

Rethinking market access

Delivering on the promise of therapeutic innovation

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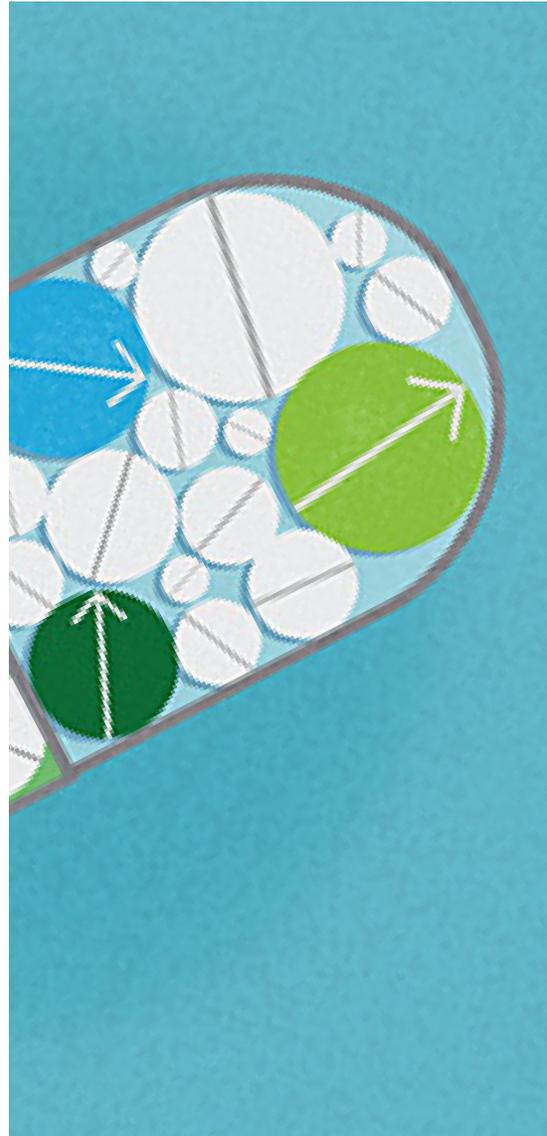
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Executive summary

THE AVERAGE COST of bringing a pharmaceutical asset to market has reached US\$2 billion,¹ yet more than a third (36%) of all new launches in the United States fail to meet expectations.² Market access strategy and execution—life sciences companies’ ability to demonstrate clinical and economic evidence, negotiate with health care access stakeholders,³ and enable affordable and timely product fulfillment for appropriate patients—is one of the primary contributors to product launch success and failure.⁴

Without effective market access, patients lose trust in the ability of the entire health care system to ensure access to therapies. Furthermore, market access challenges can undermine the trust of other important stakeholders: providers who prescribe and administer treatments, private and public payers that pay for them, and researchers and investors who contribute to innovation.

While successful market access strategy and execution are universally important, our research suggests that more nuanced approaches are necessary. We found that market access activities behind successful launches often vary based on product type. Therefore, we introduce a therapeutic archetype framework that can help life sciences companies improve the success of their product launches and deliver on the brand ambition.



We propose five archetypes that take into account product, patient, disease area, market characteristics, and product technology, and the evolution of drug pipelines from broad patient populations to more targeted indications and personalized therapies. The archetypes are:

- Vaccines
- General medicine (such as cardiovascular, diabetes, or respiratory)
- High-volume specialty (such as multiple sclerosis, immunology, hepatitis C)
- Oncology
- Rare disease, including cell and gene therapies

Our research suggests that launch preparation should begin much earlier in the development process by incorporating market access perspectives, engaging a wider set of industry stakeholders, and involving deeper cross-functional collaboration. We report our research findings within the context of the strategic choices that organizations should make.

- **What is the winning ambition?** A disciplined approach to market access should begin with formulating the objectives for the brand and how these objectives will support the overarching commercial goals. This includes a robust understanding of the access landscape

and cross-functional alignment on clear and specific access goals.

