Executive Summary

Pharma's Commercial Reset

For the past five years, Numerof & Associates has conducted a study of the evolution of the commercial model across U.S. pharmaceutical manufacturers. The first Commercial Model Survey, conducted in 2021, outlined the responses of commercial organizations to the draconian conditions imposed during the COVID-19 pandemic. In the years that followed, manufacturers moved beyond the immediate disruption of the pandemic to address changing customer decision-making, provider and payer integration, and growing demands for clinical and economic value, while evolving their approaches to digital engagement and strategic account management. By 2024, ongoing economic and regulatory changes, particularly the emerging implications of the Inflation Reduction Act (IRA), had become increasingly important drivers of commercial strategy.

Since our 2024 survey, many of the policy changes that were emerging at the time have begun to take effect, creating a more complex and interconnected commercialization environment. In the U.S., the IRA has fundamentally changed the pricing environment, while initiatives such as Most Favored Nation (MFN) are creating new considerations for how U.S. and international prices are set. In Europe and other global markets, evolving requirements such as the Joint Clinical Assessment (JCA) and other pricing and access reforms are raising the bar for demonstrating differentiated clinical and economic value.

At the same time, growing frustration with the cost and outcomes of the U.S. healthcare system is driving greater scrutiny of how healthcare is delivered and priced. Manufacturers face increasing pressure from regulators and the public to demonstrate greater value, accountability, and transparency and to more clearly justify the pricing of their products.

For decades, the commercial model relied heavily on broad physician engagement and a "feet on the street" sales approach to drive product adoption. As purchasing decisions have become more complex and expectations for value have increased, that approach is no longer sufficient on its own.

The 2026 Commercialization Survey explored how pharma companies are evolving their commercial models in response to a rapidly changing global economic and regulatory environment. Our interviews indicated that executives are increasingly rethinking how they approach commercialization as the demands of the market change.

Policy and regulatory complexity have become a dominant force in commercialization strategy, prompting manufacturers to reassess pricing, access, launch sequencing, and portfolio decisions across markets. At the same time, these changes are also increasing the need for manufacturers to bring cross-functional perspectives into commercialization decisions earlier and work more closely across the product lifecycle. Organizations vary considerably, however, in how effectively they have put these approaches into practice.

The bar for demonstrating value has also risen, with evidence increasingly expected to support not only regulatory approval, but pricing, reimbursement, adoption, and competitive differentiation. This is driving greater emphasis on sophisticated evidence, market access, HEOR, and analytics capabilities.

AI is adding another dimension to the changing business environment, presenting both opportunities and challenges as organizations try to determine how to apply rapidly evolving technologies in ways that create meaningful value.

Taken together, the findings underscore the continuing need for manufacturers to bring fresh thinking to the multiple challenges of adapting to a rapidly changing policy and market environment. Not only must they resist the temptation to stick with what's comfortable, but they also must be prepared to redefine the way functional parts of the organization work together, expanding some and shrinking others in anticipation of where the business environment is going next. Those organizations that continue to rely on legacy approaches or wait for greater certainty risk falling increasingly out of step with the demands of the market, and that has significant costs.

The following report summarizes insights captured from a broad range of interviewees across the pharmaceutical industry. Questions were open-ended to draw out insights and perspectives based on interviewees' unique experiences. Numerof drew on our extensive expertise across the healthcare industry to analyze the findings and develop the insights throughout the report.

Introduction

Pharma's Commercial Reset

Changes in healthcare policy, structure, and market dynamics have been eroding the effectiveness of the legacy commercial model on which most manufacturers have relied for some time. As the healthcare environment has continued to evolve, Numerof set out to understand how manufacturers are adjusting their commercial models to meet these changing demands. Since 2021, we have conducted an ongoing research effort to highlight how companies are adapting to these pressures and how they are changing their approach to commercialization. This report summarizes the results of our qualitative interviews with pharmaceutical executives across varying functions and organizations, and what we have learned about the evolution of commercialization in pharma. The resulting insights provide a view into how manufacturers are adapting today, where the commercial model is headed, and what organizations will need to do differently to succeed.

The pricing and regulatory environment is undergoing profound change, increasing pressure on manufacturers to reassess long-standing assumptions about pricing, market access, portfolio investment, and commercialization. Growing frustration with the cost and complexity of the U.S. healthcare system is adding to pressure on policymakers and industry to demonstrate greater affordability, transparency, accountability, and value. With the first IRA-negotiated Medicare prices taking effect in 2026, manufacturers have been forced to assess the implications of the IRA for R&D, portfolio pricing, market access, budgets, and underlying costs. With additional products expected to become subject to the negotiation process, manufacturers are having to consider these implications more broadly across their portfolios. The evolution of MFN pricing policy is putting greater pressure on global pricing strategies, requiring manufacturers to balance pricing and access objectives across markets while protecting the economics needed to support innovation.

At the same time, payers are raising the bar for evidence of effectiveness, making requirements for approval and reimbursement more complex. The JCA, CMMI initiatives, and growing payer scrutiny are reinforcing the need to demonstrate clinical and economic value earlier in the product development lifecycle and build a stronger evidence story to support pricing, reimbursement, and adoption.

