One Shot at Liftoff: Turning Scientific Excellence into Launch Execution

A guide for emerging biopharma companies

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A biopharma launch often behaves more like a rocket launch than a product rollout

Five characteristics of high-risk launches:

1. Ignition leaves little margin for error; early decisions determine the outcome, and many failures surface during liftoff or early ascent
2. You can't pause mid-launch to fix what wasn't built—gaps reveal themselves when options are most limited
3. Small missteps compound quickly as issues cascade across tightly coupled systems
4. Liftoff is only the start; mission success depends on sustained execution after launch
5. There is rarely a second shot—failure can be existential

Emerging biopharma launches: high science, high stakes—and how winners beat the odds

Innovation leadership concentrates launch risk

Emerging biopharma companies (EBCs)—including private and small- to mid-cap public companies (SMIDs)—lead in new modalities, increasing regulatory, operational, and commercial uncertainty at the clinical-to-commercial transition.

With limited portfolio buffers, a single launch can materially shift enterprise value.

Launch failures are predictable—and preventable

Most EBC launch failures stem from recurring execution gaps across five key areas, amplified by fragmented cross-functional operations and mismatched launch playbooks.

Winning EBCs benchmark against the right launch archetype and close gaps early before they compound.

Winning EBCs de-risk launch, not just plan it

Leading EBCs move beyond static planning to dynamic risk prioritization—focusing scarce time and resources on the execution risks that matter most and adapting leadership attention as conditions change.

High innovation.
Little margin for error.

While EBCs lead in innovation, they are more prone to launch failure than Big Pharma

Launch risk is higher for EBCs because innovation amplifies uncertainty

Pre-approval risk:

- EBCs bring first-in-class modalities, novel mechanisms, and new manufacturing platforms to market—heightening regulatory and CMC uncertainty and increasing CRL risk.

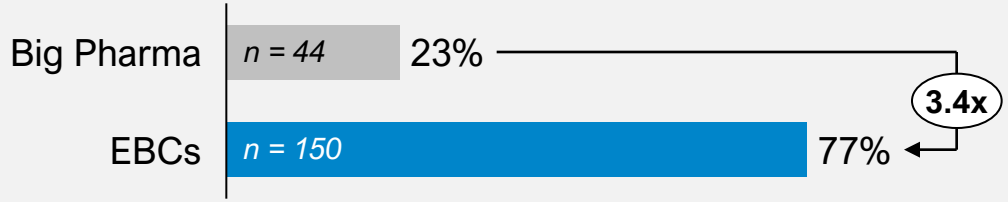
Post-launch risk:

- Those same breakthroughs define new patient populations and treatment workflows, making early adoption uneven and demand harder to scale—raising forecast miss risk.

Elevated failure rates are the predictable consequence of innovation intensity.

EBCs have a 3.4x higher likelihood of receiving a CRL than Big Pharma, and a ~34% higher share of launches that miss forecast.

% receiving a CRL, 2020-2024 (n = 194)



% of launches missing forecast, 2020-2024 (n = 227)

CRL = complete response letter
Sources: FDA, GlobalData, A&M analysis

And the stakes are higher: without a diversified portfolio to cushion setbacks, a single launch can make or break an EBC

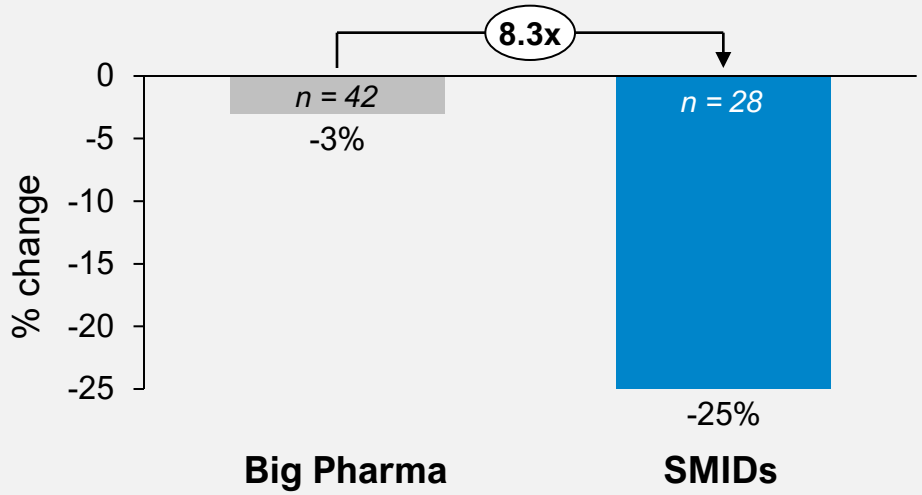
CRLs are existential for SMIDs because setbacks compress time, capital, and optionality:

