Product Launch Excellence: A Pre-Commercial Roadmap for Biopharmas

Veeva

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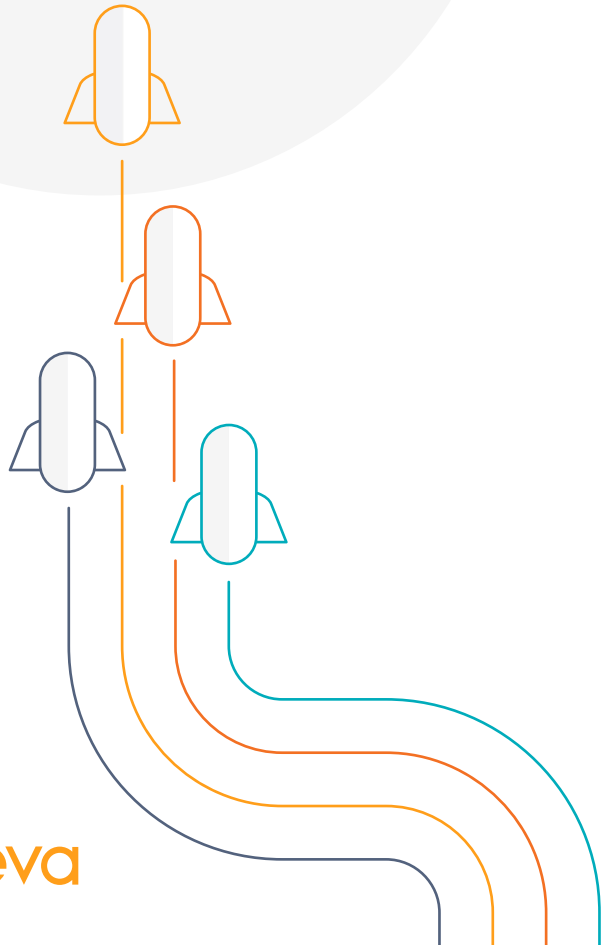

The evolving pre-commercial landscape

Research shows that companies' actions during clinical development, early commercialization, and product launch strongly determine drug sales performance at launch and well into the future. Consider that 70% of products that miss launch expectations continue to underperform, while 80% of those that perform as expected meet or beat expectations in the future.[1]

But, resource constraints, tight timelines, and fragmented technology solutions make launch execution challenging. Companies in the pre-commercial phase often compete against mature life sciences companies with sophisticated go-to-market strategies, software, data, and established provider relationships.

113%
increase in approved drugs

70%
of drugs don't recover R&D investment

54%
of drugs were specialty drugs in 2022

With the right approach, pre-commercial companies can initiate market readiness activities and operational requirements as early as possible in the development process. A common data architecture, thoughtful go-to-market plans, and compliant technology are vital to success.

This ebook will show you how a best practices-based roadmap can help you achieve product launch excellence.

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1 "Key factors to improve drug launches," Deloitte, 2020
2 "Novel Drug Approvals, U.S. Food and Drug Administration," 2022
3 "The Importance of Pharmaceutical Competitor Analysis," DrugPatentWatch
4 "FDA Approved Many New Drugs in 2022 That Will Improve the Lives of Patients and Consumers"

A roadmap for commercial launch success

24 MONTHS TO LAUNCH

- Assess the market landscape
- Identify and engage top-tier KOLs
- Develop a medical information strategy

18 MONTHS TO LAUNCH

- Initiate a market access strategy
- Broaden scientific engagement, education, and access
- Build a customer insight and business intelligence engine

6 MONTHS TO LAUNCH

- Establish territory alignments
- Create commercial content
- Integrate third-party systems

3 MONTHS TO LAUNCH

- Coordinate omnichannel HCP engagement

Reminder: Activities may start earlier or later, depending on your specific launch strategy.

Creating your launchpad

Your launchpad is the foundation of your product launch strategy and encompasses three elements. First, companies must create frameworks to integrate plans and prioritize actions. Second, they must establish the analytics and performance insight functions to integrate multiple data sources. Finally, they need to use that intelligence to drive agile and empowered decision-making using intuitive tracking tools to focus on the right indicators for launch progress.

These activities should include:

- **Capturing and integrating the right data:** Identify data sources from thousands of data streams — such as patient, prescriber, and market data — and integrate them. Establish key performance indicators (KPIs) and critical paths to measure progress.

- **Building a centralized view:** Establish cross-functional clarity for streamlining customer targeting, field training, and resource allocation. Get a consolidated view of historical and planned HCP engagement across medical and commercial stakeholders to share learnings compliantly and drive greater integration.

- **Creating agile, cross-functional teams:** Set up teams working on 30- to 50-day sprint cycles with the right senior leadership, training, and change-management interventions to enable a think-fast, act-fast mindset. Use surveys to enhance and continuously update customer profiles and purchased data sets.