Healthcare delivery has become more consolidated and economically pressured, with physician practices and community hospitals increasingly becoming part of larger healthcare systems and integrated delivery networks

(IDNs), while payer-provider integration and vertical consolidation continue to reshape the healthcare landscape.

For pharma manufacturers, U.S. market consolidation has created fewer, larger customers with greater leverage. The physicians who once drove purchasing decisions are increasingly employed by large IDNs. That small number of influential physicians who controlled purchasing decisions is being replaced by system level committees on which physicians are but one voice.

Over the course of the past five years of research, we have identified a number of trends. For example, our research has documented a progression from pandemic-driven changes in customer engagement to broader shifts in how manufacturers deploy commercial resources, engage customers, and integrate commercial perspectives across the product lifecycle.

Our earlier surveys found that COVID accelerated the shift toward digital and virtual engagement, while manufacturers began recognizing that traditional sales-force models were no longer sufficient to grow sales. Over prior surveys, product adoption decisions became more centralized and subject to more strategic and economic criteria. Manufacturers developed new customer-facing capabilities and tailored communication strategies for key customer segments. Organizations also accelerated the shift toward smaller, more targeted sales teams focused on key KOLs and clinician influencers, while investing in more sophisticated strategic account management.

Our prior research revealed that manufacturers were increasingly recognizing the need for a more integrated, cross-functional approach to commercialization, with greater involvement across functions and throughout the product lifecycle. By 2024, the effects of the pandemic were no longer among the primary challenges facing manufacturers. Instead, organizations were focused on the economic recession and its potential impact on pharma innovation, the price-setting effects of the IRA, increased government scrutiny of healthcare practices, and the impending election and subsequent change in administration. Despite the current economic recovery, the continued evolution of policy, demographic, and market forces remain a serious strategic threat to the pharmaceutical industry.

Against this backdrop, this year's survey set out to understand how manufacturers are adapting to a changing commercial environment and what will be required to succeed. We explored how manufacturers are responding to increasing policy and pricing pressures, how they are evolving the capabilities and ways of working needed to navigate a greater, more complex, and demanding market, and how they are approaching the rapidly changing

role of AI. We examined how these forces are influencing decisions across the product lifecycle.

As a leading advisor to management in customized approaches to product and service commercialization, Numerof has committed to conducting ongoing research on the trends we see happening in the field. As evolving legislation and market consolidation ratchet up the pressure on price, it's important that manufacturers understand what competitors are doing so they can determine the best path to adapting their own commercial model. This year's report summarizes the changes in play, the lessons learned, and the challenges that must be addressed going forward.

About Numerof

Numerof & Associates has worked globally across the healthcare sector for more than 30 years, with a successful track record of engagements throughout industry segments – including pharmaceutical, medical device and diagnostic manufacturers, major payers, and academic and community healthcare delivery organizations. Our unique perspective allows us to anticipate market challenges from diverse stakeholder viewpoints. We understand how policy, demographics, and technology drivers are shaping the global environment and placing a growing premium on economic and clinical value. Numerof anticipated the changing attitude of payers and other critical stakeholders towards economic and clinical value, and we've helped clients differentiate their products in the face of changing policy dynamics, demands for more stringent evidence to justify premium pricing, intensifying competition, and pressure from external stakeholders. These dynamics have implications for commercialization and launch sequencing of products.

Numerof's expertise encompasses crafting global commercialization strategies and analyzing stakeholder value requirements. We work with Regulatory, Clinical, Medical, Commercial, Market Access, and HEOR organizations, informing crucial decisions in R&D, clinical program design, pricing, and launch sequencing. This deep experience has solidified our reputation as a thought leader in global regulatory, access, and commercialization strategy, enabling us to provide strategic, operational, and tactical guidance.

Within the U.S., our firm has served as an advisor to members of Congress and CMS on healthcare reform, innovation, new payment models, and evidence requirements to support reimbursement. Numerof was commissioned to write a series of white papers on strategic development, market access, strategic pricing, and lifecycle management in the changing global healthcare environment and have done extensive writing on these

topics for organizations like *BioPharm International* and *Pharmaceutical Executive*. Our firm's most recent book, Bringing Value to Healthcare: Practical Steps for Getting to a Market-Based Model, outlines a market-based model emphasizing transparency, accountability, and outcome-based payments, themes also explored in Dr. Rita Numerof's Forbes column.

For further information, please call us at (314)-997-1587 or email us at info@nai-consulting.com.

Methodology

In conducting this research, Numerof wanted to continue to explore the longer-term challenges manufacturers see in the market – specifically, recent policy changes like the IRA, MFN, JCA, and CMMI initiatives. We also wanted to understand the impact other market factors like inflation and the implementation of AI have had on efforts to reconceptualize the commercial model.

In this fifth year of our study, we utilized the same approach as in prior years; we conducted a qualitative survey of 175 executives from 67 pharmaceutical companies to gather insights and perspectives. The majority (69%) of the interviewees represented the following 5 functions: Market Access (34%), Medical Affairs (10%), Commercial (14%), Marketing (5%), and HEOR (6%). The remaining 31% represented a variety of related functions, such as business development, clinical and regulatory affairs, and R&D. Small-, medium-, and large-cap organizations were selected to ensure broad representation. While we spoke with many executives who brought a global perspective, findings focus on the U.S. landscape.