- **Where to play?** Manufacturers should consider factors such as the treatment context, how stakeholders make decisions about using the product, who the priority stakeholders are, which access options are most appropriate and viable, and the trade-offs that come with them.
- **How to win?** Winning in a competitive market requires thinking through how to define and communicate the brand's value to stakeholders, and determine approaches to pricing, contracting, reimbursement, affordability, and fulfillment.
- **How to execute?** Organizations should define, prioritize, and execute cross-functional actions while continuously monitoring results and adjusting to market conditions. This may require conscious trade-offs and adjustments to the execution plan.

As launches become more complex, companies should consider these strategic questions and specific launch and market access requirements. Operationalizing these requirements through archetype-based launch planning can help them execute new launches successfully.

Introduction

THE EVER-INCREASING COSTS of drug development, intense competition, payer controls, and complex distribution logistics have made it challenging for pharma companies to get the launch strategy right. [Deloitte's study that analyzed drug launches](#) in the United States shows that success at launch significantly impacts the product's revenue trajectory in later years, yet 36% of drugs launched between 2012 and 2017 missed their launch forecasts. Half (50%) of drug launch failures were attributed to limited market access, followed by inadequate understanding of market and customer needs (46%) and poor product differentiation (44%).⁵

As we look to the future, we expect market access will continue to loom large over the entire product life cycle. Complex benefit designs, increasingly sophisticated utilization management practices, and payers' rising market power due to industry consolidation have put market access at the center of launch success. This raises the stakes for launch teams and requires intentional and careful planning around potential access challenges early in the development process and throughout the product life cycle.

In the absence of effective market access, new therapies, even after launch, remain an unfulfilled promise, undermining patient and caregiver trust in the ability of the health care system to ensure access to treatment. Additionally, market access challenges can erode the trust of other key stakeholders: providers who prescribe and administer treatments, private and public payers that pay for them, and researchers and investors who contribute to innovation. Biopharma manufacturers ought to rethink market access and their relationships with stakeholders to ensure market adoption of new treatments.

In this article, we explore critical launch considerations across different types of biopharmaceuticals and share ideas on how to refine future launch approaches based on the unique characteristics and needs for each therapy. We propose that processes based on therapeutic archetypes (see sidebar "Therapeutic archetypes can optimize launch decision-making") can improve the effectiveness of launch planning and execution.

ABOUT THIS STUDY

The Deloitte Center for Health solutions conducted this study to understand the challenges and leading practices associated with launching new products in different therapy areas (TAs). We also wanted to understand major similarities and differences in market access considerations and launch activities across different types of products and how organizations can improve their launches.

Between September and November 2021, we interviewed 16 industry participants who are experts in market access, commercial strategy, marketing and launch excellence from biopharma companies (14) and market access consultancies (two).

Research findings

End-to-end market access strategy

In Deloitte’s experience, a successful market access strategy considers a set of strategic choices, optimizes process coordination across functions and affiliates, brings clarity around roles and responsibilities, and employs digital technologies toward efficient and effective operational execution. Our [market access excellence \(MAx\)](#) methodology recognizes that organizations make decisions based on incomplete information and that strategic

choices come with trade-offs, upstream requirements, downstream implications, and knock-on effects. We use the following strategic choices to illustrate our research findings (figure 1):

- What is the winning ambition?
- Where to play?
- How to win?
- How to execute?

FIGURE 1

Strategic choices that illustrate our research findings



Source: Deloitte analysis.

THERAPEUTIC ARCHETYPES CAN OPTIMIZE LAUNCH DECISION-MAKING

The technologies behind new therapies entering the market are changing rapidly. As new therapies, such as biomarker testing for certain cancers, target smaller and smaller populations and some, such as gene therapies, are custom-made for individual patients, we have entered the age of personalized medicine. The market's response to all of this can be hard to predict. Reimbursement dynamics and payers' willingness to pay can vary, and evolving benefit designs can restrict access or impose high patient cost-sharing.