- **Deploying intuitive tools:** Establish forecasting and scenario modeling capabilities with real-time integrated KPIs and critical path-tracking tools. For example, you'll want the ability to agilely monitor account plan progress to continuously revise and update plans to improve timeliness and responsiveness.

These activities set the stage for your pre-commercial product launch roadmap, including market readiness activities and the related operational requirements across all clinical trial phases. It also aligns sales, medical, and marketing functions around key activities, creating a coordinated commercialization approach that engages customers with agility, efficiency, and precision.

24 months until launch

The earliest phase of the launch roadmap will focus on understanding the market landscape, identifying and engaging with top-tier key opinion leaders (KOLs) on disease state awareness, and creating a medical information strategy.

Assess the market landscape

The right data can help define the market up to two years before launch – even before reps, medical, or medical science liaisons (MSLs) are in place. The focus should be on finding the relevant patient populations, understanding the patient journey, building profiles of customers, and forming connections with KOLs and experts who will determine the product's ultimate success.

A market assessment is the first and most important analytical study, typically initiated toward 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 have the patient population size, the scope of treatment options, and a forecast of product profitability.

OPERATIONAL REQUIREMENTS

The right mix of **patient and prescriber data** is integral to success at this stage. Ensure data sources are high quality, available on demand, and privacy safe. This data should help answer some fundamental questions, including:

- What is the overall prescriber base?
- Where are eligible patients located?
- Where are relevant HCPs located?
- What does the patient journey look like?

KOL Engagement Best Practices

EVOLVING NATURE OF KOL DISCUSSIONS

ENGAGING KOLs

Medical congresses and symposia

Advisory board consultations

Scientific publications

Identify and engage top-tier KOLs

Identifying, engaging, and establishing credibility with the right KOLs is one of the most important aspects of a new product launch. Field medical activity before launch is science-focused, relationship-based, and most likely in-person, as MSLs connect with KOLs in the relevant treatment areas (TA). This **early education sets the foundation for treatment adoption at launch** and beyond, where a hybrid approach using in-person and digital channels will sustain access across the product lifecycle. You can reinforce the validity of clinical data through medical congresses and symposia, scientific publications, and advisory board consultations.

At the end of Phase II, use newly generated scientific data to develop peer-reviewed, evidence-based clinical information and add definition to disease state education programs, including planning, budgeting, and tracking meetings.

OPERATIONAL REQUIREMENTS

Build effective team collaboration with a single source of truth to **identify KOLs and prioritize engagement**, including tracking speaking engagements, publications, and digital activities. Technology enables organizations to look beyond traditional methods of KOL selection to identify digital influencers on social media and other channels, emerging experts, and untapped KOLs with a global reach.

ANI Pharmaceuticals expedites launch with on-demand patient data

ANI Pharmaceuticals launched its first patented, branded rare disease therapeutic just 75 days after receiving FDA approval on its supplemental new drug application (sNDA).

That meant that within weeks, the company needed to fully understand the patient journey, potential prescribers and treatment patterns, and market landscape — and enable the field with insights from each.

ANI leaned heavily on **Veeva Compass Patient data** to quickly answer these questions and make critical business decisions.

The resulting insights ANI gleaned included:

- The company's prescriber base
- Patient locations
- HCP locations
- The entire patient journey and experience

In addition to using Compass for launch, ANI adopted the complete suite of Veeva Commercial solutions across its business. The combination of software, data, and services provided by **Veeva Commercial Cloud** and **Veeva Business Consulting** helped the company establish its digital foundation quickly.

Develop a medical information strategy

Start developing scientific materials approximately 24 months before the expected product launch to enable MSLs and medical information teams as the trial enters Phase III. Companies should expect to act quickly on requests for data and information as the trial progresses.

Medical affairs teams' ability to quickly and compliantly develop, review, and approve a wide variety of medical content – clinical results, mechanism of action studies, and health economics and outcomes research (HEOR) – is essential. Medical affairs must also respect the compliant nature of data requests while aligning with customers' channel preferences and learning objectives.

OPERATIONAL REQUIREMENTS

Medical affairs teams should take a **centralized approach to creating, managing, and distributing scientific content**, enabling teams to:

- Disseminate the most recent scientific information through a pre-launch knowledge hub.
- Secure approved and regulated content with transparent auditability and traceability, and eliminate the risk of sharing unapproved content.
- Track content shared with KOLs/stakeholders and capture feedback to update and anticipate scientific needs.
- Make it easy to act on data requests and speed new data to market.
- Develop and approve a wide variety of medical content.

18 months until launch

The next phase of the launch strategy should focus on market access, broadening and deepening relationships with KOLs and scientific experts, and building out the customer intelligence engine.

Build a customer insight and business intelligence engine

The commercial team's activities accelerate as the new therapeutic nears NDA submission, including developing a prospect database. The 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.