Numerof used an open-ended interview approach to explore the ways pharmaceutical companies have adapted their commercial models in response to major market shifts. Our validated, proprietary approach to the interview process is structured to ensure capture of deep insights and the ability to project anticipated reactions with a higher level of confidence than is typically uncovered through traditional market research methods (e.g., advisory boards and surveys).

We first asked interviewees to discuss how evolving regulatory and policy trends are shaping commercialization strategy. Next, we explored how organizations are adapting their commercialization approach, including cross-functional planning, evidence generation, targeting and segmentation, market conditioning, and evolving organizational capabilities. Finally, we asked interviewees to describe how their organizations are preparing for future commercialization demands and where they anticipate the greatest opportunities and challenges.

Key Themes and Insights

Numerof focused on 4 key areas pertaining to how organizations are adapting their commercialization approach in response to market shifts: a) Navigating regulatory and policy complexity; b) Cross-functional integration across the product lifecycle; c) Evidence planning for competitive differentiation; and d) Capability needs for future success. Insights from the survey are described below.

Navigating Regulatory and Policy Complexity

All interviewees recognized that rapid, unprecedented shifts in policy globally (e.g., the IRA and CMMI initiatives including MFN in the U.S., JCA in the EU, and others) are fundamentally changing the commercialization environment that manufacturers have historically operated within.

Interviewees reported that the current era of policy change is unlike anything they have experienced before – and is unlikely to be temporary.

Policy shifts are occurring across markets, with the common theme of increasing scrutiny of clinical and economic value to justify pricing and reimbursement decisions. For example:

- In the U.S., the IRA fundamentally transformed drug pricing by granting Medicare the authority to directly negotiate maximum prices for high-spend drugs.
- CMMI initiatives such as MFN tie the prices paid for a drug in the U.S. to the price paid in other countries, rather than allowing U.S. prices to be determined independently – the objective being to reduce the price gap between the U.S. and comparable international markets.
- In Europe, the JCA centralizes evaluation of relative clinical effectiveness and safety for new health technologies across member states and imposes more rigorous evidence requirements for demonstrating differentiated value.
- Meanwhile, the EU Pharmaceutical Package lowers drug prices through accelerated generic competition while aggressively raising the clinical and real-world evidence bar required for market access.

- At the same time, while Japan's recent drug pricing reform rewards innovation for select, niche populations, it also intensifies cost-containment measures through annual (from biennial) price revisions, profit claw backs, and steeper price cuts for high-cost drugs.

Taken together, many interviewees described policy uncertainty as the dominant force impacting commercialization strategy.

"The policy environment is like an earthquake; it's not going to settle down soon."

"MFN is certainly going to be the most influential factor in the near future, and it will definitely change how we make launch decisions outside of the U.S. market."

"I don't think these pressures are going away. The cost of healthcare is going to remain an issue, and politicians will continue looking for ways to address it."

"While there has always been change throughout the industry, the past 24 to 36 months have felt more exponentially transformative than anything I have seen over the last 30 years. What we may experience over the next five years could exceed the cumulative level of change we saw over the previous several decades."

There is broad acknowledgement that pricing, access, and launch decisions in one market now have implications across other geographies. This represents a major change from when the impact of decisions made in one region were largely confined to that region.

Greater use of reference-pricing mechanisms means that pricing and access outcomes in one geography can influence negotiations and decisions elsewhere.

- For instance, a lower price negotiated in an international market can establish a benchmark that affects U.S. pricing.
- The same dynamic is emerging in Europe. While individual member states retain control over economic evaluations and pricing, a negative or weak JCA clinical assessment can create an unfavorable baseline for subsequent national negotiations, potentially weakening a manufacturer's bargaining position.

Taken together, companies are not only evaluating the economics of an individual market, but also how a decision in one geography could affect outcomes elsewhere.

"The biggest challenge/transformation I've seen is that historically, we treated Europe as Europe. Now we need to look at countries in the context of U.S. pricing and MFN, which creates a new layer of complexity that people are still working through and addressing."

"For the longest time, most companies in the industry didn't need to concern themselves with the price discrepancy between U.S. and international markets. However, with the implementation of MFN pricing, it has become a reality that we must fundamentally rethink our global pricing strategies."

Many organizations are revaluating which products they launch, in which markets, and when, and reassessing evidence that is needed to demonstrate differentiated value.

Given cross-market consequences for price and access decisions, many manufacturers are considering the potential global implications of launch decisions made in specific markets and beginning to look at them more comprehensively.

"We're looking at our target markets as a single, unified marketplace rather than a collection of separate entities. Whenever we develop a strategy for the U.S., we're also working to implement it for Europe and vice versa."

"It used to be a straight math exercise, but now there are a lot of qualitative inputs involved."

To this end, launch sequencing is particularly important. Companies are evaluating whether, and when, to launch in individual countries based on the potential downstream implications in other markets, including whether launching in a lower-price market could affect the price achievable elsewhere. In some cases, the implications are significant enough to influence whether a company launches in a market at all.

