Driving Launch Success:

Best Practices for Emerging Pharma and Biotechs in the Digital Era

Overview

COVID-19 has caused unprecedented rates of change in the life sciences industry. Established companies and start-ups alike have adapted to emerging engagement trends. While COVID was a catalyst for change, the need for digital engagement strategies will continue long beyond COVID. Thoughtful go-to-market plans and compliant technology, therefore, are increasingly vital to success.

Research indicates the actions sponsors take during clinical development, early commercialization, and product launch determine 81% of future drug sales performance .[1] The first six months post-launch are vital to the long-term commercial success of a drug.[2] During this critical period, pre-commercial companies have the opportunity to outperform established competitors through agile, intelligent customer engagement.

Sponsors introducing their first product should plan and execute a best practices-based launch strategy, building a scalable commercial program tailored to their organization's unique strategy. This helps proactively address two of the most common commercialization challenges:

1. Overcoming resource constraints that prevent the implementation of all necessary operational requirements, and;
2. Initiating market readiness activities earlier in the development process, rather than the highly condensed timelines typically associated with a first-time product launch.

Companies that successfully employ a defined launch plan have an opportunity to outperform the competition, and are more likely to attain their revenue goals. According to a McKinsey & Company report, "about two- thirds of new drugs fail to meet pre-launch consensus sales expectations for their first year on the market." This same study finds that a majority of these drugs continue to underperform even three years post-launch,[3] costing the industry hundreds of millions of dollars in lost revenue.

The life sciences industry has a unique opportunity to change this pattern and generate faster time to peak revenue. Pre-commercial companies can place the customer at the center of their commercial strategy using coordinated, intelligent engagement. As technology is no longer a barrier to delivering educational or scientific content, it is critical to connect and engage with healthcare professionals (HCPs) and institutional decision makers. Insights generated through customer interactions enable the organization to align with a customer's specific scientific needs.

Pre-commercial companies can leverage this data-driven process to deliver new content to HCPs and other stakeholders in their preferred method of communication.

81%

Future sales performance
determined around **launch success**

67%

Fail to meet
launch expectations

70%

Continue to lag
3 years post launch

[1] M. Corstjens, I. Horowitz, E. Demeire: One bite at the cherry, Journal for Economics of Innovation and New Technology, 2005.
[2] Launch Excellence IV: A New Launch Environment, 2013.
[3] McKinsey & Company. (2014, March). The secret of successful drug launches.

Foundation for Commercial Launch Success

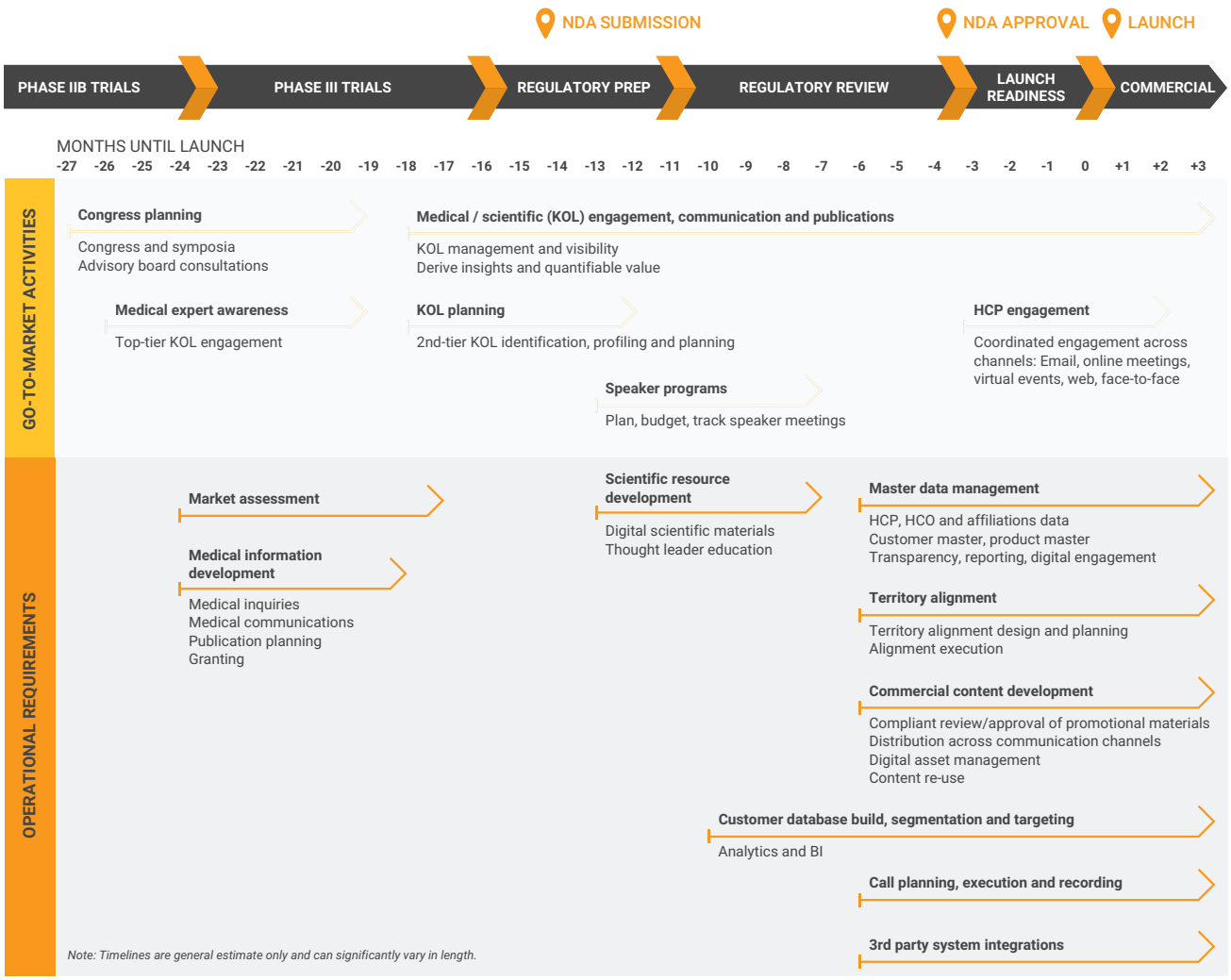
Companies in the pre-commercial phase encounter distinct challenges when introducing their first drug to market. They often compete against mature life sciences companies with sophisticated go-to-market strategies and established provider relationships. COVID-19 drastically reduced in-person access to physicians and complicated the launch process with new demands for digital interactions. Even in a post-COVID world, life sciences organizations will need to offer hybrid (digital/in-person) events and deploy digital engagement strategies to ensure success. Thus, pre-commercial companies are more likely to succeed if they follow a customized commercialization program.