One-size-fits-all approaches to market access are no longer viable. We propose a framework of therapeutic archetypes (figure 2), first introduced in [Commercializing specialty pharmaceuticals: Raising the game on channel strategy and analytics](#). Archetype-based launch approaches can incorporate critical considerations that are product-specific and simplify the creation of bespoke launch plans for each product.

Based on the product and market characteristics outlined below, our five archetypes account for stakeholders' growing sophistication in managing increasingly complex and expensive treatments and the shift from high-volume therapies for chronic diseases to highly specialized therapies for narrowly defined patient populations.

- **Patient characteristics:** Size of the patient population, patient demographics, types of physicians who diagnose and treat the illness, and how the patient population is covered by payer types
- **Disease area maturity:** Level of understanding of disease etiology, manifestation and progression, existence of and degree of agreement on the standard of care, and existence of and clarity around reimbursement pathways
- **Product characteristics:** Drug-handling requirements, mode of administration, therapy complexity, technology, and mechanism of action (MOA) behind the therapy, safety profile, and typical administration sites (e.g., home, outpatient, hospital)
- **Competitive intensity:** Direct competition from generics, biosimilars, and other brands in the same therapeutic class and indirect competition from drugs in other therapeutic classes

One aim of our research was to test our therapeutic archetype framework, and it validated many of our core hypotheses and pointed to a few refinements.

Some respondents said that further segmentation of general medicine may be useful: How payers and providers view benefits or manage utilization may differ depending on whether the product is used on a chronic basis (such as statins) or on a short-term basis (such as anti-infectives or topicals).

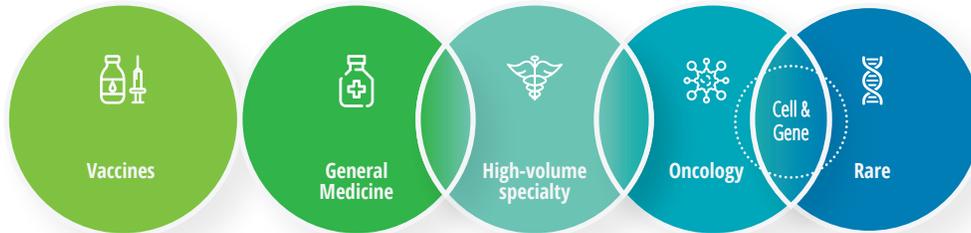
Another suggestion was to subcategorize oncology, whose evolution is expected to reflect customers' approach to management: Established mature products facing biosimilar entrants are expected to be managed differently from products with novel MOAs that come with greater financial and clinical uncertainty.

Digital therapeutics⁶ may become a stand-alone category, perhaps with its own reimbursement pathways.

While respondents agreed that cell and gene therapies deserve to be a stand-alone archetype, market access considerations today mostly resemble those within oncology and rare disease. Recognizing these similarities, we propose that cell and gene occupy a subsegment within the oncology and rare disease archetypes for now. As the field matures, we envision it will evolve into its own archetype with distinct approaches to access, channel dynamics, payment models, pricing, and reimbursement.

FIGURE 2

Therapeutic archetypes



Note: The archetypes are not mutually exclusive or static. For instance, oncology and rare overlap for rare cancers, and specialty drugs migrate into general medicine as they become generic.

Source: Deloitte analysis.

What is the winning ambition?

A disciplined approach to market access begins with formulating the objectives for the brand and how these objectives will support the overarching commercial goals. Organizations should consider trade-offs—such as time to access, market share, volume, discounts and rebates, cost of patient affordability programs, fulfillment solutions, and required commercial capabilities—recognizing that goals and costs will be adjusted as the investigational asset progresses through clinical development.