"There is an understanding that we may or may not launch products in certain geographies depending on the implications of MFN and the broader global pricing strategy."

"What's happening in the policy environment today is also changing how we think about launching products outside the U.S., particularly for high-priced specialty products. Increasingly, we're thinking about a U.S.-first launch and then determining whether and when to expand internationally."

Launch sequencing considerations extend into clinical development and evidence strategy.

- Companies are questioning whether the markets they ultimately plan to enter should influence the endpoints they generate and how early that evidence is available.

  "If we're not going to launch in X, Y, and Z markets first, do we really need to bring these trial endpoints so early on, or can we do something differently later on?"

- Indication sequencing is also becoming more deliberate. Companies are re-evaluating the order in which indications are developed and launched based not only on policy changes in the focal market but on downstream impacts elsewhere.

  "If there is another indication that will get you a higher price ex-U.S., do you target that piece first even if the population is smaller, or do you go from the broader indication and then limit your price in the U.S.?"

- Several interviewees also questioned the future viability of the multi-indication blockbuster drug model. They anticipate that more targeted therapies for smaller patient populations may offer a stronger value proposition and therefore justification for premium pricing.

Taken together, the evolving policy landscape, combined with more stringent expectations for evidence and value, is prompting organizations to grapple with a new set of complex questions and strategic trade-offs.

As one interviewee illustrated:

"Take Product X: Do I go in with just one Orphan Drug Designation? But what if it works with a second indication – do I delay? Do I wait for the bigger indication versus a smaller orphan indication? Is there a potential pricing game that I can play? How do you overlay MFN on top of this? What is the value I'm going to get from the ex-U.S. market? Those are the kinds of trade-offs that we are all dealing with."

Cross-Functional Integration Across the Product Lifecycle

Many organizations are moving toward a more enterprise-based approach to commercialization across global markets to navigate a more complex and interconnected environment – representing a significant shift from past models.

Most interviewees characterized the "traditional" approach to commercialization as no longer sustainable or appropriate to address today's demands for differentiated value.

Interviewees generally characterized the traditional approach to commercialization as:

- *More oriented toward getting across the regulatory approval threshold*, with less thought/emphasis on building the evidence and value proposition that will be required by the stakeholders that ultimately drive access and adoption (e.g., payers, health systems, etc.).
- *Marketing-led*, with other functions, such as Pricing, Finance, Market Access, and Medical, brought in later to execute against decisions already established.
- *Organized around discrete functional silos*, with teams focused primarily on their own priorities and responsibilities rather than shared objectives.

Interviewees noted that a limitation of the traditional model is often *timing and sequencing* of cross-functional involvement. By the time functions such as Market Access, HEOR, or Medical were engaged, key product decisions were often already established, limiting their ability to meaningfully shape downstream decision-making.

"We're currently operating in a world where the commercial engine is often turned on too late in the clinical process. I believe we must flip this model entirely so that the most critical phase of commercialization occurs during Phase 1 and Phase 2, because if you get that foundation right, the backend of the process will be much more streamlined."

Many organizations are responding by bringing cross-functional perspectives into commercialization decisions earlier in the product lifecycle and more closely aligning development, pricing, access, and launch strategies.

Interviewees reported that functions such as Market Access, HEOR, Medical, and Policy now have a stronger voice in commercialization decisions than in the past. These functions anticipate access requirements, shape evidence generation, develop compelling value propositions and pricing strategies, and ultimately drive commercial success.

"I've noticed that the voices of certain functions now carry significantly more weight than they did in the past. Market access, for instance, used to be a secondary component tacked on to a brand plan. Today, it's evolved into one of our core strategic pillars. I believe that if you are not thinking about access early in the lifecycle, you simply can't have a successful drug."

"Market access and distribution teams are now brought to the table years in advance, sometimes during early R&D, to shape launch strategy rather than just securing formulary position at the end. These discussions are happening much earlier than they used to because the environment we live in is constantly being shaped by policy"

"Market access decisions have significant financial implications … commercialization, distribution, and patient support decisions can materially impact overall business viability and profitability."

Organizations differ in their level of preparedness and sophistication in operationalizing a more integrated model that adequately accounts for shifting policy and value expectations.

Leading companies recognize that simply asking people to "collaborate more" is not enough. They have established formal mechanisms for joint decision-making, including cross-functional forums, clear roles and decision rights, and structured points in the development process where functions must collectively assess the implications of major decisions.

- Importantly, they take a disciplined, sophisticated approach to continuously refining their strategy as market levers change. They build "strategic optionality" into their plans by anticipating different scenarios, identifying potential strategic pathways, and pivoting as needed.
- For example, one organization conducts an annual "Plan B" analysis that evaluates downside change scenarios in policy pricing legislation and develops contingency plans accordingly. This organization has also made structural changes to increase agility, including establishing a dedicated U.S. affiliate leader with authority to make staffing, organizational, and operational decisions quickly in response to major policy or market changes. As the interviewee noted,

"Scenario planning has really become a routine part of how we think about long-term strategy."

- These companies are also making significant investments in dedicated teams to respond more effectively to an increasingly dynamic external environment. For example, another organization established a dedicated 340B Center of Excellence and health analytics function specifically to address emerging policy issues.

