White paper

Medical communications

Biotech medical information: ensuring a successful product launch

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Executive summary

Bringing the first product to market is a defining moment for any biotech company. The pressure is high, the margin for error is small, and the expectations, both internally and externally, are growing. While clinical and commercial strategies often take center stage, medical information is a critical piece of the launch puzzle that can determine whether a new therapy gains traction or stalls. This white paper explores how a purpose-built medical information and contact center strategy helps companies prepare with confidence and deliver with impact.

In this white paper, you will learn:

- Why early medical information and contact center planning is essential to launch readiness
- How AI and advanced technologies are reshaping medical information operations
- Common mistakes companies make — and how to avoid them
- What to look for in a medical information and contact center partner to ensure global scalability and launch success

Whether you're months from approval or just starting to map your post-approval needs, this guide will help you ask the right questions, set a clear strategy, and move forward with the support your product and your patients deserve.

Why first launches matter more than ever

For many emerging biotechs, a first product launch is more than a milestone — it's a defining moment that shapes the company's future. These organizations are often built around a single investigational asset. Without a successful launch, continued growth, or even survival, can be difficult to sustain.

The pressure is especially high in rare diseases. These specialties are characterized by small patient populations and limited prescriber bases, leaving little room for error. In these cases, launch success depends on more than just reaching the market. It's about being ready to support every provider, every question and every patient from day one.

The risks of falling short are significant. Even with regulatory approval, market success isn't guaranteed. Physicians won't prescribe treatments they don't understand or trust, and unanswered questions or delayed safety responses can slow adoption. Patients may be exposed to misinformation or have other concerns that companies can address to make patients more likely to fill prescriptions and stay compliant.

At the same time, launches have grown more complex and more financially consequential. Biotechs face mounting pressure to maximize asset value and demonstrate return on investment from the moment a product enters the market. That means being ready to educate providers, engage advocacy groups, manage real-world inquiries, and fulfill post-market requirements like adverse event (AE) and product complaint (PC) intake. For many companies, this level of coordination is a new challenge, and nearly 40% of industry leaders cite growing launch complexity as one of their most pressing concerns.

What's missing: early investment in medical information

Despite the high stakes, some first-time companies overlook the role of medical information in launch planning. Medical information is treated as a post-approval necessity rather than a launch-critical function.

In reality, medical information is central to building prescriber confidence and ensuring appropriate product use. When engaged early, medical information helps companies anticipate common questions, prepare scientific responses and ensure inquiry handling workflows are ready. It also establishes a channel for timely AE and PC reporting, which are core components of a compliant and responsive post-approval program.

Without sufficient time to build this foundation, companies risk delays, miscommunication and missed opportunities to connect with patients and providers during the most important window for adoption.

Why biotechs need a different kind of support

Unlike large pharmaceutical companies, many biotech companies don't have large medical information teams or significant experience managing post-approval responsibilities. These companies are often fueled by passion and innovation but can benefit from guidance from experienced partners who understand the intricacies of medical information and launch execution. With tight timelines and limited resources, what biotech companies need goes beyond outsourcing — it's partnership. A strategic collaborator that brings the infrastructure, expertise and foresight to support a launch that's both compliant and customer ready.

Medical Information lays the foundation for launch success

Medical information is often viewed as a post-approval function, but it plays a central role in launch readiness and should be developed well before a product reaches the market. The ideal time to begin building a medical information strategy is during phase III trials, when NDA submission is underway and cross-functional planning accelerates.

Companies that begin later can find themselves rushing to create standard operating procedures (SOPs), develop response content, and stand up contact center capabilities in the final months before approval. Early engagement helps avoid these fire drills. It allows time to establish and test systems, train staff, and ensure alignment across medical, commercial, and regulatory functions before launch pressures escalate.

Proactive preparation reduces risk and builds confidence

Physicians and other health care providers (HCPs) expect timely, accurate answers to product questions, especially for new therapies. If a company isn't equipped to respond quickly, confidence can erode, and prescribing decisions may be delayed or deferred altogether.

Preparing for common inquiries ahead of launch helps ensure a smoother provider experience and reduces early adoption friction. It also creates an opportunity to capture and analyze inquiry trends in real time. These early insights can reveal gaps in provider understanding and help refine broader communication strategies across functions.

Establishing the right infrastructure before launch

Being ready to respond means having both the right answers and the infrastructure to support scale, speed, and compliance. That includes:

- Staffing a contact center with trained agents who understand the therapeutic landscape
- Creating a database of scientifically accurate response documents
- Developing and validating SOPs for inquiry handling, AE reporting and product complaints
- Implementing systems to intake, triage and track inquiries
- Building dashboards and analytics tools to surface actionable insights

Structured project plans, templates and checklists will streamline setup and give companies the operational foundation they need, without starting from scratch.

Planning for hypercare: the launch-critical phase

Even the best-prepared launches bring surprises. Inquiries may spike, unexpected questions may surface, or process gaps may emerge that require immediate attention.

A hypercare model addresses this reality. It provides elevated support in the first 30 to 90 days post-launch, when agility and responsiveness are most important. This model ensures that emerging issues are escalated quickly, inquiry patterns are monitored closely, and adjustments can be made without delay.