An important input into this exercise is landscape assessment that informs “where to play” and covers the following areas:

- The disease, patient population, and patients’ unmet needs
- Detailed understanding of the patient and access journey
- Current and future ecosystem dynamics:
 - Customers: How health care professionals and other customers think of the disease and treatment; their pain points

- Competition: Current and future therapies that represent direct and indirect competition
- Context: Policy, economic, societal, and technological
- Priority access stakeholders—such as health plans, pharmacy benefit managers (PBMs), integrated delivery systems, and value assessment bodies—and how each defines value
- Anticipated approaches to utilization management and benefit designs

Our research suggests that even at a very early stage, incorporating commercial insights into the clinical development program can prove exceedingly valuable, as it can help shape future evidence development, trial design, and formulation strategy. In many instances, the window of opportunity can be quite narrow, as one of our respondents explains:

“Adaptive trial designs move very quickly from phase 1 to phase 2/3. So, if the phase 1 team is designing a phase 2 study, you have to bring the market access professional before the protocol is closed for the phase 2 design. And if it’s a phase 2 adaptive 2 to 3, then there’s only one opportunity [for commercial] to provide input; so getting the study right becomes really critical.”

— *Vice president, market access, HEOR and pricing, small biopharma company*

Respondents gave examples of the types of insights from commercial that can inform goals for the brand:

- Many therapies will see indication expansion throughout the product life cycle. These indications may span multiple archetype categories, meet different needs, and target populations of varying sizes, raising critical questions on sequencing, prioritization, and future access.
- Future competitive dynamics could affect how well-protected a certain new MOA or product is going to be, once commercialized.
- Certain design elements of clinical trials could invite utilization management restrictions down the line, or access could be influenced by product formulation and mode of administration.
- Sometimes the system of care cannot support a therapy, even one clinically superior to current alternatives. For instance, a treatment regimen for working-age patients that requires frequent in-office infusions and leaves them unable to drive will probably see low uptake.

Where to play?

In deciding where to play, manufacturers should consider factors such as treatment context, priority stakeholders, how stakeholders make decisions about using the product, the most appropriate and viable access options, and the trade-offs that come with them. Doing this homework helps them avoid mistakes associated with the second most common reason for launch underperformance: inadequate understanding of market and customer needs.⁷

We heard that the approach to landscape assessment may differ by therapeutic archetype. For instance, for rare disease therapies that target small populations, landscape assessment must get increasingly granular to address uncertainty: e.g., do prescribers, provider organizations, and public and private payers understand and agree on the burden of disease; what do they think about current treatment options; where do current treatments for this disease fall in their budget; and where will the new therapy fit within the system of care? Understanding what they do and do not know and how stakeholders make decisions about treatment choices can inform manufacturers’ medical education, communication, and regulatory strategy. Communication platforms may include medical and scientific engagement with population health decision-makers, such as burden of disease

education and preapproval information exchange; communication with health care professionals through conferences or continuing medical education programs; and engagement with value assessment or guideline organizations, such as ICER or NCCN.

Respondents stressed the importance of presenting a compelling story about the burden of illness and unmet needs. They also emphasized the importance of generating evidence that addresses those needs through carefully developed endpoints in randomized controlled trials or targeted evidence development using real-world data. This sets the foundation for evidence-backed value discussions with stakeholders down the line.

Examples of decisions about where to play include indication, target population and subpopulation, line of treatment, distribution channel, and priority accounts.

“Value of generating evidence [in rare] is more impactful than for other archetypes. Everything is magnified in terms of evidence. In rare, literature is limited, evidence is developed by the manufacturer developing the drug. How many patients are out there—that translates into budget impact. Unmet need is heavily influenced by the literature developed by the manufacturer. Ideally, many months before launch, in phase 2 you should invest in understanding the literature. No one knows anything about the disease—understand pain points from clinical or economic perspective, illustrate the burden of disease. In phase 3, you should design endpoints to address those pain points.”

— Director, global market access,
large biopharma company



How to win?

Companies should think through the choices in front of them as they define and communicate the brand’s value to different stakeholders and determine their approaches to pricing, contracting, reimbursement, access, fulfillment, and patient affordability. In addition to bringing market access insights earlier into clinical development, respondents spoke about classic market access activities, such as segmentation, targeted stakeholder engagement, product positioning, and price/value assessment. Doing this right could help avert the third most common reason for missing launch expectations—poor product differentiation.⁸

“You want people to tell you if your baby is ugly or not before you bring it to market and then find out it’s ugly and you have invested a billion dollars bringing it to market.”