Others have begun to respond but face disconnects between broader enterprise strategy and functional execution.

- Some organizations have a strategy in place at the macro level but are challenged to operationalize what it means and successfully translate it into concrete execution. These companies may have difficulty defining what has changed in the environment, articulating the operational implications for their business, and what should be done differently.

  "We know the game is changing. But we don't know where the bar is, and we don't know where the target is."

  "I can plan for a lot of different scenarios, but if I don't know exactly what I'm planning for, that's what makes it so difficult."

- In contrast, some companies react at a functional level. Upon a major market change, they default to addressing the near-term need in a specific market (e.g., quickly analyzing product-specific pricing implications), without connecting it to a broader enterprise-wide strategy.

  "Many organizations are still in reactive mode rather than operating from a fully formed strategic playbook."

- Global and local teams in these organizations do not always connect effectively. This can limit the incorporation of local market context and payer/customer realities into broader development, access, and launch decisions. Conversely, global evidence and value strategies may not fully account for market-specific requirements, making it more difficult to successfully execute the strategy at the market level.

Finally, there are a few companies that remain paralyzed by uncertainty and take a watchful waiting approach; they want greater market certainty before making significant commitments to major commercialization decisions (e.g., launching in a market or not).

"Right now, there's still enough uncertainty that companies have some room to wait and see what happens because so much is still up in the air."

Key Themes and Insights

"Companies playing the wait-and-watch game end up finding challenges in how they resource this going forward. Decision-making gets delayed."

Pharma's Commercial Reset

Organizational philosophy and leadership orientation were consistently identified as key factors that determine whether the company fully embraces a more nuanced and sophisticated approach characterized by strategic optionality.

Leading organizations set expectations for greater agility and cross-functional/market collaboration to understand the interconnected levers shaping global access and pricing. Organizations making the greatest progress appear to be those where leadership has established shared accountability for the product outcome, rather than leaving individual functions accountable primarily for their own portion of the commercialization process.

"Every morning it feels like there is another tweet, announcement, policy statement, or market development; and organizations are constantly evaluating how those changes could impact the business and what they ultimately mean strategically and operationally. That pace is forcing teams to communicate more closely, coordinate more quickly, and react in a much more integrated way than in the past."

Others default to more siloed approaches that have historically driven success. Organizations with more entrenched functional silos and weaker cross-functional leadership alignment were less likely to consistently embrace integrated decision-making. In these organizations, interviewees reported resistance from leaders who are reluctant to recognize the global dynamics that require fundamental shifts to established ways of working.

"The greatest source of friction comes from helping long-tenured employees move away from traditional ways of working. Many employees who have been with the organization for a long time naturally continue to rely on familiar approaches, making it more difficult to adopt new ways of thinking and operating."

"Some organizations accept the changes, but others refuse to believe these changes are happening and continue with the old vision."

"Our organization can be rigid. There's an arrogance rooted in past scientific success. When you don't have transformational drugs in the near-term pipeline, it becomes harder to drive change. You need to flip the whole ship."

The consequences of not having fully developed strategies that incorporate strategic optionality are becoming much greater, as policy changes become more frequent and interconnected across global markets.

Without considering evolving market and policy scenarios early, companies can become locked into decisions that are difficult or costly to reverse – they may generate the wrong evidence, select suboptimal endpoints, or delay evidence that is critical for access decisions.

As market uncertainty persists, "wait and see" can also become a strategic risk. Delaying decisions until there is greater certainty may result in missed launch opportunities or insufficient time to adapt.

Evidence Planning for Competitive Differentiation

Interviewees emphasized that the bar has been raised regarding the requirements needed to demonstrate value and the implications for evidence generation. Strategies to achieve competitive differentiation, access, and adoption cannot be approached as they have been historically, as today's environment demands a rethinking of conventional approaches.

Interviewees consistently noted that traditional measures of clinical value are insufficient in today's market; safety and efficacy are key, but not enough to secure access and adoption. While this has been true for the last several years in key markets in Europe in particular, the requirements have increased and characterize most global markets, including the U.S.

Interviewees noted that while regulatory approval is fundamental, other influential stakeholders (e.g., payers, health systems, and HTA bodies) require more diverse types of evidence to support their decision-making.

- Payers now expect significantly more robust evidence packages, including comparative efficacy data, HEOR analyses, cost-effectiveness studies, and real-world evidence, which demonstrate differentiation versus the standard of care.
- Health systems are placing greater emphasis on *total* value of therapies rather than acquisition cost alone, including added value to current treatments, operational efficiency, and total cost of care.
- HTA bodies expect evidence demonstrating outcomes that matter to patients and families.

Taken together, the access environment no longer supports investment in incremental innovation. Companies are being held to significantly higher standards for justifying clinical utility, value, and reimbursement for high-cost interventions. The extent to which 'added benefit' over standard of care is demonstrated will determine reimbursement and ultimately product value.

