



## Charting your course: Navigate your launch journey with certainty

Product Launch Guidebook

The life sciences industry is constantly evolving, presenting new challenges and opportunities for companies launching innovative therapies. To achieve a successful product launch, it is essential to have a well-defined strategy and a meticulous plan, early.

This guide will provide you with expert insights and actionable strategies to navigate pre-launch complexities and set your product up for success. Drawing on insights from Inizio Advisory experts, we'll explore the key pillars of successful pre-launch planning:

- Understanding the market
- · Optimizing your launch planning and decisions
- · Validating your approach

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## Part 1: Understanding the market

A successful product launch hinges on a deep understanding of the market landscape. Without this foundation, even the most promising treatments can fall short of expectations. It is within the pre-launch phase, typically beginning around the time a company commits to Phase IIIb trials, that this critical market understanding is developed. This phase usually begins approximately two years prior to launch. Note that this timeframe may vary for products undergoing accelerated approval pathways.

A primary goal of this phase is to gather the necessary insights to inform the development of a robust go-to-market strategy. This involves a comprehensive exploration of the market, including:



Understanding the market landscape: Identifying key trends, competitive forces, and unmet needs.



Sizing the opportunity:
Determining the potential market size and patient population.



Developing a go-tomarket strategy: Defining the target audience, value proposition, and marketing mix.

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Pre-launch planning involves everything from understanding the market to sizing the opportunity to developing a go-tomarket strategy. That's a lot of set-up and planning.

Liza Pliss, VP at Research Partnership

### The risks of misunderstanding

Misunderstanding the market or making incorrect assumptions about the target audience can seriously affect a product launch. Without a deep understanding of patient needs, healthcare provider perspectives, and the competitive landscape, even the most innovative treatments may struggle to gain traction.

Thorough market research is essential to uncover potential barriers to adoption, identify unmet needs, and tailor your launch strategy accordingly. Failing to invest in this critical step can lead to:



#### Missed opportunities:

A lack of market understanding can result in misaligned messaging, ineffective targeting, and missed opportunities to connect with the right audiences.



#### Financial losses:

A lack of market understanding can result in Misjudging the market can lead to poor uptake of the product, resulting in financial losses and potentially impacting future development efforts.



#### Reputational damage:

A poorly executed launch due to inadequate market understanding can damage the company's reputation and erode trust among healthcare providers and patients.

By investing in robust market research and analysis, companies can mitigate these risks and increase the likelihood of a successful product launch.

### Key research methods

To gain a comprehensive understanding of the market, several research methods are crucial:



#### **Patient journey research:**

This approach provides a 360-degree view of the patient experience, from the initial onset of symptoms to treatment and beyond. It captures both functional and emotional components, offering invaluable insights into patient needs and challenges.



#### Market insights:

This encompasses a wide range of activities, including gathering insights into market dynamics, conducting competitive landscape assessments and understanding patient needs and preferences. Demand assessments are also crucial to avoid overestimating the likelihood of physicians prescribing a drug.



#### **Segmentation:**

A poorly executed launch due to inadequate market understanding can damage the company's reputation and erode trust among healthcare providers and patients.

### The role of data

In addition to market research, a robust data strategy is essential for effectively leveraging data throughout the prelaunch phase and beyond. This includes:

- · Data for targeting specific patient populations
- Data-driven market maps to visualize the competitive landscape
- · Performance tracking data to monitor sales and penetration
- Operational and functional data to support internal processes
- · Real-time dashboards to provide up-to-the-minute insights

It's important to keep in mind that it takes time to get data in place, and then it takes more time to get the analytics in place.

**Gan Tan, Partner at Putnam** 

Learn more about Inizio Advisory's market research & insights and data strategy & analytics expertise.





## Part 2: Optimize launch planning

In today's dynamic pharmaceutical market, with increasing competition and accelerated timelines, early launch planning is a necessity. This phase, typically occurring 24–36 months before launch, involves translating your market understanding into a robust and actionable plan.

### Why early planning matters

Early launch planning offers several critical advantages:

- **Increased likelihood of success:** By proactively identifying and addressing potential challenges, you can significantly increase the probability of a successful launch.
- Adaptability: Market conditions can change rapidly. Early planning allows you to build flexibility into your strategy and adapt to unexpected events.
- Alignment: Early planning fosters alignment across teams and functions, ensuring everyone is working towards the same goals.
- Resource optimization: Careful planning helps optimize resource allocation, ensuring that you invest in the right activities at the right time.
- Launch momentum: A well-planned launch generates stronger momentum, allowing you to capture market share quickly and effectively.