- Unlike Big Pharma, EBCs lack diversified portfolios to buffer delays
- Recovery requires remediation and re-approval—not just incremental fixes
- Delays averaging ~1.7 years inflate burn and heighten exposure to competitive disruption.

For SMIDs, execution setbacks don't just delay value creation—they threaten viability.

SMIDs experience a roughly 8x larger market-cap hit than Big Pharma following a CRL

Immediate CRL impact to market cap among public companies, 2020-2024 (n = 70)

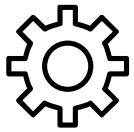


SMID = small- to mid-cap public company
Sources: FDA, GlobalData, A&M analysis

Why launch readiness is more than a checklist

The clinical-to-commercial transition is one of the hardest barriers for EBCs to clear

Reaching escape velocity marks the highest-risk inflection point, where scientific validation transitions to enterprise-scale execution.



From proof to performance

Clinical success proves the molecule works; **commercial success requires the organization to work**—across pricing, access, supply, field execution, and patient services.

Capabilities must be built, not scaled

Unlike Big Pharma, **EBCs are not scaling mature systems**—they are standing up core commercial, medical, regulatory, and operational functions for the first time, often in parallel and under time pressure.

External complexity peaks at launch

Payers, regulators, providers, distributors, and patients **all engage simultaneously for the first time**, exposing gaps that were invisible in development.

This transition is not a handoff—it is a reinvention. For EBCs, failure at this stage is rarely about the science and far more often about execution, timing, and organizational readiness.

Why do generic launch models fail at this inflection point?

Traditional launch planning relies on functional checklists that track activity rather than true readiness. This assumes launches are broadly comparable—but in reality, they vary meaningfully by asset type, patient population, regulatory novelty, and commercial model.

As a result, what works for one launch rarely translates cleanly to another. Experience only transfers when launches share the same underlying characteristics.

That's why launches should be planned against repeatable archetypes—not generic best practices.

This is where EBCs often misstep: applying one-size-fits-all models to launches that demand a fundamentally different approach.

Example launch checklist:
Post-Phase 2 readout

Regulatory	CMC / Supply	Market Access	Medical Affairs
✓ End-of-Ph 2 meeting completed ✓ Ph 3 design aligned with FDA feedback	✓ Commercial process defined ✓ Scale-up strategy and tech transfer initiated	✓ Draft payer value story and pricing hypothesis ✓ Start payer advisory input	✓ Ph 3 publication plan outlined ✓ KOL mapping and advisory board panels
Commercial / GTM	**Patient Support**	**IT / Data**	**Finance / Ops**
✓ Target segments and brand positioning drafted ✓ Early sales force sizing assumptions	✓ Preliminary hub and services model ✓ High-level patient journey mapped	✓ CRM and analytics requirements defined ✓ Vendor selection initiated	✓ Launch budget and hiring plan approved ✓ Long-range forecast updated

CMC = chemistry, manufacturing, and controls; KOL = key opinion leader; GTM = go-to-market; CRM = customer relationship management

Not all launches are the same, but many follow repeatable patterns

Assets and companies tend to **cluster into recognizable launch archetypes** with predictable implications for org design, spend, timelines, and performance.