"Today, the environment is much more demanding. You really need a compelling value proposition supported by strong evidence – whether that comes from pivotal trials, health economics studies, cost-effectiveness analyses, or real-world evidence – showing how your product compares to the current standard of care. You have to clearly demonstrate where your therapy fits within the patient journey, how it differentiates from competing products, and what value it provides to both patients and payers. If you do

not have enough supporting evidence or differentiation, products today can face major coverage barriers or fail to gain access altogether."

Pharma's Commercial Reset

Organizations are becoming more deliberate in how evidence is generated and applied, tailoring it to the requirements of specific stakeholders and markets (e.g., payers, HTA bodies, providers, and health systems). This reflects a shift away from one-size-fits-all evidence generation toward more targeted evidence planning.

Interviewees noted that payers and population-based decision makers (PBDMs) seek evidence of economic and clinical value that is relevant to their specific populations. Companies are trying to anticipate the questions that physicians, payers, and patients will ask. Increasingly, they conduct customized analyses and provide tailored evidence to address unique stakeholder needs.

Interviewees also noted distinct goals of evidence generation across the lifecycle:

- **Pre-launch:** Traditional clinical trials, publication reviews, and meta-analyses to establish unmet need and define the product's place in the treatment landscape.
- **Immediately after-launch:** Shift toward demonstrating real-world performance through claims analyses, patient and physician feedback, and patient-reported outcomes. This evidence can support follow-up payer discussions, demonstrate real-world value, and potentially support less restrictive utilization management in subsequent negotiations.
- **Post-launch/throughout lifecycle:** Ongoing claims analyses to better characterize how the drug is being used in the real world over time, including patient types, comorbidities, dosing patterns, and broader utilization trends.

Real-world evidence, in particular, has become front and center in demonstrating economic, clinical, and patient-centric value for payers, providers, policymakers, and patients.

Interviewees consistently acknowledged that every clinical trial program has evidence gaps; and RWE is a *strategic necessity* to fill those gaps, support appropriate use of the product, and broaden the evidence base.

- As noted above, RWE can help companies reinforce product performance, negotiate less restrictive utilization management, and broaden access. For example, one organization used RWE to reduce double step edit requirements to a single step and to broaden prescribing from specialists to expanded access through primary care physicians.
- RWE is increasingly recognized as critical when traditional evidence generation is difficult. In the case of rare disease, small patient populations can make large, long-term studies impractical.

One shift from prior years is the *timing* of RWE efforts, largely a reflection of changes in global requirements for such data and recent trends in the U.S. on the acceptability of such data by the FDA. Generation of RWE has clearly increased with many organizations building it into regulatory studies.

While some organizations are expanding infrastructure to support effective RWE generation, others are pulling back on prior investments.

Several interviewees noted efforts to scale backend data infrastructure, acquire larger datasets, and develop more analytic capabilities to generate sophisticated RWE and derive relevant insights.

"I think the ability to generate RWE more rapidly and cheaply is a potential game changer, especially since the agency [FDA] is starting to allow it to be used for label claims."

Despite a shift towards the increased adoption of RWE among most companies interviewed, some organizations struggle to recognize the strategic value of RWE and remain resistant to investing in it. These organizations view RWE as primarily an academic exercise and often lack clear criteria to ensure studies are fit-for-purpose, cost-effective, and explicitly linked to business impact.

"Leveraging RWE opportunities reflects a definite culture shift. We continue to have pockets of resistance among clinical trial traditionalists. At the senior level of the organization there's full buy-in, but on a personal/individual program level there is still resistance."

"The industry used to feel that every product needed an HEOR study or a real-world evidence package simply because that's what you were supposed to have. But it's not enough – you have to make sure it's producing an outcome that the payer decision-makers actually care about and will act on."

Many organizations are developing formal *integrated evidence plans* (IEPs) that ensure business objectives, clinical trial data, and RWE support a unified commercial strategy. Others continue to fall short, looking at RWE through a traditional post-market lens, thus risking product value.

Interviewees consistently noted that decisions about what evidence to develop and how are increasingly shaped by macro environment trends. However, too often, R&D remains focused on regulatory approval only and organizations lose sight of the broader evidence package needed to support commercialization and market access.

"By the time you're sitting across from reimbursors, you can't exactly go back and change what your data looks like. Your development strategy depends entirely on what the unmet need is, what's already on the market, and whether you're providing something better or addressing a gap that's currently ignored."

"Companies can reach the PDUFA date ready to launch the drug, but without a clearly established pricing strategy because no one adequately planned for the evidence required to justify that price. That then leads to a scramble to generate real-world evidence after launch in an attempt to support the pricing rationale."

To better account for broader stakeholder needs, many organizations are developing IEPs that define evidence needs for a product that address current clinical gaps and specify optimal paths to generating that evidence (e.g., traditional clinical trials or more cost-effective methods such as claims analysis). Increasingly, patient reported outcomes are included in registration trials and in post-market studies.

"We begin by asking what the aspiration is for the product. We ask what we hope to achieve, what evidence we are going to generate, and how we can position the product to demonstrate its full value."

Key Themes and Insights

Pharma's Commercial Reset

Organizations are at significantly different stages of maturity in developing and implementing frameworks to support integrated evidence planning.

