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# IT Readiness for Pre-Commercial Biotech

*Why Technology Readiness Deserves a Seat at the Launch Table*

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*Prepared for executive teams building their first commercial operating model in the US market*

## Executive Summary

The transition from development-stage biotech to commercial-stage company is one of the sharpest operating pivots in life sciences. First-time launchers now account for roughly 40 percent of new molecular entities submitted for FDA approval, nearly double their share from a decade ago. About 80 percent of projected blockbusters over the next five years sit in the portfolios of first-time or recent launchers. [1] Yet the track record is sobering: McKinsey reports that only 20 to 30 percent of first-time launchers exceeded commercial expectations over the past five years, compared with 40 to 50 percent of established companies. [2] ZS found that between 2019 and 2023, 40 to 60 percent of all pharma launches underperformed analyst expectations. [3]

This paper argues that IT readiness is a launch-critical capability, not a support function to be organized after approval. IT readiness encompasses the full spectrum: enterprise infrastructure, cybersecurity, identity management, and corporate systems, all of which must scale with a rapidly growing organization. But the area of greatest risk and greatest neglect is commercial IT: the CRM and field force platforms, customer master data management, data warehousing and business intelligence, marketing automation, compliance systems, and the governed data layer that underpins commercial execution. These are not the same systems that supported the company through clinical development. They represent an entirely different discipline, and they are where most launch-stage companies fall dangerously behind.

The common failure mode is not a total absence of technology. It is treating IT, and commercial IT in particular, as late procurement rather than early business design. That mistake creates fragmented tools, untrustworthy analytics, brittle handoffs between field and home office, avoidable compliance exposure, and costly remediation at exactly the moment when the market is least forgiving. [4][5][6] And when companies then try to layer AI on top of that weak foundation, they amplify the problems instead of solving them.

*IT readiness is not back-office plumbing. It is the operating system of launch.*

## 1. The Launch Moment Has Changed

A first product launch used to be primarily a sales and marketing event. Today it is a whole-company transformation. A pre-commercial biotech that spent years optimizing around discovery, development, and capital efficiency must rapidly become a regulated, externally facing, data-dependent commercial organization. The science may be world-class. The commercial operating infrastructure to deliver it to patients almost never is.

The financial and timing stakes are enormous. McKinsey found that first-time launchers typically invest \$80 million to \$100 million annually in SG&A beginning at launch year, with total SG&A often increasing fivefold from two years before to two years after launch. [1][2] Meanwhile, IQVIA's analysis of 559 launches found that only 1 in 10 products launched between 2020 and 2024 exceeded \$100 million in first-year sales, down from 1 in 5 during the prior five-year period. Fewer than 20 percent of launches make significant improvements to their trajectory after the critical first six months. [7][8] The investment is massive and the window is narrow.

There is one structural advantage available to a pre-commercial company: the absence of legacy drag. Unlike established pharma incumbents burdened with decades of technical debt, aging data warehouses, and entrenched vendor relationships, a younger company can design its commercial technology core intentionally. But that blank slate only becomes an asset if leadership acts early. Otherwise, it fills with rushed vendor decisions, disconnected point solutions, and manual workarounds that surface painfully when launch pressure peaks. [1][2]

## 2. R&D IT and Commercial IT Are Different Disciplines

The transition from Phase 2 or early Phase 3 to commercial launch introduces a technology challenge that most pre-commercial biotechs do not fully anticipate. The issue is not that the company lacks IT capability. It is that the IT capability the company has built, often over many years, was designed for a fundamentally different mission.

R&D IT in a development-stage biotech is sophisticated and demanding work. It supports clinical data management, biostatistics, electronic trial master files, regulatory submissions, laboratory systems, and increasingly, advanced analytics and data science for drug development. It operates in validated environments under strict regulatory oversight. It manages security, infrastructure, and vendor relationships for a growing organization. And as the company approaches commercialization, the R&D IT workload does not shrink. It intensifies, because headcount is scaling, infrastructure demands are rising, and the operational complexity of running a late-stage clinical program alongside launch preparation stretches every resource. [4][9]

Commercial IT is an entirely separate domain. It includes CRM and field force automation, customer master data management across multiple data aggregators, commercial data warehousing and business intelligence, marketing automation and content approval workflows, compliance systems for aggregate spend and adverse event reporting, and the governed data architecture that connects all of it. None of these systems exist in a development-stage company. None of them can be adapted from R&D platforms. And none of them are optional for a company that intends to sell a regulated product through a field force. [4][9]