The *"Foundation for Commercial Launch Success"* is a roadmap based on best practices that guides sponsors introducing their first product to market (Figure 1). It outlines a proven launch methodology, leveraging Veeva's experience helping hundreds of life sciences companies around the world commercialize medicines.

The product launch consists of a series of well-planned and synchronized activities, executed many months in advance of the expected product approval date. Giving launch teams enough time and resources to prepare for product introduction is critical to success. Commercial planning activities should begin as early as Phase IIb trials, as the data indicate that clinical endpoints will be met. As the study progresses, the launch program will increase in complexity.

This tailored commercialization program helps sponsors develop an agile, efficient, and intelligent customer engagement program. The launch roadmap must enable both medical and commercial functions to align and collaborate. It is organized across two concurrent dimensions: 1) market readiness activities, and 2) operational requirements.

Figure 1: Foundation for Commercial Launch Sucess



Market Readiness

Key opinion leaders (KOLs) validate and disseminate emerging scientific information with the broader medical community, significantly impacting established patient care practices. Identifying, engaging, and establishing credibility with the right KOLs is one of the most important aspects of a new product launch.

KOL engagement should begin during Phase II, focusing on the nature of the intervention and its potential to impact patient outcomes. Organizations can reinforce the validity of the clinical data through participation in congresses, publications, and medical symposia.

Upon reaching the Phase II endpoint, newly generated scientific data can be used to develop peer-reviewed, evidence-based, clinical information. Disease state education programs may be defined, including planning, budgeting, and tracking of meetings.

Over time, the nature of the discussions must evolve from disease state awareness to education around clinical results and, eventually, therapeutic outcomes.

As the clinical trial progresses, sponsors can identify, profile, and plan their outreach to more KOLs. Engagement from medical affairs teams provides greater visibility, derives medical insights from KOLs, and helps quantify the economic value of the drug.

In addition, access to payers—insurance plans, pharmacy benefits managers, government, and employee networks—is crucial to making the treatment available to patients. Market access field teams must leverage KOL-derived insights to prove the clinical efficacy and health-economic value of the new product relative to other interventions in the market.

KOL ENGAGEMENT BEST PRACTICES

Evolving Nature of KOL Discussions:

DISEASE STATE AWARENESS → CLINICAL RESULTS → THERAPEUTIC OUTCOMES

Engaging KOLs:

- Medical congresses and symposia
- Advisory board consultations
- Scientific publications

While KOL relationships may be established early, commercial HCP engagement can only begin as the drug receives regulatory approval. Care must be taken to avoid inadvertent pre-label promotions. Representatives may engage in coordinated provider engagement across personal and digital channels to ensure delivery of relevant disease state education to the broadest group possible. This allows the commercial organization to better understand their targets' communication channel preference.

