InVivo
vol. 37 ▮ no. 04
pharma intelligence ▮ informa
invivo.pharmaintelligence.informa.com
APRIL 2019

SCALING UP FOR FIRST PRODUCT LAUNCH: SEVEN HAZARDS TO AVOID

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Scaling Up For First Product Launch: Seven Hazards To Avoid

As the margin for error in the drug launch cycle continues to erode, emerging biopharma companies face a growing urgency to double down on scaling up for that first launch.

BY PIERRE JACQUET, PETER ROSENORN AND ADITYA NATARAJAN

Scaling up to launch the first product is one of the most challenging transitions for a biopharma organization as the leadership team prepares to grow an R&D-focused company with 30 to 70 employees into a multidimensional organization often at least three to five times larger, usually adding new functions, sites and geographies. Based on its extensive contacts and research with biopharma strategy and operational leaders, L.E.K. Consulting has identified seven hazards that could derail a strong first launch, for instance:

- Missing commercial and medical input on pivotal trial design may limit the ability to reach market access and pricing expectations.
- Failure to invest in a well-defined manufacturing and logistics strategy can be a launch-killer for biopharmas with novel and complex modalities, e.g., gene-based therapies.
- Underinvesting in back office functions is penny wise, but pound foolish as it may lead to launch delays if critical staff cannot be hired and on-boarded on time.

Time and again, one of the most important lessons we have learned is to start

Exhibit 1

Scaling Up for First Launch: Flashpoints To Address In Customer-Facing Organizations