The regulatory layer compounds the difference. 21 CFR Part 11, DSCSA, HIPAA, and Sunshine Act aggregate spend reporting all impose compliance obligations on commercial systems that simply did not exist in the R&D phase. Depending on the product, these requirements touch commercial

operations, medical affairs, distribution, and patient services before the first prescription is written. [10][11][12]

This is not a question of competence. The Head of IT who built and operates the R&D environment has done essential, complex work. The challenge is that commercialization introduces an entirely new set of systems, vendors, data flows, and regulatory obligations that require specialized experience the company has never needed before. Recognizing this early, and structuring the organization to address it without overwhelming the existing IT team, is one of the most important planning decisions a pre-commercial biotech can make. [4][9]

*R&D IT and Commercial IT serve different missions. The skills that were built in one do not automatically transfer to the other.*

### 3. Why IT Readiness Gets Deferred

There are structural reasons that IT readiness falls behind in pre-commercial biotech: a culture built around science rather than operations, technology work that hides inside other functions, and a scope that leadership dramatically underestimates. [13] But before examining those systemic forces, it is worth naming the specific arguments that leadership teams use to justify the delay. These are not reckless decisions. They are reasonable-sounding positions that experienced teams arrive at under real constraints. They also happen to be wrong in ways that become clear only under launch pressure.

**"We are too small to need real systems."** Common in rare and ultra-rare disease companies with small patient populations and lean field teams. The logic is intuitive: limited prescriptions and a handful of representatives should not require enterprise technology. What this overlooks is that compliance obligations are binary, not proportional. Aggregate spend reporting under the Sunshine Act, adverse event capture, DSCSA traceability, and HIPAA risk analysis apply regardless of company size or patient count. An auditor does not ask how many patients you serve. They ask whether your data is governed, your processes are documented, and your records are auditable. [10][11][12]

**"We cannot afford this before revenue."** IT competes directly with clinical, regulatory, and commercial hiring for constrained capital. But McKinsey's data is clear: the most successful first-time launchers invest earlier and more substantially in launch capabilities than their weaker peers. [1][2] Building late does not save money. It compounds cost. Vendor rework under compressed timelines typically runs 30 to 50 percent above planned budgets. Emergency staffing costs more than planned hiring. And the executive attention consumed by managing a technology crisis during launch week cannot be recovered at any price.

**"We will figure out IT after approval."** IQVIA's data contradicts this directly: fewer than 20 percent of launches significantly improve their trajectory after the first six months. [7][8] If commercial systems are not validated, users are not trained, and data is not flowing by launch day, the company is debugging infrastructure during the only window when the commercial curve can be shaped. There is no pause button on launch.

**"We just need Veeva and we are done."** CRM becomes a proxy for the entire technology stack. In reality, CRM is one platform out of 15 to 20 that a typical launch requires. It says nothing about the data warehouse, MDM, aggregator integrations, BI and analytics, marketing automation, content management, compliance systems, or the governed data architecture that connects them. A real IT strategy for a pre-commercial biotech typically spans 30 to 40 discrete projects across 8 to 10 vendors. CRM is one of them. [3][14][15]

**"We will start simple and upgrade later."** Start with spreadsheets, scale to systems when the business justifies it. The problem is that data created in spreadsheets and disconnected tools does not migrate cleanly, and worse, it creates compliance exposure from day one. By the time the company decides to upgrade, it has months of ungoverned data, inconsistent HCP records, no auditable trail for aggregate spend, and a field team trained on manual workflows they will resist changing. The upgrade is not an upgrade. It is a rebuild, conducted under more pressure and at higher cost than doing it right the first time.

**"We are a science company, not a technology company."** This is perhaps the most deeply held belief, and the most misleading. Every company that sells a regulated product to prescribers through a field force, processes claims data, reports to CMS, tracks adverse events, manages

aggregate spend, and protects patient data is, by operational necessity, a technology-dependent company. The science got you to approval. Technology gets the product to patients. [1][4][9]

### **The structural forces behind the delay**

Beyond individual rationalizations, there are systemic forces at work. Technology work for launch distributes itself across every function: medical wants engagement workflows, commercial wants CRM, market access wants payer analytics, finance wants aggregate spend controls. Because these requests appear in separate budgets and workstreams, leadership routinely underestimates the total architecture, integration, and governance work required to make the pieces operate as one. [4][9] Trinity Life Sciences found that emerging biopharma companies frequently misjudge the timing of commercial investments or underfund crucial capabilities, and the pattern is predictable: the commercial team is hired, the science is ready, and the technology is 12 months behind. [13]

### **What it looks like in practice**

In one case, a pre-commercial oncology company reached five months before launch and discovered that its BI platform had misaligned business requirements, incomplete production setups, and insufficient end-to-end testing. The data warehouse and MDM layer were in place, but nobody had validated the reporting workflows that field teams would depend on daily. [14] In another, an oncology biotech preparing for a multi-market launch had no defined IT strategy and no commercial solutions portfolio. The company needed to stand up CRM, data warehousing, analytics, privacy controls, and marketing automation simultaneously across multiple countries. [15] These are not edge cases. They are the norm.