Companies will also need to integrate commercial data sources to quickly and accurately answer critical business questions. For example, as patient data incorporated early in the launch process evolves, you can use it to track how initial HCP customer targets have changed.

OPERATIONAL REQUIREMENTS

Accurate and high-quality **customer reference data** and longitudinal, anonymized **patient 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.

Initiate a market access strategy

Ensure that when regulators approve a product for use, it is covered by insurance and available at the right distribution points for the right patients. Develop and communicate an economic and clinical value proposition and establish why and where a product should be covered on formularies and protocols.

You must also ensure that products are fairly priced and reimbursed, and identify necessary patient services to support patients' out-of-pocket expenses or provide patient and caregiver support on appropriate medication use. Establishing access to payers — insurance plans, pharmacy benefits managers, government, and employers — is crucial to making the treatment available to patients.

Patient data – medical and prescription claims – can segment the customer base beyond diagnosis and prescribing volume to understand what percentage of patients aligned to a given HCP or HCO may have a more favorable coverage status. Claims rejection and reversal data can also show you how comparable drugs perform from a patient access standpoint.

OPERATIONAL REQUIREMENTS

Market access teams must **leverage account insights** to prove the clinical efficacy and health-economic value of the new product relative to other interventions in the market. This includes building capabilities that help KAMs:

- Understand the structure, decision-makers, relationships, and committees within key accounts
- Leverage account planning capabilities, specifically for account management and hospital teams, to track formularies and protocols
- Create plans and monitor how field teams are interacting with HCO-affiliated HCPs and account formulary and care management guidelines impacting medication utilization
- Access data and insights in a single source of truth, including third-party data (e.g., who are account decision makers, what events are they attending, what and where are they publishing)

Broaden scientific engagement, education, and access

Over time, KOL discussions must evolve from disease state awareness to education around clinical results and, eventually, therapeutic outcomes. Companies should identify, profile, and plan their outreach to more KOLs as the clinical trial progresses. Engagement from medical affairs teams provides greater visibility, derives medical insights from KOLs, and helps quantify the drug's economic value.

Key activities include:

- Identifying, tracking, and engaging scientific, digital, and community leaders (including rising stars/emerging experts)
- Identifying the right relevant experts for activities such as advisory boards, publishing scientific findings, and speaking at medical symposia
- Understanding the competitive clinical trial landscape
- Capturing MSL interactions and medical insights

OPERATIONAL REQUIREMENTS

Effective MSL resource planning requires identifying key markets and congresses, accurately identifying and segmenting KOLs, and bringing new MSLs up to speed rapidly on new TAs. **A single source of truth for KOL and TA intelligence** expedites this process and allows MSLs to identify and educate the right experts quickly.

The approach should allow MSLs to tailor content to specific stages along the HCP education journey, capture patient expectations and opinions (real-world evidence), and collect insights into the new product's target disease and market, including unmet needs and scientific narrative around patient protocols. Tracking scientific awareness can also help field medical teams measure the impact of medical activities.

6 months until launch

In this period, the focus should be on defining field team size, structures, and territories, as well as finalizing key metrics and incentive compensation models for the field teams. It's also time to finalize scientific content for MSLs, prepare promotional materials for the sales and marketing organizations, and establish the necessary third-party integrations to make the commercial model work.

Establish territory alignments

As a best practice, consider field assignments within the overall information management strategy to share them 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.

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] — and decreasing the time required for significant alignments by 75% or more.

OPERATIONAL REQUIREMENTS

Best-in-class territory alignment solutions are particularly effective for 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 react rapidly to changes in the market.

An **effective territory alignment solution** integrates multiple data sources – including prescriber data – and uses visualization tools to quickly move from the big picture into the details. It should also be able to quickly generate territories by different metrics, understand relationships between HCPs and healthcare organizations, and substantially reduce the overall manual burden.

[5] Real-world results achieved by small, U.S.-based pharmaceutical company, presented at 2017 Veeva Commercial Summit

Leo Pharma launches at full speed with integrated sales planning

To address process bottlenecks and harmonize its operations ahead of a key launch, Leo Pharma implemented Veeva CRM globally. It also rolled out Veeva Align, giving it a single solution for sales planning and field force management.

Accelerated
sales territory alignment planning by 90%

Eliminated
85% of process steps with native CRM integration

Reduced
number of territories managed by 80%

The most important aspects are:

- Creation and maintenance of an optimally sized and structured field force
- Alignment of field representatives
- Assignment of HCP targets to territories
- Data inputs for field force work that you can easily refresh and deliver daily

Capturing integrated field feedback on territory definitions, target lists, and engagement plans is a best practice that can take weeks off the timeline, ensuring data is accurate and fresh at implementation.