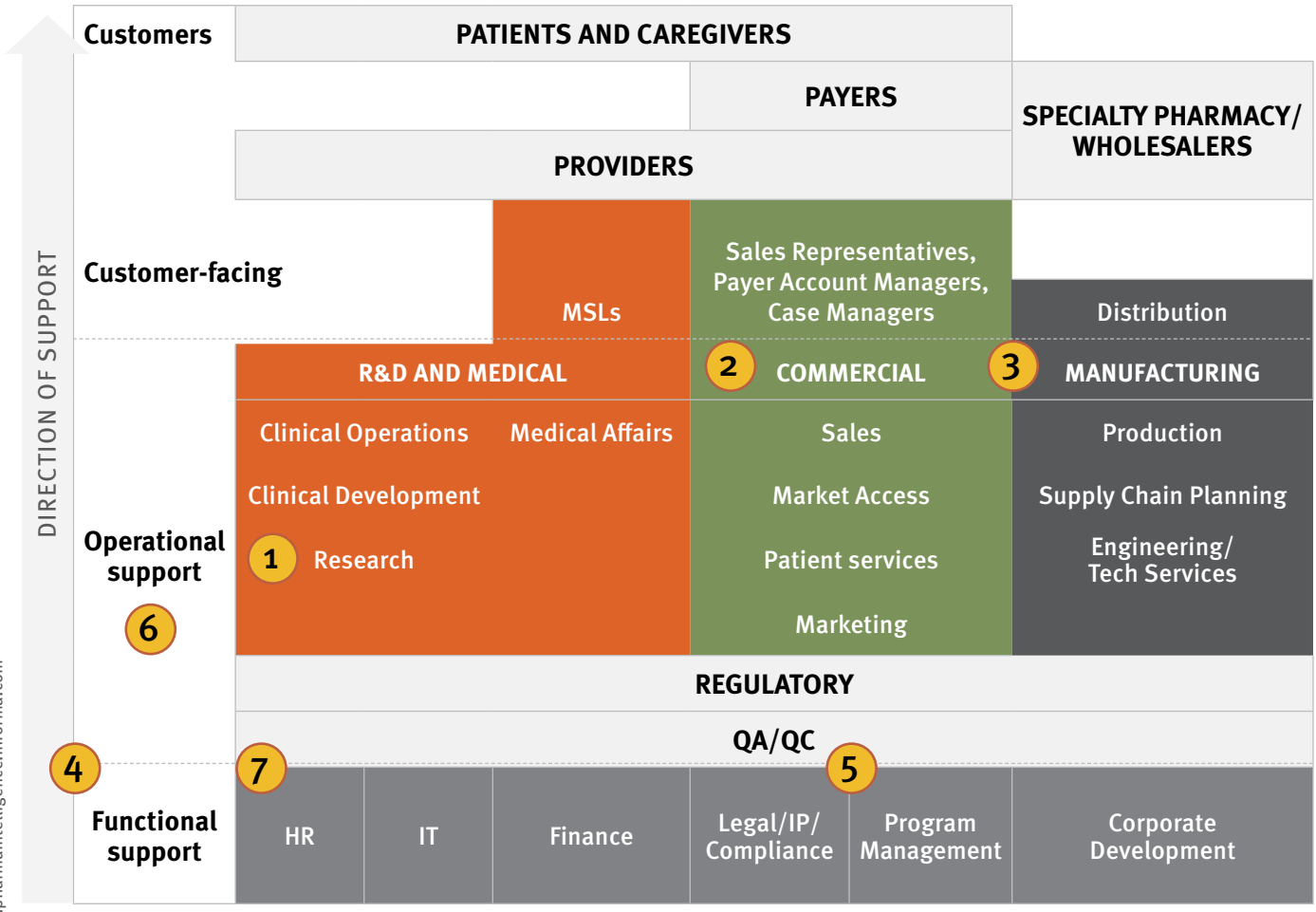
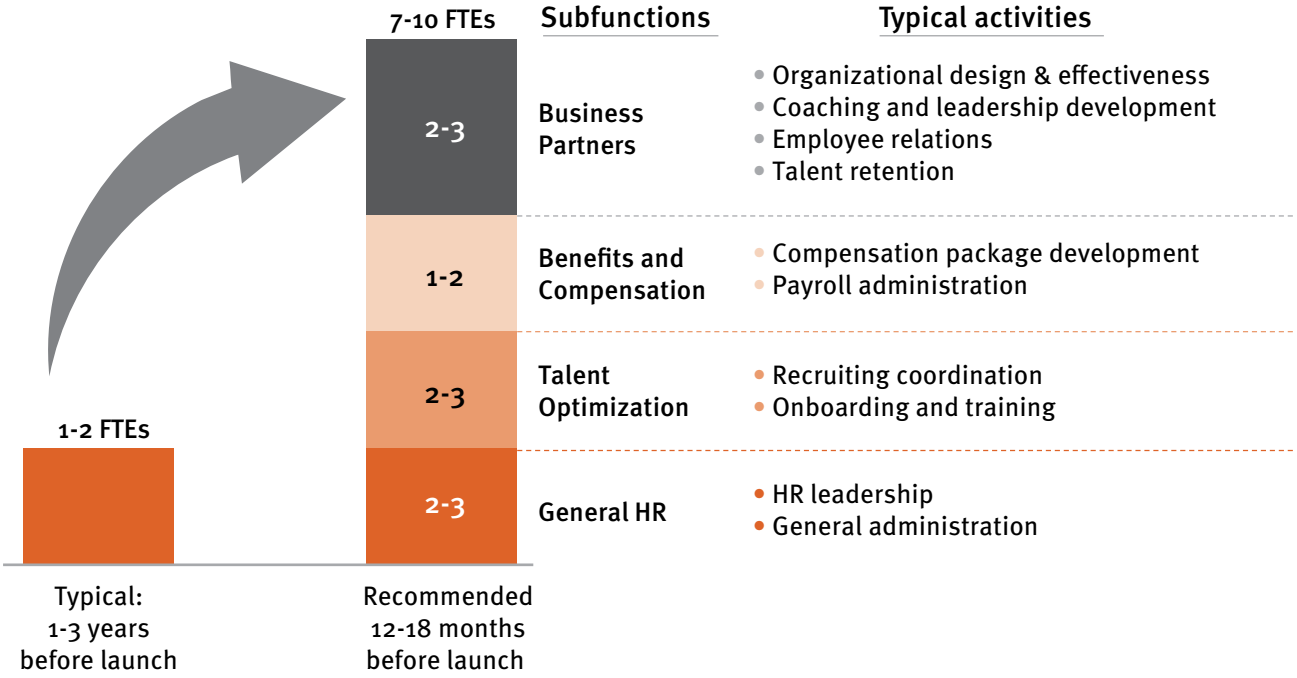


Exhibit 2

Example Of Required Pre-Launch Expansion In Back Office Functions: Human Resources



cross-functional launch planning and readiness activities early, preferably up to three years before launch.

