How Development Decisions Shape Market Access

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Executive Summary

Market access is often discussed as if it begins when clinical data is available and pricing discussions come into view.

That is too late.

In many programs, the conditions that later determine pricing and reimbursement outcomes are set much earlier: in clinical design, in manufacturing choices, and in assumptions about the market. These decisions are usually not framed as market access decisions. Yet together, they determine what can later be justified, defended, and realized.

This is why negotiations so often feel constrained. By the time formal market access activity intensifies, much of the relevant optionality has already been lost. By then, negotiations must work within the parameters that have been established through earlier decisions.

The practical consequence is straightforward. Market access should not be treated as a late-stage function. It needs to be understood as a dimension of development decisions from the outset.

The False Linearity: Why Early Decisions Determine Access

Conventional pharmaceutical development is approached as a sequence: first accumulate evidence, then secure regulatory approval, and only thereafter address pricing and reimbursement. This ordering reflects how organizations compartmentalize work and how programs move through uncertainty. It is also misleading about where access outcomes are actually determined.

Many of the factors that later shape reimbursement outcomes are fixed long before negotiations begin.

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- They are fixed when **trial designs,** including the choice of endpoints and comparators, determine what evidence will exist and what will not.

- They are fixed when **manufacturing choices** about processes and suppliers privilege near-term feasibility without fully addressing cost implications, scalability, or supply resilience.

- They are fixed when **commercial expectations** are built on untested assumptions about price points, patient populations, and competitive positioning — assumptions that rarely encounter actual payer logic until development is already committed to a particular path.

None of these individual decisions is irrational. The problem is cumulative. Decisions taken for sensible near-term reasons can narrow the room for maneuver later on.

Development decisions are made under real constraints: incomplete information, limited time, capital pressure, technical uncertainty, and organizational silos. And teams focus on different things. *Clinical* teams focus on demonstrating safety and efficacy. *Manufacturing* teams focus on manufacturing the product, establishing process feasibility, and maintaining progress. *Commercial* teams form views of future opportunity based on the best assumptions available at the time. The differing priorities aren't the problem. The problem is that the **downstream consequences** of individually reasonable decisions often remain implicit and were never examined as a connected system. Development is then optimized locally, but constrained globally.

Where Constraints Actually Come From

The pattern becomes visible in several recurring ways.

1. Manufacturing choices made for speed later define the limits of the program

An early formulation or process may be good enough to enter clinical development. Under controlled conditions, it performs adequately and supports progress. But later, under broader operating conditions or higher volume requirements, weaknesses emerge.

At that point, the issue is no longer a minor technical adjustment. Core features of the manufacturing approach may need to be revisited. Timelines slip. Comparability questions arise. Cost and supply implications become harder to contain.

What appears late is often rooted early.

In some modalities, especially advanced therapies, this becomes even more pronounced. Manufacturing is more than a support activity. It is part of the product itself. A process change can alter critical attributes and create consequences for regulatory strategy, comparability, and commercial viability at the same time.

2. Evidence can be strong enough for approval and still weak for access

Clinical development is usually designed around regulatory requirements. That makes sense. Approval is a non-negotiable milestone.

But regulators and payers do not ask the same question. Regulatory review asks whether a therapy is safe and effective. HTA bodies and payers ask how it compares to existing standards of care, how meaningful the outcomes are in practice, how robust the evidence is in the relevant population, and what the consequences are for the healthcare system. Those are different decision logics.

A clinical program can therefore succeed on its own terms and still leave major weaknesses from a market access perspective. Endpoints may show activity without demonstrating comparative relevance. Comparator choices may support approval while remaining misaligned with payer expectations. Study populations may not map cleanly onto the populations for which reimbursement decisions are actually made. By the time these gaps become fully visible, the cost of closing them is often high and the practical room for redesign is small.

3. Market assumptions can be internally coherent and externally wrong

A third source of later constraint lies in early commercial assumptions. Programs are advanced on the basis of forecasts about patient numbers, treatment positioning, unmet need, willingness to pay, and likely differentiation. Those assumptions are unavoidable. No program moves without them.

But they are not always tested early enough against the people and institutions that will later shape real access conditions. An internally convincing market thesis can come apart once local stakeholders enter the picture. The addressable population may be smaller than assumed. Clinical use may be narrower. The price corridor may be materially lower than expected. The health system may apply a different logic from the one built into the internal case.

When this kind of misalignment is recognized late, it can force a fundamental reassessment of the opportunity itself. The original view may have been internally coherent, but it had not been tested sufficiently against external reality.

How a Technical Decision Narrows Later Access Options

In one pediatric anti-infective program targeting emerging markets, the initial formulation strategy was chosen to solve a genuine technical stability issue and to support early clinical progress. Under controlled conditions, it was entirely defensible at that stage. What was less immediately visible was what the same choice implied downstream: higher manufacturing costs, greater operational complexity, and a reliance on specialized production environments poorly suited to the low-resource settings. None of this was prohibitive early on, when the priority was feasibility and momentum.