— *Senior vice president, sales and market access, medium biopharma company*

Respondents discussed the value of early stakeholder engagement, particularly payers—in many cases 18–24 months before launch. Most have experience with preapproval information exchange⁹ that conveys the details of the molecule, MOA, clinical trials, and existing competition.

“You will get a feeling for payers’ enthusiasm. You will know whether they are intrigued by the science of the product or they are like ‘this is just an old blah-blah.’ You get a feel for their pain points, and if there is something they don’t really understand, or they are asking a lot of questions on. You know that those are the areas where you need to tighten up the story or you are going to need strong objection-handlers.”

— Chief commercial officer, small biopharma company

Manufacturers should help payers and prescribers understand the new therapy’s most appropriate uses, its potential for off-label use, how it compares to other options, and its key benefits. Early discussions enable manufacturers to develop a better understanding of customer needs and to explore elements that help identify the right patients and inform utilization management criteria like diagnostic testing, and the type of clinical documentation payers will find useful.

As they build upon the evidence and publication strategy, manufacturers can refine and tailor value

“Help payers understand how it will help, especially if it substitutes for an existing product. ‘My new product will fit into the treatment paradigm where you currently have this, and you are already paying X. What you are going to get is greater efficacy, better response across patients treated, and more durable, safe treatment.’ Building a narrative that shows you understand what payers do today, what that investment buys, and how you can come in is important.”

— Vice president, immunology/inflammation launch strategy, small biopharma company

messaging to address individual customers’ questions and pain points.

Establishing a pricing and contracting strategy for new therapies requires extensive market understanding. Tools range from pricing and value assessments to budget impact, cost-effectiveness, actuarial modeling, stakeholder driver and barrier impact/sensitivity analysis; to price-volume optimization, often performed throughout late-stage development and up until approval and launch. There is growing use of advanced analytic models, which consider a range of variables and take advantage of increased data availability. Examples of critical questions addressed here include: setting WAC/list price, unit pricing, price guidelines over time, and segment-specific contracting guidelines, and estimating effects of fulfillment and affordability solutions on access and volume.

“General medicine is the scariest [of all the archetypes]. You most likely have a number of competitors, including generics. The most important thing is your pricing—price it as competitively as possible. The price differential vis-à-vis generic or other brands needs to be justified by the efficacy or safety differential that you bring to the market. Are people going to pay a nickel for that difference, a dime, or a dollar?”

— Senior vice president, sales and market access,
medium biopharma company

Value and price assessment methodologies vary by therapeutic archetype due to differences in maturity and competitive intensity. Life sciences companies should also keep an eye on how stakeholder economics change over time due to consolidation, new payment models, or policy changes, as well as the implications of state drug price transparency requirements. This calculus becomes even more complicated for products with multiple indications, as indication-specific pricing remains challenging to execute.

Regardless of therapeutic archetype, manufacturers should develop an overall integrated evidence development plan early and ensure that real-world data collection can begin on day one after the launch. As the understanding of market needs crystallizes, stakeholder segmentation and mapping can provide insights for the real-world evidence (RWE) strategy. This could be an opportunity to incorporate elements into the phase 3 trial design that will support and create continuity of evidence-generation through patient adherence tools and electronic patient-reported outcomes, which could be achieved through digital companions¹⁰ or other digital health tools.



“There may be an interest on the part of a health plan to measure adherence and incorporate certain digital devices that promote adherence. These are useful data points to ensure that if the health plan is covering a medication, the patient is doing his or her part to remain as adherent as possible.”

— Director, strategic market access marketing,
large biopharma company

Negotiations and contracting should take into account customers' economic drivers, such as patients' out-of-pocket costs under typical benefit designs, rebate revenue for plans and PBMs, and practice and pharmacy economics, which can vary substantially by therapeutic archetype.