In addition to the many unexpected turns required to adapt in a fast-changing marketplace, there are multiple decisions that must be made to successfully move the launch process forward. These include deciding the level of retained ownership of the first product in each geography, identifying the optimal commercial model for the product, and developing the underlying enterprise model that enables customer-facing functions to build and execute the launch plan, while simultaneously continuing R&D expansion.

A key part of a successful launch is a well-prepared organization, and in this article, we draw upon L.E.K. Consulting's experience working with biopharma companies navigating this critical transition to highlight seven scale-up hazards that executives should avoid as they prepare for launch. We indicate where they are most relevant within the customer-facing operating model, and we close with a set of key questions that management can use to self-assess whether their organization's scale-up activities are on track.

To prepare for a successful launch, emerging biopharma companies need to acknowledge and avoid these seven common scale-up hazards:

1. Leaving Research Behind

When significant cash is needed pre-launch for investments in pivotal trials and building out the manufacturing and commercial functions, research is often an area that feels investment-constrained. Companies must walk the fine line between going "all hands on deck" for their first launch and ensuring that the discovery engine has sufficient resources to continue to fill the pipeline. While there are no easy solutions, management should ensure that a systematic portfolio prioritization and stage-gate framework are in place to make investment trade-offs that ensure research investments are considered through the lens of long-term corporate growth as well as near-term cash requirements.

2. Missing Commercial And Medical Input On Pivotal Trial Design

Emerging biopharmas typically establish the core commercial and medical functions *after* pivotal trials are already underway. By waiting this long, companies risk missing out on informing clinical development plans with a robust market understanding, including who their key customers are, what trial endpoints and comparators are most meaningful to drive adoption, and how US and ex-US pricing and market access negotiations can be best supported by trial evidence. Management should consider onboarding a handful of core marketing, market access and medical affairs team members *prior* to designing pivotal trials to ensure that such findings and feedback can be incorporated into the pivotal trial design.

3. Delaying Clinical And Commercial Manufacturing Scale Up

Establishing a validated supply chain for GMP-grade drug products and drug substances is a necessary condition for late-stage clinical trials and filing, and doing so can take years. This is becoming increasingly critical as biopharmas launch novel therapeutic modalities. For example, viral vector manufacturers have been identified as a bottleneck for gene therapy commercialization, requiring several years' lead time for process development and scale-up. While not all such challenges can be foreseen, management should ensure that manufacturing

timelines are developed sufficiently in advance and incorporated into clinical development, filing and launch plans.

4. Underinvesting In Back Office Functions

While companies know they need to build clinical, medical and commercial functions prior to launch, back office functions such as HR, IT, legal and finance are commonly overlooked. Delaying their build-out can result in process inefficiencies that can compound to threaten the launch if not addressed quickly. For example, recruiting and onboarding of talent can slow down critically without sufficient HR resources.

Exhibit 2 shows how the HR function typically *should* scale up to meet the needs of the growing organization. Another example is that enterprise-wide software decisions cannot be made efficiently without a sufficiently staffed IT department.

5. Neglecting Program Management

Strong program management is critically important to drive cross-functional collaboration and streamline tasks by development program to limit functions operating in silos. While project managers often exist in R&D, as assets advance through clinical development and show commercial potential, it is important for a company-wide program management function to be formed to facilitate cross-functional alignment and manage the interface between executive leadership and each program team.

Our perspective is that program management should report to a corporate Executive Leadership Team (ELT) member, potentially the CEO, to ensure that the function is perceived as objective and empowered by leadership. Without such empowerment, functional leaders may not take program managers seriously, preventing them from effecting change and holding individuals accountable. Effective program management requires senior leadership to buy into its importance and emphasize it as such in company-wide communications. Exhibit 3 presents an example of a governance structure with corporate program management liaising between individual program teams and executive leadership.