The program recognized this conflict explicitly before it became irreversible. A dispersible tablet formulation was developed instead — better suited to pediatric use, more scalable, and substantially more viable from a cost and supply perspective. The trade-off was real: the shift delayed the clinical start by approximately nine months, but it preserved access optionality instead of locking the program into a cost and manufacturing profile that would have narrowed the range of credible access outcomes. The revised formulation was subsequently validated clinically and approved, ultimately supporting patient access at a scale the original approach could not have sustained.

The point here is that the broader implications of the original formulation choice became visible early enough to be weighed against the immediate technical benefit. Once those implications were made explicit, the program could make a deliberate trade-off in light of its overall objective. When that objective becomes the shared point of reference, cross-functional consequences can be surfaced, discussed, and resolved at program level — before clinical architecture is locked, before manufacturing commitments are made, before the delay would have been counted in years rather than months. That decision space exists in most programs. The key is to use it while access can still be shaped rather than defended.

Why This Keeps Happening

These patterns recur because they are built into the structure of development. Development proceeds step by step. Each step is taken with a specific immediate objective in mind. Proof of concept. Regulatory progress. Clinical execution. Technical feasibility. Capital efficiency. Milestone delivery. That structure is not inherently flawed. It is necessary.

The weakness lies elsewhere: decisions with long-term consequences are often taken without making those consequences explicit at the time. As the program advances, reversibility decreases. What was once still a choice hardens into a constraint.

This is why late-stage negotiation teams often inherit a problem they

did not create. They are asked to optimize outcomes within conditions that were largely shaped upstream. By then, the strategic question is no longer, "What is the best imaginable access outcome?" It is, "What outcome is still achievable, given the path already taken?"

What This Means for Negotiation

Negotiations are rarely the place where market access outcomes are fundamentally made. They are the place where prior decisions become visible in economic and institutional form.

By the time negotiation begins, the range of plausible outcomes has already been narrowed by the available evidence, the comparability of the product, the definition of the target population, the credibility of the value story, the manufacturability of the product at scale, and the assumptions built into the program over time.

Negotiation still matters. It can protect value, lose value, sequence trade-offs well or badly, and shape how a case is understood. But it cannot compensate indefinitely for value that was never built into the program in the first place. To expect that from negotiation is to misunderstand its role.

What Needs to Change

The answer is not to add another layer of process or to expand market access activity in a vague way. The answer is to frame certain decisions differently.

A useful starting point is to define the decisions before defining the data. Evidence does not create value on its own. Its value depends on the decisions it is meant to support. The more important question, therefore, is not only what data can be generated, but what later decisions that data must credibly support in the eyes of regulators, payers, and investors.

Market access has to be treated as a property of decisions, not as a downstream function.

The relevant question is not how early market access was formally invited into the room, but whether major development decisions were made with their access consequences explicitly in view.

Clinical design should not be judged only by whether it supports approval, but also by whether it generates evidence that can sustain a defensible value proposition.

Manufacturing choices should not be judged only by whether they enable early progress, but also by what they imply for robustness, scalability, comparability, supply, and cost.

Commercial assumptions should not remain internal narratives for too long. They need to be challenged against external conditions before they quietly become strategic premises.

Cross-functional trade-offs need visible ownership

Many of the decisions that later determine access sit *between* functions rather than inside one function. That is precisely why they are easy to miss. Clinical choices affect pricing potential. Manufacturing choices affect comparability, cost, and reliability. Commercial assumptions influence where evidence is generated and how differentiation is framed. No single function fully owns the consequences, yet the program as a whole lives with them.

If those trade-offs remain fragmented, they will usually surface late – when change is expensive. Programs therefore need explicit ownership of cross-functional consequences, so that system-level trade-offs are actually seen and addressed.

Sequencing decisions by irreversibility

There are choices that can be revised later without major cost. Others quietly define the future room for maneuver.

Comparator strategy, endpoint selection, manufacturing platform, and target population framing often belong to the second category. These are technical decisions with strategic consequences. They shape what can later be claimed, defended, and paid for.

The more irreversible a decision is, the less acceptable it becomes to treat its downstream implications as a later problem.

Conclusion

Market access challenges do not suddenly emerge at the end of development. That is simply where they become visible. The underlying constraints are created much earlier, through decisions that were reasonable at the time, but whose longer-term consequences were never made explicit.

This is why attempts to optimize outcomes at the point of negotiation are inherently limited. By then, the range of plausible outcomes has already been shaped.

The greater leverage lies upstream: in how decisions are framed, connected, and sequenced while optionality still exists and value can still be built rather than defended. By the time negotiation begins, much of that work has already been done— or left undone.

About Crowlight Partners

Crowlight Partners advises on complex market access and negotiation challenges, with particular attention to the upstream decisions that shape later outcomes.