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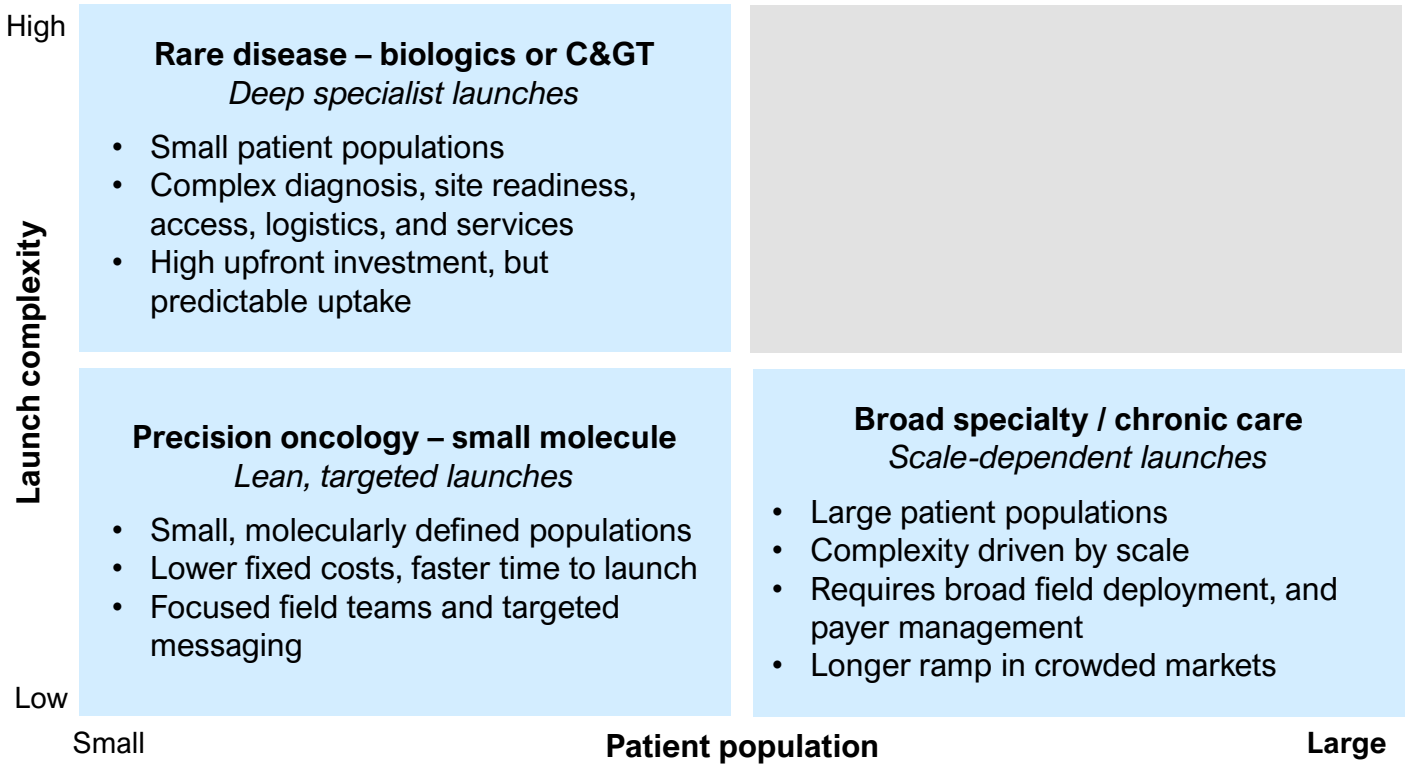
Example launch archetypes



These clusters predict differences in

- Organizational design and headcount needs
- Commercial and development spend profiles
- Development and approval timelines
- Early launch performance and ramp shape

By analyzing launch archetypes, companies can tailor their execution strategy to reduce risk while preserving upside.

The right benchmark is not Big Pharma—it's the right launch archetype. Tailored playbooks beat generic launch models.

The execution gaps that derail EBC launches—and how to close them

Five execution gaps drive most EBC launch failures

Where execution breaks down:

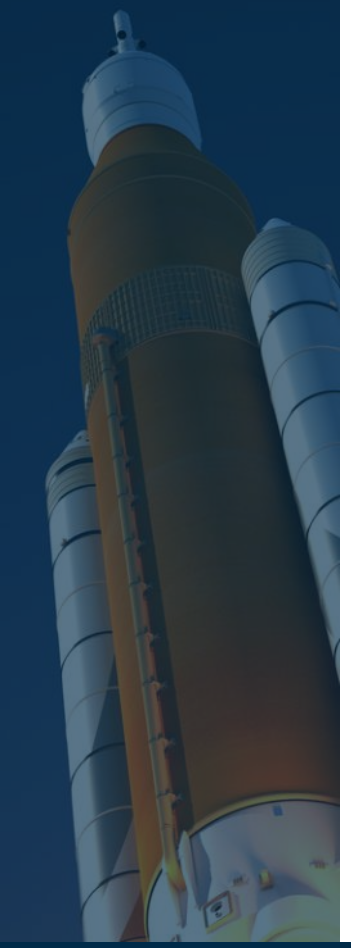
EBCs tend to be strongest in clinical and medical affairs, where capabilities naturally extend from the R&D engine. Approval, uptake, and revenue are therefore more often derailed by execution gaps elsewhere—across regulatory and CMC, market access and evidence, go-to-market execution, and real-world adoptability.