6. Unclear Governance And Reporting Structures

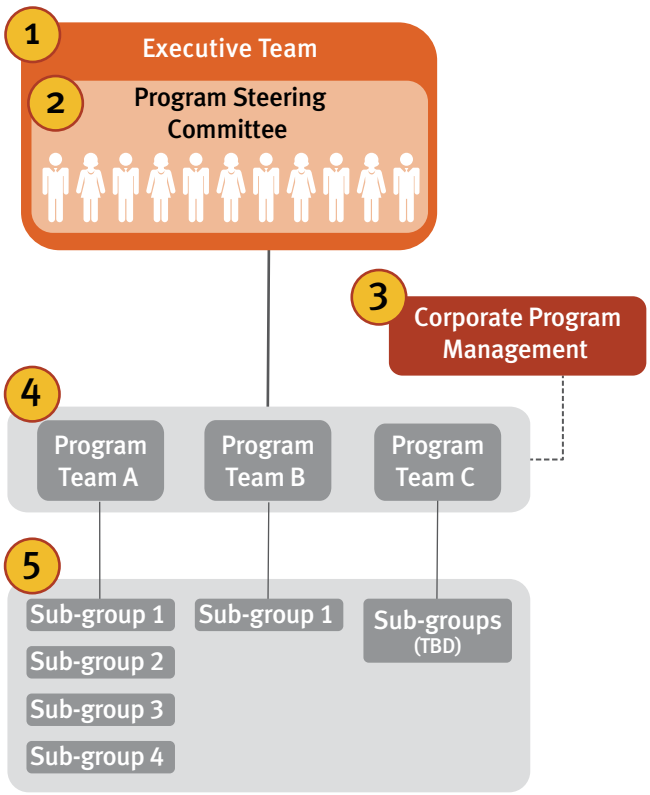
As a biopharma scales up, new functions are typically established by hiring VP or other executive-level individuals who then go on to build out those functions. This growth in management means that a relatively flat reporting structure — which may have worked for the executive leadership team (ELT) when the organization had 30 to 60 full-time equivalents (FTEs) — may not be as effective as headcounts quadruple or more over two to three years when initiating pivotal trials and preparing to launch. To minimize costly overlaps and gaps, the ELT needs to review and evolve organizational responsibilities, reporting hierarchies and governance structures as the company reaches growth inflection points.

7. Insufficient Time To Hire Key Talent

Companies are often behind their hiring timelines because finding the right talent in competitive markets usually takes much longer than expected. In par-

Exhibit 3

Example Of Governance Structure With Centrally Reporting Program Management



1 **Executive Leadership Team (ELT):** Focused on corporate strategy, setting priorities and monitoring cross-functional execution

2 **Program Steering Committee:** Subset of ELT members focused on providing guidance to program teams, regulatory strategy, clinical trial design, etc.

3 **Corporate Program Management:** Serve as facilitator between Steering Committee and Program teams, and gaining alignment with functional heads

4 **Program Teams:** Oversee program execution and provide platform for alignment on issues not requiring functional head input, clinical protocol review, trial product supply, etc.

5 **Program Team Sub-groups:** Plan and execute activities relevant to subset of functions, NDA development, packaging, etc.; escalate issues when required

Exhibit 4
Organizational Scale Up Self-Assessment

	SCALE UP STATUS QUESTION	ALL-SET	OK	WORK-TO-DO
1	Have the go-to-market strategy and customer-facing model been clearly defined and socialized with the ELT and board?			
2	Do we have a process to systematically make investment trade-offs that ensure long-term growth?			
3	Are the pivotal trials designed to support pricing and reimbursement, not just approval?			
4	Are commercial-scale manufacturing timelines established and on track?			
5	Does our scaleup plan explicitly incorporate back-office needs (HR, IT, Legal and Finance) to support the rest of the company?			
6	Does our Program Management function drive programs forward with cross-functional input, on time and on budget?			
7	Are our governance structure and processes well-understood throughout the organization?			
8	Are we on track with hiring of critical talent?			

SOURCES FOR ALL EXHIBITS: L.E.K. analysis

ticular, companies preparing to launch their first product may not be well-known or could be seen as less attractive to high-quality yet risk-averse candidates. Management would be wise to build in sufficient buffer time and start recruiting for required positions at least three to six months in advance, and even more for executive roles like chief commercial officer or specialized roles in such areas as quality, regulatory, biostatistics and pharmacovigilance.

Keeping Track: Pointers For Self-Assessment

We close with a few questions based on these scale-up hazards that senior leadership can use to self-assess whether their organizations are on track (*see Exhibit 4*). While there are many key questions for management to consider, it is our experience that failure to address these seven potential hazards creates significant obstacles to a successful launch on time and on budget. Preparing to commercialize the first product is one of the most challenging moments in a biopharma company's evolution, but having executive leadership committed to the launch, well-informed about potential roadblocks and possessing the right tools to address the issues is foundational to preparing the organization for success.

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