Because the market is so complex and competitive, it's requiring teams to start thinking about how they're going to bring their product to market much earlier in the product life cycle.

**Ashley Stanley, Product Launch Practice Lead at Vynamic** 

### Defining launch scenarios

Throughout the lead-up to an approval, there are numerous internal and external events with uncertain outcomes or timing. These could include internal events such as data readouts and study timelines, as well as external factors like competitor events, regulatory reviews, supply chain considerations, and policy or legal changes. Identifying and understanding those possible inflection points proactively and early is critical for proper scenario planning. Sufficient lead time is necessary to prepare and ensure a flexible fit-for-purpose plan as a seemingly minor change has the potential to cascade and significantly alter the launch.

Here are some examples of how to recognize and address launch scenarios that may impact launch planning:

- Consider your portfolio and indication strategies
  Evaluate your organization's existing therapeutic areas and identify potential new ones. This will help you determine the best fit for your product and anticipate potential challenges in the market.
- Factor in the complexity of your product
  Consider the specific characteristics of your product, such as personalized therapies or complex delivery mechanisms. This will help you anticipate potential challenges in manufacturing, distribution, or patient adoption.
- Proactively plan for different scenarios
   Prioritize potential scenarios based on their likelihood and potential impact. Develop contingency plans to mitigate risks associated with each scenario, ensuring you are prepared for a range of possibilities.

- Align local teams with the global strategy
   Consider cultural nuances and potential adaptations needed for different markets while ensuring this is still consistent with your global strategic approach. This will help confirm your launch strategy is relevant and effective in all regions.
- Monitor for ongoing developments

  Continuously review the scenarios and refine as new information is learned or based on market events. Ensure that your leadership team is informed of the plan, any risks, and in-flight initiatives, and request additional support/funding as needed.
- Test global campaigns globally
  Include representation from different regions to identify potential challenges early on. This will help ensure your marketing materials and promotional assets are culturally appropriate and resonate with your target audience in all markets.



### Leveraging technology

Technology plays a vital role in optimizing pre-launch planning decisions. Tools such as project management software, data visualization platforms, and collaborative workspaces can streamline processes and enhance decision-making.

I think this is an area where there is a greater need for teams to start thinking about how technology can be leveraged to alleviate some of that burden, and also plan accordingly.

**Ankit Patel, Partner at Putnam** 

### Key milestones and team roles

To ensure a smooth and efficient launch process, it's important to define key milestones and clarify the roles and responsibilities of different teams. This includes:

- Market research and analysis: Gathering insights into customer needs, competitive landscape and market dynamics.
- **Product positioning and messaging:** Developing a clear and compelling value proposition that resonates with the target audience.
- Marketing and communications planning: Creating a comprehensive marketing and communications strategy that encompasses all relevant channels.
- Sales and field force enablement: Equipping the sales team with the knowledge, tools and resources they need to effectively promote the product.
- **MSL enablement:** Equipping Medical Science Liaisons (MSLs) with the necessary data, clinical trial results, and scientific information to effectively communicate the value proposition of the product to healthcare providers and address their questions and concerns.
- Launch monitoring and measurement: Establishing metrics to track launch performance and identify areas for improvement.

Key milestones are critical to success with far-reaching downstream impacts. If you get one of them wrong, everything else downstream will potentially fail as well.

**Brian Stamm, Product Launch Practice Lead at Vynamic** 

Explore Inizio Advisory's <u>launch planning consulting</u> <u>services</u> and <u>strategic commercialization</u> expertise.



## Part 3: Validate launch approach

While thorough planning is essential, it's equally crucial to validate your launch approach before going to market. This phase involves rigorous testing, refining, and pressure testing your strategy and plans to ensure they're robust and ready for the real world.

### Launch readiness: testing and refining

Validating your launch approach involves testing key elements with your target audience:



#### **Positioning:**

Does your product's positioning resonate with HCPs and patients? Qualitative research is ideal for exploring interpretations and subconscious reactions, and you can refine your positioning based on the findings.



#### Marketing materials:

Are your marketing materials and promotional assets effective? Test them for both rational and emotional impact, and gather feedback from your target audience to optimize their effectiveness.

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It's absolutely critical that you test and refine marketing materials and promotional assets. You can have a really firm understanding of the market and develop a watertight launch plan, but it's your communication materials that will be seen by your end customers and that will bring the strategy to life in their eyes.