Respondents also recommend being realistic about addressing the following questions:

- How do our customers define value and how should we define value?
- How do our customers measure value and how should we measure value?
- How should we allocate and capture value?

VALUE-BASED CONTRACTING IS IN EARLY STAGES

Respondents shared a few observations about value-based contracts. Several noted that the capabilities to execute such arrangements are still underdeveloped. Constraints include agreeing on outcomes and who takes the risk, ease of measuring these outcomes, pragmatic execution, misalignment of value capture (e.g., impact on medical versus pharmacy versus total cost of care; weight of patient-reported outcomes), time and duration of impact, and incorporating digital health tools.

"A lot of value-based contracts ended up being rebate contracts with a little value built in somewhere. It can be especially hard in general medicine because if the cost of the product is not tens or hundreds of thousands a year, you can't afford to do what's required for value-based contracts—it will cost you more than it's worth. If it's a product that has really large utilization and it's easy to measure, then it can be very different. Take smoking cessation: It was easy to measure if a patient smokes or not, and when they stop, the savings are immediate—like three thousand a year. But how do you do that for depression? What is the outcome, what is not the outcome? If a patient can function better, the patient gets value, but the payer doesn't."

— Senior vice president, sales and market access, medium biopharma company

"Value-based contracting doesn't work if you make people work too hard. If it's performance-based and it's a huge population and you have to monitor test results of individual patients, forget about it. If it's population-based, it can work."

— Vice president, immunology/inflammation launch strategy, small biopharma company

"If I try to execute a value-based or outcome-based contract, one key thing is the data that is going to inform that agreement. That is probably going to require the use of a wearable device or some other type of digital health innovation that would engage the patient."

— President-founder and chief strategy officer, small biopharma company

How to execute?

Based on our experience and research insights, we conclude that life sciences companies should ensure that market access is effectively integrated into early and ongoing pipeline and launch activities. This may call for a different allocation of launch resources, systematic application of best-in-class market access execution activities, continuous market monitoring, agile strategic and tactical adjustment, and willingness to make conscious trade-offs in pursuit of sustainable, profitable market access.¹¹

Archetype-specific launch playbooks can be a way to codify, standardize, and operationalize leading practices; outline activities, timing, and interdependencies; clarify the roles and responsibilities; and improve cross-functional collaboration. Doing so can help anticipate nuances that a one-size-fits-all approach cannot. For instance, involvement of government affairs, advocacy, or policy groups may be more necessary in rare disease than in other product archetypes. We list some archetype-specific considerations in figure 3.

“Consider the stage when you’re doing disease opportunity assessment for phase 1 assets. Many companies are not involving market access professionals at that stage. The most sophisticated ones tend to think of market access around phase 2. The less sophisticated ones bring some market access individuals at phase 3, closer to phase 3 readout. And, in either case, that’s too late.”