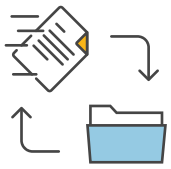
Operational Requirements

Sponsors must also ensure that they are operationally prepared to support their go-to-market program. The goal is to establish a business environment that fosters agile, efficient, and intelligent customer engagement. Even in this early pre-commercial stage, the company should aim to develop business processes, and a supporting commercial infrastructure, that support the organization's expected growth. Employ special consideration to ensure that it can also be leveraged for future product introductions.

Medical Information Development

These operational programs should be implemented well in advance of the product launch. To properly educate KOLs, scientific materials must be developed approximately 24 months prior to the expected product launch. As the trial enters Phase III, the medical science liaison (MSL) and medical information teams should be fully enabled. Due to the high-profile nature of clinical trials, especially in rare diseases or oncology, medical launch teams must anticipate the scientific needs of the treating community. Companies may expect to act on requests for data and information as soon as it has been presented publicly. This can be achieved if Medical Affairs has the ability to develop, review, and approve a broad variety of medical content, such as clinical results, mechanism of action studies, and Health Economics and Outcomes Research (HEOR). Medical affairs must respect the compliant nature of data requests while aligning to the customer's channel preferences and learning objectives.

Benefits of an Integrated Commercial Cloud Deployment



Efficient

90%
Faster data change requests

Agile

96%
Faster deployment

Smarter

6x
Increase in sales performance

Sources
1. Veeva study: Veeva OpenData resolves DCRs in under one day on avg., compared to 10 days avg. for legacy data vendor, a 90% reduction.
2. Pre-commercial companies are able to successfully deploy complete infrastructure in just 8-14 weeks.
3. Veeva study: Avg. click-through rate for Veeva CRM Approved Email is six times higher than industry average.

Customer Data, Territory Alignments, and Prospect Database

The organization's ability to efficiently and effectively manage the flow of information across the enterprise is a key enabler to the success of the launch. Organizations should consider deployment of their analytics and business intelligence platforms in parallel to the development of scientific materials. Market assessment is the first and most important analytical study, typically initiated towards the end of Phase II. It delivers key insights and guidance for developing the brand strategy and product messaging for launch and ongoing promotion. Upon completion, commercial teams will be armed with the size of the patient population, the scope of treatment options, and a forecast of product profitability.

CUSTOMER SUCCESS

Results Achieved at Small Life Sciences Organizations through Best-in-Class Territory Alignment Systems

Cost Savings[4]

- 5 to 10-fold reduction in process steps
- 50% fewer resources required to hire

Speed to Market[5]

- 95% reduction in use of spreadsheets
- >95%-time reduction for minor alignment changes
- 75%-time reduction for major alignment changes

Accurate and current customer data, analyzed via scalable and repeatable processes, provide critical insights on the launch. These will guide stakeholders to optimize commercial performance using a 360-degree view of customer activity. Key components to implement are the master data management platform—including both customer and product master—the data warehouse, and statistical modeling and reporting tools.

[4] Real-world results achieved by small European-based pharmaceutical company (2017).
[5] Real-world results achieved by small US-based pharmaceutical company, presented at 2017 Veeva Commercial Summit.

The most important aspects of the analytical environment are:

- Creation and maintenance of an optimally sized and structured sales force
- Alignment of sales representatives
- Assignment of HCP targets to territories

As a best practice, assignments should be considered within the overall information management strategy to ensure they are effectively shared with downstream analytics and incentive compensation systems. An integrated territory master, similar to a master data management capability, allows users to archive historic alignments for analytical purposes, current alignments for execution, and future alignments for scenario planning.

Best-in-class territory alignment systems are particularly effective at smaller life sciences organizations.

These organizations often rely on legacy territory alignment processes that require multiple weeks to conduct a major alignment, limiting their ability to rapidly react to changes in the market. In real-world instances, an integrated alignment solution achieves a five- to ten-fold reduction in process steps—translating to a 50% decrease in resources needed to conduct alignments[5]—as well as decreasing time required for major alignments by 75% or more.[6] In a highly competitive environment, companies can achieve significant cost savings while supporting revenue growth through greater business agility.

As the new therapeutic nears NDA submission, the commercial team's activities accelerate.

A prospect database should include reliable information on target HCPs, healthcare organizations (HCOs), and their respective affiliation data. Access to accurate and current target customer data solves this problem through immediate eligibility confirmation.

Customer Success: Commercial Content and Digital Asset Management Deliver Speed to Market, Control, and Cost Savings

Speed to Market

57% reduction in review cycle times[1]

25% reduction in time spent on compliance procedures[1]

2x faster content to market[2]

Compliant

Instant content withdrawal

Centrally controlled

Savings

6-month ROI attainment[1,2]

40% marketing budget savings from content reuse[1]

50% reduction in training effort[2]

Sources
1. Veeva study, average across customers.
2. Results reported by top global pharma.