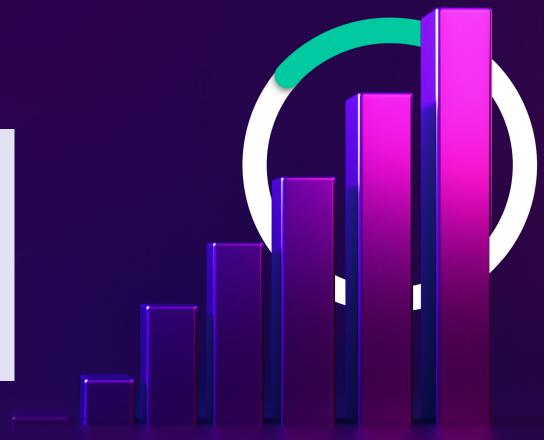
**Tom Winter, Senior Director at Research Partnership** 

### Strategic alignment

First and foremost, it's critical to confirm that all teams involved in the launch are aligned with the overall brand strategy and goals. Misalignment can lead to initial confusion and, in the long term, may result in the product being positioned off-strategy, ultimately limiting overall brand performance and trajectory. To avoid this, it's crucial to establish clear communication channels, regularly reinforce the strategy, and track progress against key performance indicators (KPIs).

One of the most common problems that we see at STEM is teams quickly drifting off strategy at launch, which can result in missed targets, internal conflicts, and damage to the brand's long-term trajectory.

Madeleine Lacaille, Associate VP, Global Strategic Accounts at STEM



### Field team readiness

Your field teams are the face of your product to healthcare professionals (HCPs). Ensuring they're well-prepared and aligned with the launch strategy is paramount. However, field teams often operate independently and may face unique challenges, which can sometimes lead to deviations from the original strategy.

To avoid this, prioritize:

- · Product knowledge: Deep understanding of the product's features, benefits and supporting data.
- Positioning and messaging: Effectively communicating the product's value proposition to HCPs in the right way, including being specific on the patients who will benefit most and how it addresses unmet patient needs.
- · Objection handling: Confidently addressing HCP questions and concerns to ensure this does not result in roadblocks.
- Engagement skills supported by coaches: Building rapport, uncovering needs and closing effectively require consistent focus to execute effectively.

Equipping field teams with the necessary knowledge and skills is essential, but it's equally important to foster ongoing support and communication. Regular feedback sessions, updates on strategic goals, and opportunities for knowledge sharing can help ensure that field teams remain aligned with the overarching launch plan and can effectively adapt to challenges in the field. This approach empowers field teams to effectively represent your product while staying aligned with the overarching launch strategy. Strong belief and confidence in the strategy is critical to guarantee strong execution from the field teams.

### Benchmarking

Benchmarking your launch plan against industry standards can provide valuable insights into your preparedness and identify areas for improvement. By comparing your execution to established benchmarks, you can gain a clear understanding of your strengths and weaknesses, and identify opportunities to optimize your approach.

- · Benchmarking offers several key benefits:
- · Identify areas to fine-tune in your launch plan.
- · Gain a competitive advantage by understanding industry best practices.
- · Understand how key drivers of HCP behavior vary between therapy areas.

STEM, for example, has collected extensive data on field team performance, allowing for country and therapy area-specific benchmarking. This data can help you understand how your field team's skillset compares to industry best practices across commercial, medical and market access functions.

Inizio Advisory can be your partner in benchmarking, offering access to comprehensive industry data and expert guidance to help you interpret and apply the results. Our team will work with you to identify relevant benchmarks, conduct thorough analyses, and develop actionable recommendations to optimize your launch plan.

Explore Inizio Advisory's <u>market research & insights</u> and <u>brand alignment</u> expertise.



Driving success: The power of pre-launch planning

A well-executed pre-launch plan is crucial for a successful product launch in the life sciences industry. By thoroughly understanding the market, optimizing your planning process, and rigorously validating your approach, you can confidently navigate the complexities of this critical phase.

Inizio Advisory is your trusted partner throughout this journey. We offer a unique blend of expertise and resources to support your pre-launch planning needs across our connected capabilities. We combine market knowledge with advanced analytics and strategic consulting to help you achieve your launch objectives.

Our goal is to empower you to bring impactful therapies to patients while achieving both clinical and commercial success.

Are you ready to navigate your launch journey with confidence? Contact Inizio Advisory today to discuss how we can help you get ahead and achieve launch excellence.