### **The scope nobody expects**

Finally, leadership dramatically underestimates the scope. When a CEO or CFO hears "IT strategy," they picture CRM and a dashboard. The reality is closer to 40 discrete projects spanning every function, from Medical Affairs and Sales to Supply Chain, Finance, Quality, and IT itself. Without a comprehensive IT strategy and roadmap completed early, there is no way to accurately budget, sequence, or coordinate across the vendors and functions involved. The IT strategy is not a formality. It is the single most important planning artifact for launch readiness.

## 4. What IT Readiness Actually Means

For a launch-stage biotech, IT readiness is the state in which the platforms, data, analytics, controls, and vendor relationships required to operate as a commercial company are operational, tested, and governed before the first product ships. This includes enterprise fundamentals like infrastructure, identity management, endpoint provisioning, and cybersecurity, which must scale from a 200-person R&D organization to a 500-person commercial one. But the area of greatest complexity and greatest risk is the commercial technology layer: CRM, data warehousing, BI, master data management, marketing automation, compliance systems, and the governed data architecture that connects them. [4][9][15]

The following framework organizes this into seven domains. Each must be addressed before launch, not after.

Domain	What It Covers	Why It Matters at Launch
1. Commercial Platform Architecture	CRM (typically Veeva), content management (Veeva Vault/PromoMats), ERP integration, marketing automation (SFMC or similar), patient services platforms	Platform decisions made 18 months out are nearly impossible to reverse 3 months before launch. Rushed selection creates integration debt that compounds under pressure.
2. Data & Analytics	Commercial data warehouse, MDM (customer/HCP/account master), data acquisition strategy (IQVIA, Symphony, SP data), KPI framework, BI/reporting layer (Power BI, Tableau, etc.), data governance	Without a governed data layer, every team builds its own version of the truth. The CCO needs territory insights, the CFO needs a commercial P&L, and the field needs call-plan dashboards. None of it works if the master data is wrong.
3. Customer Engagement Systems	Field force CRM configuration, call planning, sample management, omnichannel marketing execution, MSL engagement tracking, content approval workflows (MLR)	ZS found that launches underperform when insights are too slow, too siloed, or too generic. CRM is the execution engine that connects strategy to field activity. [3][16]
4. Compliance & Commercial Controls	Aggregate spend/Sunshine Act reporting, adverse event capture workflows, DSCSA, privacy (HIPAA, state laws), SOX-readiness for commercial transactions	Compliance gaps do not announce themselves at launch. They surface in audits, in legal discovery, and in board questions. Controls must be designed into the architecture, not bolted on after the fact. [10][11][12]
5. Training & LMS	Learning management system (LMS), field force onboarding and certification, compliance training, CRM and system training, ongoing skill development programs	A field team that is not trained on systems and compliance requirements before launch week is a field team that cannot execute. LMS must be operational, content must be loaded, and certification workflows must be tested well before the first representative enters the field.
6. Cybersecurity for Commercial Systems	Identity and access management for field users, MFA, endpoint protection for mobile CRM, vendor security assessment, incident response, backup/recovery	The 2024 Change Healthcare breach affected 190 million people because a single portal lacked multi-factor authentication. The attack cost UnitedHealth \$2.87 billion. [17][18] Small companies are not exempt from systemic risk.
7. Vendor Governance & Program Management	Vendor selection criteria, contract accountability, SLA management, PMO for commercial technology deployment, cross-	Without governance, technology decisions are made by whoever is loudest or fastest. With it, the company runs a disciplined

	functional coordination, change management	readiness program with clear milestones and executive visibility.
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The most important thing to notice about this framework is that the majority of these domains are primarily commercial in nature, requiring expertise that development-stage companies have never needed before. General IT infrastructure, network management, and corporate systems are necessary prerequisites, and the internal IT team is typically already managing them. But the commercial technology layer represents an additional, specialized body of work that sits on top of that foundation. The failure to recognize this distinction, and to plan and resource for it accordingly, is the root cause of most launch-stage IT failures.