The structural flaw that amplifies risk:

This is a structural issue, not a tactical one. It may not cause failure by itself, but it magnifies every other risk. When #5 is weak, gaps in #1–4 show up too late, aren't prioritized, lack clear ownership, and get fixed reactively instead of proactively.

1

Regulatory and CMC Readiness Gaps



These are failures in the company's ability to turn clinical success into an approvable product that can be manufactured, released, and supplied reliably at launch.

What breaks

- CMC comparability plans are incomplete or weakly supported by data
- Assays, specifications (e.g., stability criteria, release limits), or process controls fail late-cycle regulatory scrutiny
- FDA issues a CRL or imposes post-approval studies or commitments

Why it breaks

- Manufacturing processes continue to evolve late in development
- Scale-up and validation decisions are deferred
- Comparability work is treated as a technical exercise rather than a launch-critical activity

What it costs

- CRLs or approval delays trigger sharp valuation losses
- Post-approval constraints limit supply and undermine early launch momentum

What to do differently

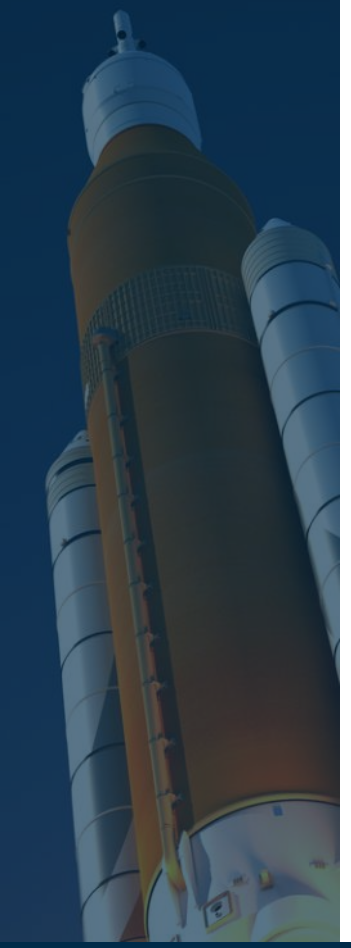
- **Commit earlier to the commercial process:** Lock scale-up, specifications, and control strategy early to avoid late-stage changes
- **Pressure-test for CRL risk:** Stress-test comparability, PPQ readiness, analytical method validation, and critical assays pre-submission

Diagnostic question Can we secure approval on time and deliver product at launch without regulatory, manufacturing, or supply disruptions?

PPQ = process performance qualification

2

Market Access and Evidence Shortfalls



These are gaps between the evidence generated and the evidence required to achieve timely, broad, and durable coverage across payer expectations, value demonstration, and post-approval evidence plans.

What breaks

- Insufficient economic and real-world evidence to support differentiation
- Payers impose restrictive prior authorization, step edits, or utilization controls
- Coverage decisions lag approval, slowing or stalling early uptake

Why it breaks

- Coverage is assumed to follow approval rather than being actively earned
- Limited investment in HEOR and RWE ahead of launch
- Access strategy is deprioritized relative to clinical and regulatory milestones

What it costs

- Regulatory success does not translate into commercial traction
- Early demand fails to convert into treated patients
- Prolonged access negotiations extend burn and compress runway