- Some more sophisticated organizations have implemented a highly structured and rigorous process with clearly defined roles, decision rights, and processes to facilitate cross-functional input.
    - For example, one interviewee described that cross-functional partners are actively involved as early as Phase I and Phase II. Discussions here focus on proof-of-concept and perceptions of meaningful clinical value through the eyes of key payer stakeholders. As clinical programs advance through Phase II and begin to consider Phase III, the IEP process becomes more rigorous, incorporating cross-functional working sessions with Medical, Market Access, Policy, and other commercial functions. These sessions address the competitive landscape, how payers are likely to evaluate new therapies against standard of care, potential budget impact, critical endpoints to include in a Phase III trial, and other market access considerations.
- In other organizations, alignment across functions remains difficult and impedes execution. In these cases, interviewees described IEP as a theoretical framework, with organizations struggling to align goals and translate plans into effective implementation.

  "We use the phrase IEP, but every time I see it, it's everything but integrated. Medical, HEOR, Access, and Commercial teams operate in different realms."

Capability Needs for Future Success

Many organizations are investing in sophisticated capabilities to address more stringent value expectations, enhance customer engagement, and improve efficiency in an increasingly complex commercialization environment. Interviewees identified three core areas for capability development: 1) investing in more sophisticated clinical and technical field expertise; 2) developing key account management discipline; and 3) incorporating AI in commercialization efforts.

1) Investing in more sophisticated clinical and technical field expertise

There is broad recognition that commercial success depends on capabilities beyond traditional sales and marketing. Interviewees emphasized the need for more clinical and scientific expertise as portfolios shift toward specialty products that require much more technical, in-depth discussions with customers.

Medical Affairs is becoming an increasingly important strategic resource; field medical teams are evolving beyond their traditional role as clinical educators toward "problem solvers"; empowered to diagnose institutional needs, represent relevant evidence that informs treatment decisions, and contribute to product development strategies.

Companies are also deepening market access expertise and seeking individuals with specialized knowledge in payer strategy, 340B, policy, and other areas to develop strategies and lead engagement with payers and PBDM customers.

These changing customer needs are also prompting organizations to rebalance field force composition. Some are reducing the size of traditional sales teams while expanding HEOR and Medical Affairs. This reflects a shift from high-volume sales coverage toward more technical, coordinated, and value-oriented customer engagement.

At the same time, this evolution is occurring against a backdrop of resource constraints. Organizations with legacy sales- and marketing-centric cultures often *underinvest* in Market Access and Medical, leaving these functions particularly vulnerable during organizational restructuring.

2) Developing key account management discipline

As purchasing decisions move from individual physicians to integrated health systems, interviewees noted a shift from the traditional "feet on the street" customer engagement approach to a greater emphasis on strategic account management discipline.

Interviewees consistently noted that the traditional model has left manufacturers with too many individuals in narrow field roles that diminish impact during customer interactions. This approach is less effective in an increasingly complex, consolidated market. Integrated customer organizations seek more streamlined, coordinated discussions around contracting, value, and strategic partnerships rather than product-by-product interactions.

Against this backdrop, many interviewees see an increasing need for key account management roles to orchestrate a coordinated approach to priority accounts. This entails understanding the broader customer organization, identifying where the manufacturer can create value, and mobilizing the right internal capabilities to address customer priorities.

Many organizations are placing greater emphasis on recruiting and developing key account management roles; individuals who combine scientific expertise with strategic thinking, relationship-building, and have the business acumen to navigate increasingly complex customer organizations.

"We are looking beyond the traditional pharmaceutical talent profile. Rather than hiring only people who have come up through conventional pharma marketing or commercial pathways, we are increasingly seeking business-minded individuals with more diverse industry backgrounds and broader strategic capabilities."

However, gaps remain in operationalizing KAM capability and replacing the traditional "feet on the street" approach. Defining key roles, developing new processes, building core capabilities, and translating needed disciplines into practice continue to trail what's needed.

Interviewees noted that questions remain on how the KAM role should be defined and executed both within the organization and with external customers (e.g., who 'owns' the account and account execution, when to bring in HEOR/Medical/Access, how resources are coordinated, etc.).

For most organizations, the development of these capabilities is built organically through role evolution rather than a formal process. Most agree

that this approach is not optimal. For example, some companies are evolving sales representatives into strategic account managers. Most noted that this doesn't translate well in the field as these staff don't typically have the broader competencies required to navigate and coordinate engagement across complex accounts.

Interviewees described that changing role expectations and ways of working is difficult in general. The challenge is exacerbated when organizations are reluctant to abandon the legacy sales and marketing model that reflects their commercial leaders' past experiences, bias about what has led to success, and limited perspective on how core markets have significantly changed.

"I fundamentally believe the traditional pharma model has been broken for over a decade, and we've been an industry that has been reticent to accept that."

"I think we are now finally on the precipice where our customers are no longer going to tolerate our very traditional ways of engagement."

3) Incorporating AI in commercialization efforts

AI was consistently identified as the most consequential emerging technology, with potential implications across the organization.