[5] Real-world results achieved by small US-based pharmaceutical company, presented at 2017 Veeva Commercial Summit.
[6] Veeva Pulse Trends, October 2020.

Commercial Content

As various operational aspects coalesce around the launch, commercial teams will need to consider their promotional strategy. COVID-19 has drastically accelerated the adoption of email and video calls, with a 596% increase in Veeva CRM Approved Emails sent and a 1,167% increase in Veeva CRM Engage Meetings from January to October, 2020 . Rapid creation and management of promotional assets for HCPs is a key competitive advantage for pre-commercial companies. Increased content speed to market, delivered in the prescriber's preferred channel, is vital to market adoption.

Resource-constrained organizations can overcome the expense and complexity of rapid content development through fast, compliant, and insights-driven management of promotional assets. It can be achieved if the process is administered through a central content management platform, enabling collaborative and efficient management of the content lifecycle through approval, distribution, reuse, and withdrawal. This integrated view into the digital supply chain helps optimize the entire content management effort. As a result, companies bring new content to market up to two times faster while saving more than 40% of the marketing budget through better content reuse.

Third-Party Integrations

To enable the most complete customer view, sponsors should proactively plan for integrations between their CRM and third-party systems. This is an important part of the pre-launch strategy, though frequently overlooked until after product launch. Since no single vendor can provide all necessary capabilities for the entire industry, the core CRM technology must be open and interoperable. This allows it to connect with the broadest possible ecosystem of partner technologies. Some of the most common integrations to consider are fulfillment and sample accountability, patient portals, expense management, analytics, and a specialty pharmacy distribution hub.

Successful Launch Execution

For maximum commercial impact, pre-commercial companies can implement a defined launch path based on established best practices that allows for flexibility as circumstances require. Technology must be an enabler rather than a barrier to the overall launch success. Agile life sciences companies rely on a proven and configurable cloud-based system rather than on cumbersome customizations or unproven technologies. Commercial teams can experiment with innovations in both business processes and technology. They are able to easily collect data (field feedback on territory alignments, provider engagement data, content use and effectiveness, etc.), draw actionable insights, and rapidly refine their go-to-market strategy.

Not every sponsor will need to implement every component of the roadmap, and each company will prioritize specific aspects of it based on their own, unique situation. The ultimate outcome is that sponsors have the opportunity to proactively build a commercial program that maximizes the chance of a successful product launch.

Customer Success

Medac Pharma, Inc. Fast-tracks Successful U.S. Launch of Rasuvo™ with Veeva Commercial Cloud

After filing the 505(b)2 application for Rasuvo® (methotrexate injection) with the FDA, Medac Pharma — successfully acquired by Medexus in 2018 — needed to quickly build a commercial foundation for product sales and marketing. Four months later, Medac Pharma was ready for business with Veeva Commercial Cloud and fully prepared to take its first product to market.

Starting with a blank slate, Medac Pharma had the rare opportunity to establish the right technology foundation from the start to maximize commercial success. The company sought a complete solution that would meet the needs of sales, marketing, and medical teams and align the entire organization around the customer. "With Veeva Commercial Cloud, we gained the full breadth of commercial capabilities in one complete solution to enable fully coordinated customer engagement across channels. And with Veeva, we were able to meet our aggressive four-month deadline and go live successfully," said Glenn Tate, Medac Pharma's Vice President of IT.

"I knew that I wanted a system that was proven, fit, and didn't require extensive customization. It needed to be streamlined, too, without pieced-together point solutions underpinning Medac Pharma's commercial operation," explained Tate. "Veeva Commercial Cloud fulfills all of our needs, including important functions like sample validation. Its flexible, multitenant architecture enables ongoing innovation and grows with us as we expand into potential new areas suchas oncology."

"With Veeva Commercial Cloud, all of our teams see the full history of customer interactions whether through an email, online detail, phone call, or face to face. There's a continuous feedback loop about where the doctor is in the sales process, which allows for rich insights aggregated across every step of the customer journey and informed future engagement," said Mike Henrick, associate director, of sales operations for Medac Pharma. "We've also gained digital channels to communicate with customers on their terms, allowing us to reach more HCPs efficiently—a critical advantage for a growing organization like ours."

Create Your Own Custom Launch Roadmap

The Veeva Commercial Cloud delivered the competitive advantage Medac Pharma needed to successfully launch Rasuvo. Please contact our commercialization experts for a complimentary one-hour workshop to begin developing your own customized launch roadmap.

Disclaimer: Veeva's "Foundation for Commercial Launch Success" guide has been developed based on direct experience gained helping hundreds of companies commercialize their products. It is intended as a general best practice guide and may not apply to every organization or medical intervention. Each pre-commercialization effort has unique timelines and requirements that affect the details of the actual product launch process.