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The essential guide to launching patient support solutions for a novel therapy

Everything you ever wanted to know about patient support for innovative pharmaceutical products

You have invested the time, expertise and financial resources to develop a novel therapy for patients. After all of your hard work and dedication, how can you ensure a successful launch? What are the key considerations for an innovator in a therapeutic area? Learn how to reach patients and improve access when launching a novel therapy.

Every step matters

From initial concept and planning to launch and ongoing program management, there's so much that goes into the launch of a product and its corresponding patient support program. Challenges and setbacks in one area can have a ripple effect on another. That's why manufacturers should have a comprehensive understanding of the launch process from end to end—not just to ensure a smooth launch, but to clear the path of ongoing hurdles for your product and patients.

Novel therapies involve a great many "firsts" for patients, providers and payers. With so much on the line, it's important for patient support services to give these products every chance of success. As new therapies make their marketplace debut, patient support solutions can be instrumental in driving product access and speed to therapy—all factors that require the right mix of services delivered flawlessly during first-to-market launches.

Building an effective, successful patient support program comes with challenges, but by engaging with a proven partner, those herculean tasks can become much more manageable.

How to use this guide

This guide is designed to give manufacturers of novel therapies an inside look at the components proven to ensure a successful patient support program. You'll glean actionable insights from Lash Group's 30+ years in the patient services industry and the collective expertise of leaders from our Launch Center of Excellence, as well as our operations, analytics and clinical teams.

We've included four key sections:

Spotlight on: **Launch Center of Excellence**

The categories covered in this guide come from the playbook of Lash Group's Launch Center of Excellence (LCOE), a business group dedicated to the successful launch of patient support solutions.

> Our proven approach and standardized toolkit help us deliver high-quality implementations every day. The Launch Center of Excellence leverages a phased methodology: assess, design, implement and operate.
>
> **– Lash Group Executive**

The LCOE framework helps ensure success when launching any new program. As you read through this guide, consider your own patient support launch through the lens of these four categories.

Assess

This is the phase when you set up project parameters and organize teams, resources and necessary information to begin working toward program design. You'll work with your patient support partner to identify specific product attributes that will impact the scope of your launch. These can include patient demographics, disease state, distribution channel strategy, competitive program services, payer mix, reimbursement and site of care considerations, and anticipated patient demand.

While the launch may still be months down the road, the actions you take to build a strong foundation now will impact the program in the short and long term.

Kickstart the assess phase by codifying these elements at the get-go. Add the components that fit the needs of your program.

Clinical objectives

Together with your patient support partner, walk through the product's clinical implications—from the end-to-end patient journey to how providers diagnose, treat and administer or prescribe. It's also important to discuss the level of support patients may need when transitioning to ongoing care from a clinical trial. Patients on clinical trials are accustomed to a highly engaged care team at the clinical trial site and may need additional support as they transition to ongoing care.

Within the mapped patient journey, you'll identify touchpoint opportunities where the patient support program can make the most meaningful impact.

- Review the product label
- Understand route of administration, anticipated dosing schedule, titration requirements, etc.
- Discuss clinical realities, challenges and opportunities
- Consider transition plan for patients coming off clinical trials
- Assess adherence rates and/or access barriers for proxy products
- Think through social and emotional considerations of a new or difficult diagnosis

Program team expectations

It can be tempting to over-engineer a new program during launch, adding as many elements and features as possible. But overexertion can zap your budget and resources—and overcomplicate a new program for providers and patients. Instead, prioritize expectations by focusing on what's most impactful so that stakeholders pursue high-value objectives.

- Benchmark proxy insights to establish realistic metrics
- Calculate month-by-month patient volume projections and the financial exposure to the organization to help determine program parameters
- Align on feasible conversion rates and speed to therapy
- Outline end-to-end resourcing, budget and scope of the program, such as field team deployments or unique deliverables

How often should I hear from my patient support partner during a program launch?

As often as the project demands. The right partner will keep your needs front-and-center during the launch process. A regular cadence of engagement through formal, ad-hoc and weekly collaboration sessions ensures that all stakeholders stay aligned on launch status and deliverables. For best results, choose a single point of contact from each party to drive open and consistent communication, and empower that point of contact to make decisions.