Maintaining a direct connection between the outsourced medical information team and company stakeholders during this period allows for fast decision-making and preserves service quality when it matters most.

When medical information is fully integrated into launch planning, it creates the structure, clarity, and responsiveness that high stakes launches require. It enables confident prescribing, faster issue resolution and a better experience for providers and patients. For biotechs entering the market for the first time, a strong medical information strategy isn't just a support function—it's a strategic advantage.

Future-proof your launch with AI and advanced technology

Artificial intelligence (AI) is transforming medical information, but risks are inherent in many uses of the technology and so human expertise remains essential. While medical information has traditionally been a human-led function, technologies like natural language processing (NLP) and large language models (LLMs) are increasingly being integrated to support faster, more scalable and consistent service.

Agent Assist platforms, for example, can surface suggested answers in real time, helping contact center agents to more efficiently and accurately answer inquiries. This technology can also help identify adverse events and product complaints and automate many aspects of the documentation of the case, improving compliance while making the process more efficient. Generative AI can also be used to simplify the literature search process and create a first draft of response documents more efficiently.

AI should be used to strengthen medical information workflows, not to automate them outright. That's why the most effective implementations follow a human-in-the-loop model. AI can accelerate and scale support, but content should be verified with the guidance of experienced teams who understand both the science and the stakes.

Early adopters will gain a competitive edge

Biotechs that integrate AI early are better positioned to deliver high-quality support at scale without overwhelming lean internal teams.

AI can analyze large volumes of inquiries in real time, flagging trends that might otherwise go unnoticed. Companies gain early visibility into recurring themes, shifts in provider sentiment and emerging safety signals — insights that would take much longer to surface through manual review.

For example, sentiment analysis tools can evaluate customer sentiment across every contact center interaction, generating "satisfaction scores" that reflect how HCPs and patients are experiencing product interactions. These scores can be trended over time and analyzed for drivers of high and low scores, helping detect changes in customer satisfaction and the reasons behind them.

Preparing now sets the stage for future success

Even though full automation remains years away, incremental AI adoption today lays the groundwork for broader transformation. Companies don't need to overhaul their entire medical information program. They can start with targeted, high-impact use cases such as:

- Generating real-time call summaries
- Monitoring quality and compliance scores
- Detecting trends across multiple agents or channels

Establishing this kind of digital infrastructure now ensures companies can scale, adapt, and meet rising expectations for responsiveness and data-driven decision-making in the years ahead.

The industry is already moving

AI is quickly shifting from experimental to essential in drug development and post-market operations. Nearly half of small and mid-size biotech and pharmaceutical companies now report actively investing in AI as a strategic priority[1].

Momentum is also building among larger players. A 2023 McKinsey report found that 40% of biopharma executives expect to invest in AI-powered medical operations within the next two years, with medical information and medical affairs identified as key opportunity areas[2].

Companies that wait risk falling behind in both operational efficiency and the ability to meet evolving expectations for service quality.

Common pitfalls that derail launches and how to avoid them

Even with strong science and sound strategy, launch missteps are common, especially for companies entering the post-approval space for the first time. Many of these pitfalls are avoidable with early planning, realistic expectations, and the right support.

#1: Waiting too long to engage medical information

One of the most common mistakes is treating medical information as a last-minute need. Companies may not realize what's involved until just months before approval, resulting in rushed RFPs, strained timelines and incomplete readiness.

Developing medical information capabilities takes time. Staffing, training, SOP development and system implementation can't be done overnight. Starting when a product is in phase III trials creates the runway needed to launch with confidence and alignment.

#2: Underestimating the post-approval landscape

Running a clinical trial is not the same as supporting a product in the real world. After launch, companies must handle real-time AE reporting, product complaints, and complex HCP and patient inquiries — all without the structure of a controlled study environment.

Regulatory expectations are higher, data capture is less predictable, product complaints are more common, and reputational risks are greater. Companies who aren't prepared for this shift may face compliance gaps and service breakdowns from day one.

#3: Using a generic approach for specialized needs

Different patient populations have different needs, and your medical information team must be ready to meet them.

For self-administered therapies, agents should be trained to address questions about dosing, injection technique, and at-home troubleshooting. Particularly in rare disease or pediatric settings, callers are often highly informed and may require deeper scientific engagement.

A tailored staffing and training strategy ensures your team can respond with the right mix of empathy, clarity and subject matter expertise.

#4: Overlooking the "every patient matters" mindset

In rare disease and other niche markets, each interaction has amplified impact. A single poor experience, whether from a delayed response or unclear communication, can undermine trust, affect adherence and damage provider and advocacy relationships.

Companies must be prepared to deliver timely, accurate and empathetic support from the very first inquiry.

#5: Failing to future-proof your strategy

Being first to market is a competitive advantage, but it doesn't last without scalability. Follow-on therapies often arrive quickly, and companies that can't evolve their medical information strategy risk falling behind.

Working with a large global medical information partner allows teams to adjust to new indications, label changes, expansion to new markets and shifting competitive dynamics without starting from scratch.