Integrate third-party systems

Companies should proactively plan for integrations between their CRM and third-party systems to enable a complete customer view. Several commercial operations systems – for example, sample accountability vendors, logistics providers, or adverse event reporting – provide critical functionality once the product launches. This step is integral to the pre-launch strategy, though frequently overlooked until after the product launch.

OPERATIONAL REQUIREMENTS

No single vendor can provide all the necessary capabilities for the entire industry. Your core CRM technology must be **open and interoperable** to connect with the broadest possible ecosystem of partner technologies. Some of the most common integrations are fulfillment and sample accountability, patient portals, expense management, analytics, and a specialty pharmacy distribution hub.

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% resuction 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.

Create commercial content

Commercial teams must consider their promotional strategy as various operational aspects coalesce around the launch. Rapid creation, approval, reuse, and management of promotional assets for HCPs is a critical competitive advantage for pre-commercial companies. Increased content speed to market, delivered in the prescriber's preferred channel, is vital to market adoption.

Engaging with HCPs via a mix of in-person and video and sharing content more frequently drives new patient starts. One oncology analysis shows the most commercially successful field teams use their access more effectively than lagging companies, using content 4-5x more frequently in meetings and experiencing 70-80% more treatment starts compared to their competitors.[6]

OPERATIONAL REQUIREMENTS

A centralized **content management platform** with modular content can overcome the expense and complexity of rapid content development. Efficient approval, distribution, reuse, and withdrawal can help companies bring new content to market up to two times faster while saving more than 40% of the marketing budget through better content reuse.[7]

[6] Veeva Pulse and Compass, April–September 2022, companies with similar field force size and reach
[7] Veeva study, a verage across customers

3 months to launch

After regulatory approval, the final three months to launch should focus on combining technology, data, and content to engage and educate customers. Field team hiring is nearing completion, and training on the product, PI, and promotional materials should begin.

Coordinate omnichannel HCP engagement

While organizations may establish KOL relationships early, promotional engagement with HCPs can only begin as the drug receives regulatory approval. Companies must be careful to avoid inadvertent pre-label promotions. Field reps should coordinate provider engagement across in-person and digital channels to ensure the delivery of relevant disease-state education to the broadest group possible.

Speaker contracts and speaker training – typically timed to support launches – are also critical during this time. Although not executed before the launch, speaker programs are essential in the U.S. market to maximize the reach of marketing, medical, and field sales teams in the shortest time possible.

OPERATIONAL REQUIREMENTS

HCPs are increasingly accessible through digital channels, and pre-commercial companies need an effective way to identify and engage HCPs early in the process. Investments in omnichannel strategies are proving particularly beneficial, as Veeva Pulse data show that **more than 50% of accessible HCPs**[8] use video to complement in-person engagement.

Insights generated through early customer interactions enable organizations to drive intelligent engagement with HCPs across the product lifecycle. Earlier access to **customer data** also helps companies accurately size the market, build customer profiles, and start forming the right HCP connections to determine product success.

[8] Veeva Pulse data, April - September 2022

SHIONOGI

Shionogi's harmonized data foundation powers multiple successful launches

Since entering the European market, Shionogi has rapidly expanded its women's healthcare product line and added a hospital specialty business. A key component of its expansion strategy has been creating a harmonized and scalable customer data foundation. As a result, Shionogi is experiencing tangible benefits across the board: the increased reach, seamless rep experience, ecosystem insights, and fast, comprehensive analytics have resulted in more streamlined product launches.

Previously, Shionogi had different disconnected solutions for customer data in each of its European markets. Having a single source of truth for customer data is transforming Shionogi's end-to-end process for launching brands in new European markets. Due to the integration between **Veeva OpenData** and **Veeva CRM**, targeting is easier and field execution more effective.

Shionogi also uses **Veeva Link** to identify key medical and scientific experts and initiate medical discussions before launch. These in-depth ecosystem insights are seamlessly integrated with OpenData through a common data architecture.

Successful launch execution and beyond

Long-term planning, flexibility, and agility are crucial to achieving maximum commercial impact, even when using a pre-defined launch plan based on established best practices. Technology should be an enabler rather than a barrier to the launch's success, and a proven, configurable cloud-based system will deliver more value, speed, and insight than cumbersome customizations or unproven point solutions. The right platform enables experimentation with business processes and technology innovations, easily collects data, draws actionable insights, and rapidly refines the go-to-market strategy.

Every biopharma's roadmap is unique, but each roadmap will create a proactive commercial program that maximizes the chance of a successful product launch. Achieving product launch excellence will rely on the following:

- Swiftly generating and sharing insights
- Engaging as one team across digital channels
- Integrating platforms and data
- Establishing a customer-centric approach
- Improving HCP targeting and continuously increasing knowledge of their preferences

Please contact our commercialization experts for a complimentary one-hour workshop to begin developing your launch roadmap.