Most organizations are making broad investments in AI, building enterprise-wide initiatives, AI roadmaps, training programs, and scorecards to track usage. Applications span the lifecycle and reflect wide-ranging efforts:

- Developing a 360-degree view of customers by combining social media data and advanced analytics to identify specific levers of influence for individual customers.
- Accelerating complex clinical analysis, including answering highly specific questions and evaluating nuanced treatment decision trees in areas such as oncology.
- Automating clinical trial operations, RWE generation, analytics, and dossier development.
- Customizing content generation, message adaptation, and personalized marketing, particularly as patients increasingly turn to AI-enabled tools and LLMs for medical information rather than traditional DTC channels like TV.

"AI represents the biggest transformation happening in our industry. We've been talking about AI for years, but now we're finally seeing its impact, particularly on speed."

"AI emerged as one of the most prominent cross-functional enablers, fundamentally changing how work gets done."

- Interviewees described substantial gains in speed and efficiency, with activities that once took months compressed into days.
- Interviewees did not view AI as an imminent threat to jobs. Rather, they describe it as changing the balance between execution-oriented work and higher-value strategic activities.

"Our jobs are shifting to focus much more on education, high-level strategy, and building deeper relationships with our accounts. I don't see it as a replacement situation at all. Since we don't have to spend hours just staring at raw data anymore, we can take that time to focus on the things that matter, like strategizing and educating our partners."

"While AI is expected to automate repetitive tasks and improve efficiency; scientific judgment, relationship-building, strategic thinking, and external engagement are capabilities that will continue to require human expertise."

Approaches to AI investment and the pace of adoption vary widely across organizations.

AI investment does not appear to follow a simple pattern reflecting organizational size or development stage.

- Larger organizations are more likely to have the resources and infrastructure to approach AI as an enterprise-wide transformation.
- Smaller or less mature organizations tend to describe more targeted experimentation, use-case-specific applications, or a wait-and-see approach.
- Interviews suggest that governance, data infrastructure, risk tolerance, and clarity around business use cases may be stronger determinants of investment approach than size or stage alone.

Responses also varied in terms of *pace* of AI adoption.

- Some interviewees reported feeling "bombarded" by AI applications; while they see potential value, they are struggling to navigate the crowded landscape and identify where AI can deliver the greatest impact.
- Many organizations treat AI as a "shiny new object", aggressively deploying discrete applications with the promise of immediate improvement in speed and quality of output.
- Others are deliberately taking a wait-and-see approach because of uncertainty around the benefit of AI. They are seeking clearer evidence that AI can materially improve productivity, decision-making, customer engagement, or other areas before committing significant investments.
- A few organizations strike a good balance, recognizing that success depends on a more structured, strategic approach rather than a generic, reactive one that fails to consider return on investment. These organizations are focused on identifying meaningful business use cases, establishing governance, and embedding AI into broader commercial transformation efforts.

"AI capabilities are advancing rapidly, but many people still do not know how to use the tools effectively. AI is transforming the way work gets done, but without the ability to envision that transformation, adoption becomes difficult."

Conclusion

The global healthcare landscape is undergoing an unprecedented level of change. Across the ecosystem, many of the assumptions that have historically shaped how organizations approach clinical development, evidence generation, launch sequencing, pricing, and commercialization are being rendered obsolete. In the face of significant regulatory change, established approaches are no longer relevant. This is not simply an incremental evolution; the magnitude and pace of change require a different level of focus, discipline, process, and willingness to make deliberate trade-offs. Importantly, organizations should not expect to return to the "normal" way of doing business.

At the same time technology is advancing rapidly, creating opportunities for new science to deliver phenomenal impact for patients. Yet markets across the globe face fiscal constraints and scrutinize healthcare costs through that lens, creating resistance to the adoption of new technologies.

The rapidly evolving policy environment is fundamentally changing how organizations think about evidence and value demonstration across the product lifecycle. Organizations are increasingly "shifting left," with earlier and more structured engagement across functions to incorporate the evidence needs of diverse and increasingly sophisticated stakeholders from the outset. This means that traditional approaches to product development that rely on handoffs between functions at discrete points in the development lifecycle can be both risky and costly. Greater integration is not simply about bringing more people to the table; it requires greater discipline in how processes are defined, decisions are made, and trade-offs are managed.

This new way of working requires new capabilities. Organizations will need deeper scientific and technical expertise as well as strategic account management discipline to translate increasingly complex science into value that is relevant to different decision-makers, markets, and care settings. Although these dynamics are not new, their intensity is. Organizations will need to build capabilities that enable them to navigate this environment with greater speed, sophistication, and precision, including the use of AI. AI should not be viewed as a standalone capability or an end in itself, but rather as an enabler of more effective decision-making, organizational efficiency, and agility.

For many organizations, however, the scale and complexity of these changes can feel overwhelming. Organizations recognize that traditional commercialization models are no longer fit for purpose, but many are

struggling to adapt their processes, structures, and talent models quickly enough to keep pace with a rapidly changing commercial environment. Deeply embedded legacy structures and functional silos remain significant barriers to change, slowing decision-making, collaboration, and execution.

Ultimately, the organizations best positioned for future success will not simply be those that respond fastest to individual changes in discrete markets. They will be those that fundamentally rethink how they operate – breaking down silos, integrating global perspectives, and strengthening the capabilities required to drive more sophisticated product decision-making and customer engagement.