Bottom line: You don't know what you don't know, and that's okay

Companies entering the post-approval space for the first time aren't expected to know everything. But they can avoid common missteps by planning early and working with partners with global resources who've launched before.

With the right support, even lean teams can deliver a launch strategy that's compliant, responsive and built to scale.

The PPD partnership difference

Bringing a product to market demands more than staffing and operational support. Biotechs preparing for their first launch often face unfamiliar territory with limited internal resources and no established roadmap. In these situations, outsourcing is not simply a matter of capacity — it's a decision to rely on a partner for guidance, expertise, and execution.

A true launch partner does far more than provide staffing resources. They bring expertise, structure and foresight. They help avoid missteps, close gaps, and ensure everything is in place before the first call comes in.

The right partner integrates, aligns and extends your team

Successful partnerships function as an extension of the sponsor's internal team rather than as a separate vendor working in parallel. That level of collaboration starts early and shows up in the details: joining strategy discussions, flagging potential risks, and maintaining alignment across medical, commercial, and regulatory functions.

The most effective medical information teams include:

- Experienced managers who keep timelines, training and launch deliverables on track
- Quality specialists who guide SOP development and ensure audit readiness
- Medical information writers who develop quality response documents
- Contact center agents trained to represent the company's brand with accuracy and empathy

When these roles operate in sync, it leads to faster decision-making, smoother execution and a more consistent experience for external stakeholders.

Global reach and scalability matter

Many biotechs start with U.S.-based launches, but few stay there. Whether expanding into new markets or licensing products internationally, companies need a partner with the scale and infrastructure to grow alongside them.

Working with a partner that offers multilingual capabilities, regional compliance expertise, and globally aligned systems helps companies reduce risk and accelerate future growth without reengineering their operations later.

Alignment and trust make all the difference

Small biotechs are often mission-driven. They're fueled by the belief that their product can change lives, and they choose partners who share that conviction.

Strong partnerships are built on transparency, flexibility and shared accountability. They're grounded in trust — not just to execute, but to advise, problem-solve, and stay invested in success even when timelines shift or challenges arise.

That kind of alignment builds confidence, which is critical when so much depends on getting it right the first time. From intake readiness to future scalability, a strong medical information partner ensures that every patient, provider and regulatory requirement is handled with care and consistency.

When supported by the right expertise, infrastructure, and experience, your launch is positioned for success.

Your launch deserves nothing less than complete confidence

For emerging biotechs, a first launch is a pivotal moment, often the dividing line between long-term growth and stalled progress. In high-stakes areas like rare disease and oncology, every patient matters, every prescriber decision counts, and the margin for error is slim. Success requires more than regulatory approval. It demands precision, foresight, and the ability to deliver support from the very first interaction.

Medical information plays a central role in meeting that challenge. When planned and executed well, medical information becomes a strategic asset. It enables faster prescribing by answering provider questions with speed and clarity, captures insights that shape broader strategy, ensures regulatory compliance, and builds trust through every patient and HCP interaction.

Companies who recognize this early are better prepared to navigate complexity, avoid missteps, and maintain momentum beyond the approval milestone.

Track record matters, especially when you only get one shot

Biotechs entering the market for the first time can't afford to learn by trial and error. They need a partner with a history of successful launches and the experience to anticipate what's coming next.

The PPD™ clinical research business of Thermo Fisher Scientific is the most experienced medical information contact center provider in the world, with:

- More than 1,500 employees globally, including strategists, frontline agents, and operational staff
- Support for over 200 pharmaceutical and biotech companies
- Experience across 150+ global product launches in a range of therapeutic areas

This foundation allows us to offer not just best practices, but custom frameworks, benchmarking data, and real-world insights that reduce risk and improve readiness.

We bring global scale with biotech intimacy

Whether you're launching in the U.S. or planning for international markets, we have the infrastructure to meet today's needs and grow with you. Our teams span North America and South America, Europe and Asia, offering multilingual support and regional regulatory expertise around the world.

At the same time, we understand that every biotech company is different. Our partnerships are built on flexibility, responsiveness and a shared belief in your product's potential.

A proven partner in an evolving industry

Drug development is becoming more complex, more expensive and more urgent. Nearly half of drug developers say it now takes longer to bring products to market than it did just two years ago[1] — despite rising pressure to maximize asset value. At the same time, more than half of small and mid-size biotechs are reevaluating vendor relationships in search of integrated, full-service partners.

Our model meets this shift head-on. We bring proven delivery, global scale and a biotech-first mindset that allows companies to streamline operations and focus on what matters most: patients and product performance.

Strengthening your launch foundation for what comes next

Your first product launch sets the tone for everything that follows: your brand, your reputation and your stakeholder relationships. Having the right partner in place ensures you're ready for day one and every day that comes after.

With our team by your side, you get more than a service provider. You gain a partner that offers clear guidance and operates with the same urgency and care you bring to your product.

When every patient counts, every decision matters. Choose a partner that's ready.

Get started now at ppd.com/our-solutions/clinical/medical-communications/.

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