— *Vice president, market access, HEOR and pricing, small biopharma company*

FIGURE 3

Strategic choice considerations specific to therapeutic archetypes

Therapeutic archetypes	Strategic choices		
	 Where to play?	 How to win?	 How to execute?
Vaccines	<ul style="list-style-type: none"> Determine channel strategy and benefit assignment (pharmacy versus medical) 	<ul style="list-style-type: none"> Enlist medical, policy and government affairs teams to liaise with CDC, policymakers, and guideline bodies Develop contingencies for a possible outcome from Advisory Committee on Immunization Practices (full recommendation, clinical decision-making recommendation, no recommendation) 	<ul style="list-style-type: none"> Ensure close coordination with manufacturing and supply chain for seamless product distribution and fulfillment Develop and execute channel strategies for target customers (e.g., retail, health systems, community practices, or government and public health entities)
General medicine	<ul style="list-style-type: none"> Segment and prioritize customer accounts 	<ul style="list-style-type: none"> Decide how to balance trade-offs: e.g., speed to access, short-versus long-term gross-to-net value preservation, broad versus narrow access Choose between traditional or innovative contracts Optimize mix among access investments, such as list price, channel discounts and rebates, and affordability solutions 	<ul style="list-style-type: none"> Ensure coordination between teams and investments in access (rebates, formulary positioning), provider support solutions, and patient affordability solutions Activities around clinical guidelines and population health measures may involve an internal clinical quality function, a different set of external stakeholders, and target different outcomes (e.g., readmission penalties)
High-volume specialty	<ul style="list-style-type: none"> Engage trade teams early to determine channel strategy Determine payer segments based on willingness and ability to control utilization, benefit design, and geography 	<ul style="list-style-type: none"> Actively articulate value proposition, where product fits within the standard of care, appropriate utilization management, and product sequencing 	<ul style="list-style-type: none"> Enable active collaboration between market access, field reimbursement support, and hub and patient services, to ensure integrated access strategy execution
Oncology	<ul style="list-style-type: none"> Determine the sequence of indications to pursue Understand and prioritize provider and payer segments based on value drivers, geography, patient population, and provider networks Identify and prioritize less traditional access stakeholders (e.g., NCCN, ICER, ASCO) 	<ul style="list-style-type: none"> Align on list price, price evolution, and contracting strategy with payers and channel partners (such as group purchasing organizations, distributors) Consider launch and future indications and possibilities of combination therapies Carefully map patient experience to understand patient out-of-pocket costs for things other than the new therapy (e.g., cost of prior or add-on therapy and diagnostics) 	<ul style="list-style-type: none"> Work with medical affairs, key opinion leaders (KOLs), HEOR, advocacy and policy, and medical societies to incorporate the new therapy into clinical guidelines. Think through companion diagnostics, biomarker testing, or any associated laboratory or screening as part of clinical guideline conversations. With input from medical and HEOR, consider how to satisfy payers' interest in endpoints not captured in trials (e.g., overall survival) Use validated quality-of-life measures in trials and RWE
Rare disease, including cell and gene	<ul style="list-style-type: none"> Engage advocacy groups to fully understand the burden of illness, system of care, unmet needs, and where the product may fit within that system, and help determine outcomes that matter to patients Understand value drivers for critical stakeholders 	<ul style="list-style-type: none"> Ensure early market shaping, educate policymakers and payers about the importance of the disease and its long-term impact Collaborate with KOLs and centers of excellence (COEs) on education about the condition, unmet needs, and value drivers 	<ul style="list-style-type: none"> Proactively engage with KOLs, policy, and advocacy to align on value and patient access frameworks Compliantly coordinate between medical and commercial/market access to enable engagement of KOLs, COEs, and access stakeholders Define long-term outcome measures to include in clinical trials and RWE For cell and gene, develop patient registries to collect long-term patient data

Source: Deloitte analysis.

Conclusions

THIS RESEARCH REINFORCES the fact that market access strategy and execution is the primary driver behind launch success. While the discipline of market access continues to evolve, we propose a set of principles¹² that should underlie market access strategy.

- Follow a rigorous and disciplined approach to develop, evaluate, and evolve effective market access strategies. Ensure adequate resources and cross-functional execution across market access, brand, medical, HEOR, sales, and finance.
- Start with what matters most to access stakeholders and work backwards to demonstrate and communicate the value. This calls for incorporating market access perspective into early clinical development and consistently throughout the product life cycle.
- Develop an overarching value and evidence strategy, identifying outcomes that matter to each type of stakeholder, and apply considerations specific to therapeutic archetypes.
- Ensure alignment and cross-functional coordination with overall brand strategy.
- Build in flexibility to adapt to changes affecting customers, competition, and context (policy, economic, societal, technological), and make conscious trade-offs in pursuit of sustainable, profitable market access.



Endnotes

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3. Examples of access stakeholders include public payers (such as Medicare and Medicaid programs), private payers (such as health insurers, PBMs, and employers), integrated delivery networks.
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Project team

Sonal Shah developed the project concept, provided project oversight, and helped organize the findings for the paper. **Wendell Miranda** contributed to conceptualizing the therapeutic archetype concept, helped with instrument development, and conducted primary and secondary research.

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