## 5. The AI Paradox: Why It Cannot Rescue a Late Start

AI is the most discussed topic in every biopharma boardroom, and rightly so. ZS has demonstrated how AI-enabled launch insights hubs can allow commercial teams to pivot within days instead of months. Accenture reports that 87 percent of biopharmaceutical R&D leaders now view AI and machine learning as crucial to success. KPMG found that 75 percent of life sciences CEOs call AI a top investment priority, and 80 percent report significant spending on agentic AI. [3][16][19][20]

But in pre-commercial biotech, AI almost always enters the conversation at the wrong point. Deloitte notes that biopharma has deployed AI far more extensively in discovery and clinical development than in commercial functions, where systems and processes still lag. PwC points to uneven analytics maturity driven by challenges in culture, talent, and integrated data environments. KPMG reports that despite executive enthusiasm, robust data infrastructure, governance, and compliance are prerequisites for sustainable value. The companies that will extract real value from AI at launch are the ones that built a clean, governed, integrated data foundation 12 to 18 months earlier. [5][6][19]

The practical implication is blunt. AI is a force multiplier, and it multiplies whatever sits underneath it. If the customer master data has duplicates and misattributed territories, AI-driven call planning will optimize against the wrong targets. If the data warehouse ingests claims data that has not been reconciled against prescription data, AI-generated dashboards will present confident-looking insights built on conflicting numbers. If the content approval workflow is manual and slow, generative AI will produce compliant content faster, only to watch it sit in a queue for three weeks waiting for MLR review.

*AI does not fix bad data. It just moves wrong answers faster and makes them look more credible.*

## 6. The Cost of Getting It Wrong

### Quiet failure: commercial drag

The most common form of commercial IT failure is not a catastrophic system crash. It is drag. IQVIA links inadequate readiness to restricted market access, weaker pricing and reimbursement outcomes, poor market preparation, delayed timelines, flatter uptake curves, and unnecessary last-minute costs. [7][8]

This drag shows up in predictable, painful ways. Field representatives lack the territory dashboards they need and revert to spreadsheets. Marketing cannot get content through the Veeva Vault approval workflow fast enough to support the launch wave. The data warehouse produces reports that nobody trusts because the HCP master data was never properly reconciled across aggregators. The CFO asks for a commercial P&L by territory and geography and nobody can produce one.

Each of these gaps is individually survivable. Together, they slow the entire commercial engine during the window when speed matters most. And they are almost always avoidable with 6 to 12 months of earlier planning.

### Loud failure: operational disruption

The 2024 Change Healthcare cyberattack illustrates the extreme case. Hackers gained access through a Citrix portal that lacked multi-factor authentication, disrupting claims processing nationwide and

affecting an estimated 190 million individuals. UnitedHealth Group reported total impacts of approximately \$2.87 billion. [17][18] A pre-commercial biotech is unlikely to face a breach at that scale. But when a growing field force is using mobile CRM, accessing patient hub data, and transmitting HCP engagement records across cloud platforms, the attack surface is far larger than it was during clinical development. Basic lapses in identity management, vendor security, or access controls can turn a technology gap into a revenue event, a board event, and a reputational event.

### **The timing penalty**

IQVIA has consistently found that the first six months after launch are the most critical in determining a product's long-term commercial trajectory. When companies wait until approval to address commercial platforms, data, controls, or executive visibility, they compress essential readiness work into the exact period where mistakes are hardest to absorb and the commercial curve is most sensitive. You cannot debug your data warehouse while simultaneously trying to read the market. [7][8]

## 7. A Practical Roadmap for IT Readiness

The right answer is not to buy more technology. It is to complete a rigorous IT strategy and roadmap first, and then sequence a minimum viable, launch-aligned technology core early enough that the company can configure it, validate it, train on it, and govern it before the market depends on it. The strategy must be driven by the launch plan, not by vendor timelines or technology preferences.

[1][4][13]

The IT strategy and roadmap is the foundational deliverable. It defines every system, every vendor, every integration, every data flow, and every budget line item that the company will need to operate commercially. Without it, there is no reliable budget, no defensible timeline, no coordinated vendor management, and no executive visibility into what is actually required. In practice, this document typically runs to 80 or more pages and covers 30 to 40 discrete projects across every function touched by launch. The companies that skip it are the ones that discover six months before launch that their budget was off by 40 percent and their timeline was missing three critical integrations.