# Want to hear more insights from Inizio Advisory experts?

Check out the <u>PM360 podcast series</u>, "Navigating Pre-Launch," where our experts discuss key strategies and considerations for successful product launches



### Appendix: Collaborators page



#### Liza Pliss, VP at Research Partnership

Liza Pliss is a seasoned market research leader with over a decade of experience in research and consulting. She currently serves as Vice President at Research Partnership, where she leverages her expertise in consumer behavior, customer insight, and data analysis to drive impactful strategies. Previously, she was Director and Head of the NYC office at Research Partnership, leading teams in delivering high-quality market research solutions. Liza is passionate about storytelling through data, helping clients uncover meaningful insights that inform strategic decisions. She holds a B.S. from Macaulay Honors College at The City University of New York and an MBA from Brandeis International Business School.



#### Gan Tan, Partner at Putnam

Gan Tan has supported pharmaceutical and biotech clients across a range of therapeutic areas. His recent engagements include competitive landscape assessment, launch strategy development, center profiling, institutional opportunity assessment, value / pricing / managed markets strategy, KPI development, product positioning, sales/operational efficiency assessment, opportunity assessment, and portfolio prioritization.

He has extensive experience with qualitative and quantitative methods such as qualitative and quantitative research, segmentation and scenario testing, patient conversion and persistence analysis, forecast models, real-time dashboard visualizations and big data analysis including claims, EMR, inventory/shipments, HUB, and CRM. Gan graduated magna cum laude from the Wharton School of the University of Pennsylvania in 2010, as part of the Roy and Diana Vagelos Life Sciences and Management Program. Prior to that, he attained a B.A. in Biology and a B.Sc. Econ with concentrations in Finance, Insurance and Risk Management, and Actuarial Science.



#### Ashley Stanley, Product Launch Practice Lead at Vynamic

Ashley has a focus on guiding clients through the entire product launch lifecycle, she is dedicated to bringing innovative therapies to market and fostering impactful collaborations. Ashley's professional journey includes a B.A. in Communications from Villanova University. She has extensive experience in the life sciences sector and has partnered with teams to prepare for and launch their first products, witnessing firsthand the positive impact on patients' lives. Ashley is passionate about building strong relationships and collaborating with individuals who are energized by new ideas and complex challenges.

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#### Ankit Patel, Partner at Putnam

Ankit has spent over a decade supporting major pharmaceutical and biotechnology clients on early-stage asset assessments, new asset launch, product positioning and messaging, mapping detailed patient treatment journeys, customer segmentation, financial forecasting, and strategic brand planning in the US and globally. He has considerable experience across a range of specialty diseases, including oncology, hematology, neurology, immunology and rare diseases. Ankit has a keen interest in leveraging big data to inform product commercialization strategies. Ankit also worked at Healthcasts/MDcentRx, an HCP education and promotions platform, where he focused on developing new big data and Al focused product offerings for biopharma clients. He holds a Masters in Biotechnology from University of Pennsylvania and a Bachelor's degree in Biotechnology from Pennsylvania State University.



#### Brian Stamm, Product Launch Practice Lead at Vynamic

Brian has a strong background in life sciences, Brian specializes in operating model and organization design, product launch, and strategic planning and mobilization. Prior to joining Vynamic, he served as a Senior Management Consultant at PricewaterhouseCoopers LLP, where he assisted clients across various industries in refining customer experiences and aligning brand strategies through consumer insights and transformational change initiatives. Brian holds a B.S. in Marketing and Supply Chain Management from Syracuse University. Passionate about bringing life-changing therapies to patients, he actively participates in community causes such as Cycle for Survival.



#### Tom Winter, Senior Director at Research Partnership

Tom is a highly experienced market research professional with over 20 years in the industry. He currently serves as a Senior Director at Research Partnership, where he plays a key role in delivering strategic insights and guiding clients through complex market landscapes. Starting as a Director at Research Partnership, Tom has built a strong foundation in data-driven decision-making, leveraging his expertise in analytics, customer insights, and market research methodologies. He holds an MA in Natural Sciences (Part II Genetics) from the University of Cambridge. With a passion for uncovering actionable insights, Tom is dedicated to helping clients navigate the evolving healthcare and life sciences industries.

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#### Madeleine Lacaille, Associate VP, Global Strategic Accounts at STEM

Madeleine is a dynamic healthcare strategy professional with over seven years at STEM, where she has progressed from Business Analyst to Associate Vice President of Global Strategic Accounts. She combines her expertise in biomedical sciences and digital marketing to develop tailored, data-driven solutions that drive business growth and enhance strategic execution. Leveraging her analytical skills and industry experience, Madeleine helps optimize marketing campaigns and expand patient reach. She holds a Bachelor's degree in Biomedical Sciences from Durham University and a Diploma in Professional Digital Marketing from The Chartered Institute of Marketing. Passionate about innovation, she is committed to delivering solutions that meet the evolving needs of clients and stakeholders.