What to do differently

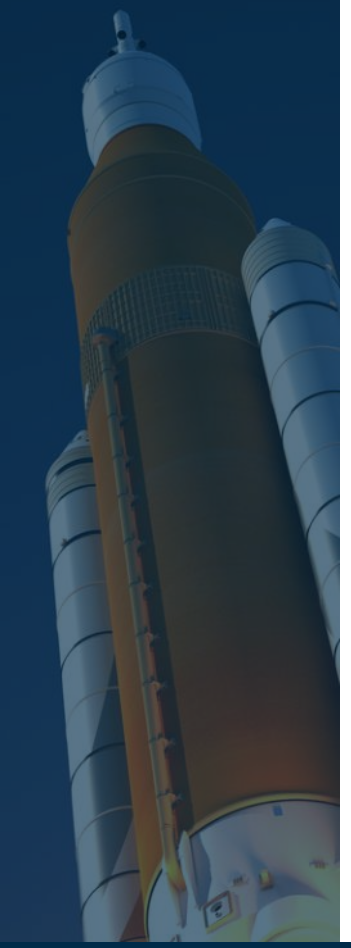
- **Earn access before approval:** Build and align HEOR, RWE, and payer value stories early enough to shape coverage decisions at launch
- **Design evidence for payer decisions, not just regulators:** Anticipate prior authorization, step edits, and comparators and generate evidence to proactively address them

Diagnostic question Does the evidence package credibly support pricing, coverage, and utilization in real payer decision-making?

HEOR = health economics and outcomes research; RWE = real-world evidence

3

Go-to-Market Capability Gaps



These are internal breakdowns in the company's ability to execute the launch end-to-end across coverage, targeting, engagement, service operations, and data-driven management.

What breaks

- Field coverage uneven and messaging is inconsistent
- CRM, targeting, and analytics are immature or poorly integrated, limiting decision-making
- Patient support and hub services struggle to scale with demand, creating bottlenecks
- Commercial execution lacks efficiency

Why it breaks

- Commercial build-out lags regulatory timelines
- GTM readiness is equated with headcount rather than end-to-end execution
- Delayed investment in field scale, analytics, and infrastructure
- Launch lacks proper KPIs, slowing course correction

What it costs

- Missed or uneven capture of early demand
- Inconsistent coverage and messaging
- Commercial inefficiency that erodes investor, payer, and internal confidence

What to do differently

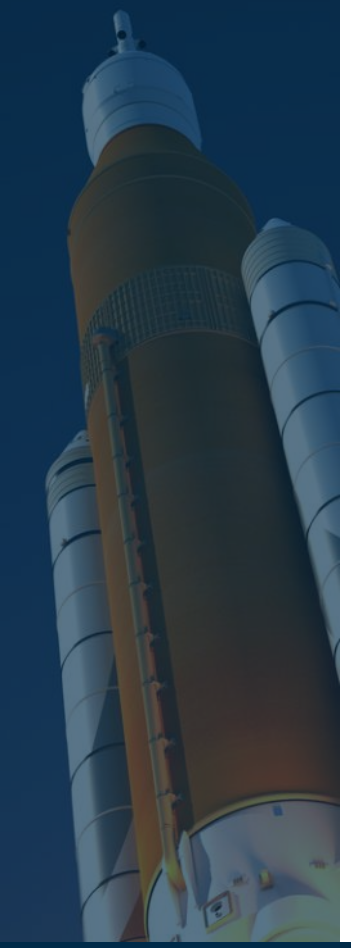
- **Design GTM for execution:** Integrate field coverage, analytics, and patient services end to end, rather than just scaling reps
- **Stress-test capabilities:** Rehearse field mechanics, pull-through workflows, and system readiness to surface gaps
- **Build the commercial spine early:** Stand up CRM, targeting, data flows, hub scalability, and clear launc KPIs ahead of Day 1

Diagnostic question Can we consistently find demand, convert it into starts, fulfill therapy, and scale efficiently through integrated field execution, analytics, and patient services?

KPI = key performance indicator

4

Real-World Adoption Friction



These are limits in the healthcare system's ability to start and sustain use—i.e., whether sites, patients, payers, and channels can adopt given workflows, staffing capacity, incentives, logistics, and coverage requirements.

What breaks

- Referral pathways, handoffs, and ownership are fragmented
- Sites lack the staffing and capacity to start patients at the forecasted pace
- Access friction delay new patient initiation
- Infusion/pharmacy complexity and buy-and-bill incentives suppress starts

Why it breaks

- Adoption is inferred from KOL enthusiasm rather than real-world workflows
- Site-of-care requirements and incentives are not fully mapped pre-launch

What it costs

- Uptake lags forecast despite strong clinical interest
- Operational friction accumulates at the point of care
- Early launch momentum stalls and is hard to recover

What to do differently

- **Validate workflows:** Pressure-test patient identification, initiation, and onboarding with frontline sites
- **Map and design for the site of care:** Fully understand site workflows, incentives, and constraints, and tailor support to remove operational friction
- **Pilot and fix before scaling:** Run pre-launch pilots with sites to surface and fix bottlenecks

Diagnostic question Even if we execute well, can the healthcare system realistically adopt at the speed and shape our forecast assumes?