Phase	Key Activities
24 to 18 months before launch	Define the commercial operating model and translate it into technology requirements. Conduct a commercial IT readiness assessment. Establish a data strategy (what data will you buy, from whom, and how will it flow). Select core platform vendors (CRM, data warehouse, content management). Appoint commercial technology leadership with launch experience. Define a stage-gated funding approach tied to milestone delivery.
18 to 12 months before launch	Build the commercial technology core. Configure CRM and begin field workflow design. Implement the data warehouse, MDM, and data integrations with aggregators. Build the BI/reporting layer with the KPIs and dashboards the business will need at launch. Establish compliance system integrations (aggregate spend, AE reporting). Define vendor SLAs and accountability.
12 to 6 months before launch	Operationalize and validate. Run end-to-end testing across commercial workflows (order to cash, field engagement to reporting, content creation to MLR approval). Train users. Conduct data quality audits on master data. Tighten cybersecurity posture for field-deployed systems. Rehearse launch scenarios. Confirm that leadership can see the business through the analytics layer.
Last 6 months before launch	Run a launch readiness control tower. Track readiness milestones across all seven domains. Manage critical defect resolution. Run KPI baseline exercises. Conduct a launch simulation with live data flows. Finalize the support model and escalation paths for post-launch issues.
First 90 days after launch	Stabilize and optimize. Eliminate manual workarounds. Tune dashboards and reports based on real commercial activity. Improve segmentation and targeting models with actual prescribing data. Introduce AI use cases selectively, now that production data exists to learn from. Begin planning for the next indication or geography.

The most common and most costly mistake is not starting implementation too late. It is skipping the strategy entirely. Companies that jump straight to Veeva CRM implementation without first completing a comprehensive IT strategy and roadmap end up with a beautifully configured CRM that feeds into a nonexistent data warehouse, producing reports nobody asked for, measured against KPIs nobody agreed on. They discover integration gaps in month 10 that should have been identified in month 2. They present a budget to the CFO in Q3 that bears no resemblance to the actual spend by Q1 of the following year. The strategy is what makes the difference between a coordinated 18-month execution and an 18-month scramble.

*A CRM without a data strategy is just an expensive contact list. A data warehouse without a KPI framework is just an expensive hard drive. And any implementation without an IT strategy and roadmap is just an expensive guess.*

## 8. The Leadership Question

IT readiness for launch cannot be managed as a side project. It requires someone who speaks the CCO's language about commercial outcomes, the CFO's language about investment sequencing, and the Head of IT's language about architecture and operations. McKinsey found that the most successful first-time launchers hire key leaders earlier than weaker peers. The same principle applies to technology leadership. [1][2]

The most effective model separates two roles. The architect designs the IT strategy and roadmap, aligns it with the launch plan, governs vendor relationships, defines the data strategy, and ensures the C-suite has visibility into readiness milestones. The builder -- typically the internal IT team and managed service partners -- executes the plan, manages day-to-day operations, and supports the growing headcount. Both roles are essential. Neither can do the other's job. Whether the architect comes as a full-time hire, a fractional engagement, or an advisory relationship, the critical requirement is that this leadership arrives early enough to shape decisions before the launch window closes. [1][13][15]

The worst outcome is not a technology failure. It is a leadership vacuum where technology decisions are made reactively, by whichever function is loudest, under the greatest time pressure, with no governing strategy. That is how launch-stage companies end up with six disconnected systems, three versions of the HCP master list, and a BI layer that the CCO does not trust.

*The right time to build commercial IT readiness is before approval, not after the market exposes the gap.*

## Conclusion

Pre-commercial biotech companies do not miss launch expectations only because the science is weak or the market is unforgiving. Many miss because the operating infrastructure was not ready when the market needed it to be. In that setting, IT readiness is not a secondary concern. It is the connective tissue between commercial strategy and field execution, between compliance requirements and auditable controls, between raw data and the insights that drive daily decisions, and increasingly between AI ambition and the governed data foundation that makes AI worth deploying.

Companies that treat IT as a first-order launch capability gain three distinct advantages. First, they reduce commercial risk by building visibility and controls into the operating model before it faces market pressure. Second, they accelerate time to effective execution by ensuring that field teams, analytics, and compliance systems work on day one, not day ninety. Third, they build a reusable technology core that serves the next indication, the next geography, and the next stage of growth without starting from scratch. In every case, the advantage begins with the same thing: a comprehensive IT strategy and roadmap completed early enough to guide every decision that follows.

Pre-commercial biotech still has one structural advantage over larger peers: the opportunity to design the technology model without legacy drag. That opportunity is real, but it has an expiration date. The companies that act on it deliberately, with the right strategy, the right sequence, and the right leadership, will be the ones that turn a blank slate into a lasting competitive edge.

*On launch day, the focus should be on the patient and the product. Not the plumbing.*

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