Data and analytics

Benchmarks are critical to establish during the assessment stage and serve as an important reference point throughout the life of the program. With a data-driven set of objectives, patient support programs have a much higher chance of success by deploying the right services and the right engagement strategy.

- Determine which team members will collect and synthesize the pre-launch data (e.g., patient population info and volume projections)
- Review proxy data to determine projected conversion rates
- Determine the need and program parameters for specific services, such as copay support programs
- Explore adherence insights for the particular patient segment

Getting everyone on the same page

Getting a program launch-ready requires that all stakeholders are present at the table—or virtual table—from the outset. After all, building systems, infrastructures and processes will yield little impact if different vendors, such as data aggregators or specialty pharmacies, join midstream and require modifications.

- Identify resource needs and map out the vendor ecosystem
- Hold group kickoff meetings with all stakeholders
- Share contact lists and designate a single point of contact

Design

The design phase combines all the learnings from assessment into a blueprint for execution—creating an end-to-end proof of concept for program launch. This is the time for ongoing discussion and decision-making about the program ecosystem and process flow, and it is when you rally stakeholders for next steps. During this phase, you should also account for unexpected market or economic forces and be ready to act on those contingency plans.

Ecosystem mapping

A well-structured program design maps out the full ecosystem of launch components throughout the care continuum, from the payer to the provider, patient, pharmacy and supplier. By outlining the program's involvement with each component, manufacturers can better predict and respond to changing market conditions at various points in the patient journey and react to assumptions that need to be adjusted in real time.

Guidance on the enrollment form

Informed partners can help structure the enrollment form for a streamlined approach to information collection. This includes guidance on which fields to add or skip and which ones to make optional. A well-developed form determines how fast a patient can get on therapy and how well patients experience the support program.

Technology

There can be a lot of hype around healthcare technology. Before signing up for something that's flashy or new, this is the time to assess and define what type of tools can bring value to your specific patient and program.

Manufacturers should always consider the proper implementation of technology for their programs—understanding that not all software use cases, such as artificial intelligence, mobile apps or online portals—make sense for all patient populations. The right patient support partner will work with you during the design phase to match technology options to your program's needs, including:

- Product attributes and patient population
- Anticipated coverage
- Patient and prescriber tech uptake and compatible technologies
- Program technology needs that may evolve over time
- Cost of technology investment versus the projected return

Rallying stakeholders

Just as all stakeholders needed a seat at the table during the assessment phase, they also deserve that voice during the design process. For example, working with legal and compliance partners to understand requirements can help avoid delays and setbacks during implementation. Getting buy-in from everyone at the start helps ensure things continue as intended throughout the launch and beyond.

Process flow

The design phase also carves a workable process flow for how the launch will forge ahead. Codifying this flow typically involves many workflow checkpoints, from configuration documentation and portal taxonomies to data transfer agreements.

Timelines

Novel therapies come with new territory that can create uncertainty in even the most ironclad timeline. While you may not be able to control all variables that come your way during launch (such as a pandemic), you can identify numerous variables to help keep programs on track. An experienced patient support provider can help create contingency timelines for the program and account for the unexpected.

- Estimate realistic runways for stakeholder review, including legal and marketing
- Identify and address potential roadblocks, such as the availability of resources or decision makers
- Explore timeline needs for IT configurations, such as portal development and third-party integrations

> To close out the design phase, we look for an approved program design and a baseline schedule so that, moving into implementation, we have the scope locked down and we are all working toward an agreed-upon schedule. That helps us determine when we can launch and what tasks could impact the schedule/critical path.
>
> **– Lash Group Executive**

Implement

Pre-Launch

Implementation takes place right before the program's target go-live date. It's when teams work through every last detail to ensure program readiness for launch—from SOPs to testing, training and the official go-live countdown. To keep things on track, every implementation plan requires a disciplined project management team. Preparing for launch by creating a detailed plan and defining roles and responsibilities is an important piece of the implementation phase.

Project management

Effective approaches use tools and methods deeply entrenched in risk-mitigating project management to increase the ability to deliver on time, on budget, and on schedule. That's why project management, while in every phase of the launch process, is the most critical piece of implementation. With practical project management tools and personnel, there's a lesser risk of backlogs, delays and burnout.