5

Fragmented Launch Leadership and Operating Model

These are failures of ownership, governance, and cross-functional coordination that prevent the organization from making integrated decisions and resolving trade-offs before and after launch.

What breaks

- Functions operate in silos with misaligned priorities
- Launch risks are identified but lack clear ownership, decision rights, or escalation paths
- Critical trade-offs are delayed, revisited late, or made in isolation
- Operating cadence breaks down as teams scale and new functions come online

Why it breaks

- Lean organizations often lack formal launch governance and decision forums
- Functional leaders balance launch work alongside other enterprise priorities
- Launch accountability is split across functions

What it costs

- Execution gaps compound instead of resolving
- Leadership attention is diluted across competing issues
- Predictable launch failures escalate into existential events

What to do differently

- **Prioritize launch**: Focus leadership attention and resources on execution during the launch window
- **Appoint a single owner:** Assign clear end-to-end accountability for launch risk, decisions, and trade-offs
- **Enforce cross-functional governance:** Establish a standing decision forum to escalate and resolve issues quickly

Diagnostic question Do we have clear leadership and an operating model that enables fast, aligned decisions across functions throughout launch?

How leading EBCs de-risk launches

Launch success requires dynamic risk prioritization and disciplined leadership

Leading EBCs recognize that launch risk is not static—it evolves as the organization, market, and asset move from approval into execution.

Here, we outline how top performers reduce execution risk through two levers: a dynamic **risk-prioritization framework** that focuses attention on what matters most, and a launch **leadership playbook** that clarifies ownership, decision rights, and escalation under pressure.

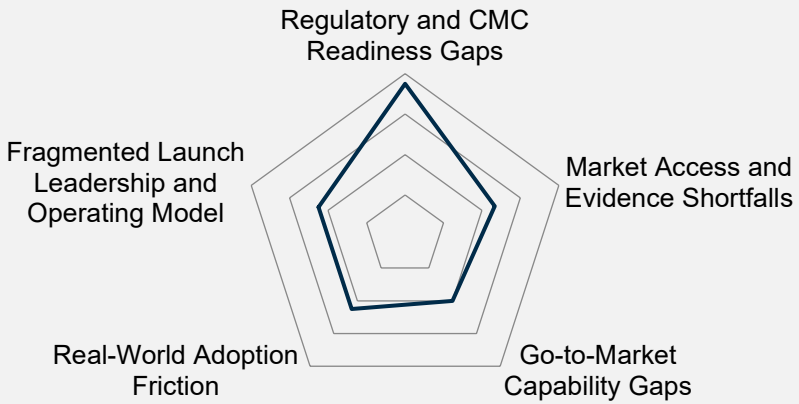
Together, these approaches help EBCs anticipate execution gaps early, act decisively, and preserve value through the most fragile phase of the company's life cycle.

De-risking launch means prioritizing the execution risks that matter most

Identify the greatest sources of launch risk

Undertake a rapid, cross-functional risk scan to identify where execution risk is concentrated across the launch—revealing critical gaps and functions most likely to drive failure.

Execution Gap Assessment



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Fix what must be flawless

Rank launch risks by impact and controllability to clarify priorities, make trade-offs, and determine where leaders must decide early and lock execution—versus where flexibility is acceptable.

Launch Risk Triage Matrix

Priority #	1	2	3	4

Controllability: High / Low

Impact: Low / High

Monitor

Document assumptions, set tripwires

- Long-term indication or geographic expansions
- Potential channel shifts

Don't over-invest early.

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Iterate

Move fast, keep it lightweight

- Field and patient support mechanics
- Data and CRM hygiene

Good enough beats perfect.

Lock

Decide early and lock for Day 1

- CMC and quality readiness
- Day-1 patient access plan
- Launch sequencing and site-of-care readiness

These are non-negotiables. Make them flawless.

Prepare

Scenario-plan with triggers

- Competitive shocks
- Major policy, care delivery, or payer behavior changes

Avoid surprises.

How EBC leaders manage risk amid constant change and constraint

Launch Leadership Playbook

	What successful leaders do	Decision rule	Why it matters
Run one cadence	Establish a single weekly leadership forum to surface risks, make decisions, and resolve cross-functional trade-offs	If it affects launch risk, it belongs in the cadence—no side meetings or parallel decision tracks	Fragmented forums create blind spots; one cadence forces alignment
Scale only where it reduces risk	Keep leadership and core teams lean; deploy external partners selectively at inflection points where speed or expertise reduce risk	Add capacity only to close critical gaps or accelerate non-negotiable decisions	Uncontrolled scaling adds complexity without benefit
Protect execution with clear ownership	Define clear RACI, align ways of working, and plan backfills early to prevent coverage gaps	Unclear ownership drives execution failure—clarify roles early	Lean teams succeed only with unambiguous accountability
Integrate fast	Onboard new hires and partners rapidly to contribute immediately to risk mitigation and solution design	If new resources can't add value within weeks, integration has failed	Delayed integration compounds launch risk
Treat risk as a live signal	Continuously reassess risks and reallocate attention and resources as conditions change	Plans are static; risk is dynamic—leadership focus must move accordingly	Most launch failures stem from known risks deprioritized too long

Successful EBC launches are not driven by perfect plans, but by disciplined risk management

RACI = responsible / accountable / consulted / informed

Ready to de-risk your launch?

A&M Launch Readiness Support

A two-step, *no-regrets assessment* to identify where launch risk is most likely to emerge—and what to do about it.

Step 1

Quick Diagnostic:
Where are we exposed?

Rapid, quantitative scan of readiness across five core launch domains

What we'll assess together

- Where execution risk is accumulating across the launch
- Early functional signals that indicate downstream execution pressure
- Asset- and stage-specific vulnerabilities that shape launch risk

Decision-enabling outputs

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Function	Diagnostic Domain	Readiness (1–5)	Status	Observations / Gaps
Clinical & Medical Affairs	KOL engagement network maturity	4		Strong engagement but limited coverage outside US
	Scientific narrative & publications	3		Publication plan in place but lacks payer-relevant evidence
	MSL training & deployment readiness	2		Hiring in progress; no field materials approved yet
Regulatory	NDA / BLA submission tracking	5		Submission on track; clean FDA queries
	Labeling & pre-approval inspection prep	2		Mock audit planned but not yet executed
	CMC validation & documentation	2		Validation runs complete; awaiting batch certification
Market Access & Pricing	Value proposition refinement	2		Core value dossier incomplete; limited payer input
	HEOR / evidence generation	3		Model framework built; data pending from Phase III
	Pricing & contracting readiness	2		Contract templates drafted; GPO outreach not started
Commercial	Brand positioning & messaging	4		Messaging tested and approved
	Field team readiness	3		Training in progress; CRM rollout delayed
	Omnichannel campaign readiness	2		Digital assets under regulatory review; no media plan locked
Supply Chain & Logistics	Manufacturing / packaging validation	4		Commercial lots validated
	Logistics & DSCSA compliance	3		Data exchange testing with 3PL ongoing
	Inventory & demand planning	2		Forecast accuracy low; alignment with finance pending

Step 2

Risk Assessment Workshop:
What do we do about it?

Interactive, A&M-facilitated leadership session to validate risks and set clear execution priorities

- Where cross-functional friction is constraining execution
- Relative severity and timing of execution risks (manage now vs. monitor)
- Tailored critical success factors that determine launch performance

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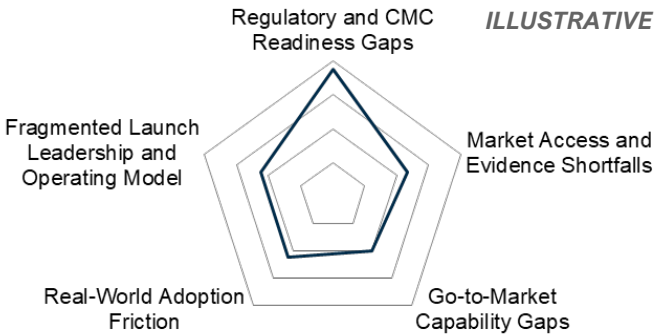

Thank you

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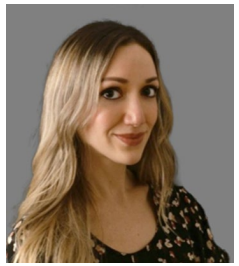

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