> "Project management overarches all phases and is the heart of the LCOE process. The implementation of project management tools and processes increases the likelihood of a successful, on-time launch."
>
> **– Lash Group Executive**

Technical readiness

System readiness requires a cross-departmental check-in to ensure all processes are aligned and ready for next steps, including:

- CRM setup
- Data integration
- Portal readiness
- Technical testing and business simulation

Training

As with system readiness, programs also require personnel readiness. This can include dedicated training programs for both field and remote staff—including scenario-specific FAQs, technology platform use, business simulation, and disease state and product education. It can also include empathy training and customer service skills for roles that interact with patients.

Adaptability

Nimbleness matters, and even robust plans must adapt as they move from non-production environments to go-live. Successful programs can shift in real time as long as everyone at the table is empowered and informed to make those decisions on the fly.

Operate

Launch

You've reached the program launch date. The time, dedication and problem-solving has paid off and your program is live. **Congrats!**

Now what? After a while in-market, it becomes critical to review and compare current program performance with anticipated results. Work with your partner to determine which metrics you will use as benchmarks for growth. Capitalize on your success and make adjustments if you find opportunities to remove barriers for patients or speed up their access to therapy.

This is important because in today's healthcare landscape, change is inevitable. From market developments to innovations in program design, a partner that ensures flexibility and has a defined change management process can continue to deliver on the goals of the program. During the operation phase, they can help you:

- Review the cadence of team communications and adjust to fit the needs of the program post-launch
- Explore ongoing ways to ensure operational success
- Drive change with an established change management process
- Assess key metrics and business review timelines

The next step:
Find the right patient support partner

There are many vendors vying to help you launch your patient support program. As you compare and consider potential partners, look for these key attributes:

Demonstrated experience and flexible solutions

Generally, potential partners should have a strong understanding of the label, disease state, route of administration or other clinical mechanics of the therapy. But when this is not entirely possible with a new therapy, it's essential to partner with an experienced provider with proven chops in programs similar to yours. That way, they can offer flexible solutions to meet your needs.

Reimbursement expertise

New therapies raise many questions about reimbursement, which means you'll need someone with expertise related to payer engagement, benefit verifications, prior authorizations, appeals support and other coverage factors. Access to outsourced field reimbursement teams, who help support reimbursement questions among providers, payers and manufacturers, can separate effective patient support partners from the pack.

Data-driven processes

Patient support partners can aggregate and analyze data to identify benchmarks and assess program performance. Ensure that your partner provides data-driven insights and guidance, not just anecdotes. And most of all, ensure that they make those insights regularly available to you. For example, reporting and analytics at launch can flag issues in coverage and other market dynamics that might impact success.

Ongoing strategic support

Ensure your patient support partner provides program management after launch. Look for partners that aim to maximize patient access throughout the product lifecycle. Tracking market trends and the data from your program, your support partner can help guide you to appropriate services and modifications.

An eye on innovation, always

The solutions your patient support partner develops to drive access and adherence to your product should be as novel as the therapy itself. The right partner will be one step ahead of leading edge and ever-aware of the challenges specialty drugs could face as the market evolves—and never willing to stop exploring new ways to break down barriers to therapy.

Questions to ask:

Which product attributes might make my patient support program challenging?

How many launches have you helped make possible? What challenges did those launches present and how did you overcome them?

What are the lessons you've learned from your work with previous launches?

How do you see the patient services landscape evolving?

How do you train your personnel to ensure they stay up to date on market trends?

How does data inform the recommendations you provide?

How do you work with third-party vendors?

What information will you need from me to help make our partnership successful?

Get your therapy launch-ready

The launch of a novel therapy can be simultaneously exciting and challenging. By following a phased approach from assessment and design to implementation and operation, manufacturers can ensure their patient support program positions their therapy to improve outcomes for patients.

Working with a consultative, skilled and experienced partner can bring that approach to life.

Learn more

Lash Group pioneered the patient services industry. Three decades later, we continue to innovate with purpose, putting the patient at the center of everything we do. And we continue to lead the patient support industry in finding new ways to drive access to innovative therapies.

Find out what's possible when you launch a program with Lash Group.

To learn more, visit **lashgroup.com**.

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