pci PHARMA SERVICES

Optimizing Your Clinical to Commercial Journey

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The average cost of a delayed new drug launch is $15 million per day — which can significantly impact pharmaceutical companies, particularly small-to-midsize or biotech startups.

Optimizing Your Clinical to Commercial Journey

What if you could eliminate avoidable delays and have a seamless transition from clinical trials to commercialization when launching your new drug? How should pharma and biopharma companies think about optimizing the journey from the development stage of clinical trials through to commercialization?

A key problem contributing to launch delays is the disconnect between the clinical development and commercialization teams. Much of that disconnect is because their goals are quite different: The focus of clinical development is clinical trial success and regulatory approval; while the goal of the commercial launch team is to bring new medicines to market with an acceptable unit cost that delivers on revenue goals, while also benefitting patients.

Yet, there is an opportunity to achieve the goals of both the clinical and commercial sides when they work together for the same purpose. Key elements of this partnership include:

- **Quality product** – Focusing on the right site (internal or external) to produce a high-quality product that ensures patient safety and uninterrupted supply chain
- **Speed to market** – Avoiding launch delays prevents unnecessary cost overages and delivery on forecasted targets
- **Staying on budget** – Ensuring launch cost controls can make or break an organization, while risking financial performance and ultimately product success and patient access
- **Reliability of the supply chain** – Anticipating potential obstacles, including border closings, staffing shortages and material sourcing challenges will help mitigate any risks

Key Phase II to Phase III Considerations

How do you ensure your clinical plan will lead to commercial success? Start focusing with the end in mind, even when you are in Phase II:

GLOBAL LOGISTICS

It is important to think about global logistics and the countries where you will launch your new compound. For instance, assessing international regulations and the importation and exportation of a clinical trial medication in terms of time and cost, which will eventually be part of the commercialization plan.

For example, Brazil and Argentina have extensive regulations, yet lack standardized approval processes and times, making their rules more difficult to navigate. In turn, Japan sets a high bar with requirements but is very prescriptive, making it easier for companies to move through licensing and clearances. Consider this as you think about your importation strategy for Phase III trials, especially if you have cold chain products and are planning to launch, and not just conduct clinical studies in these countries.

Additionally, being proactive regarding temperature requirements, the risks of moving materials around the world, and depot selection/management are critical. Do you use single hubs in Asia or go country specific, such as in China or Japan? Keeping in mind these clinical trial considerations will have an impact as you transition to Phase III. Ensuring you are on top of these considerations, in addition to regulatory requirements, will be the keys to commercial launch success.

FINALIZED FORMULATION

Moving from Phase II into Phase III clinical trials, you

must be confident in the final formulation for launch, the dosage form and strength, and how it will affect patients. This information will drive manufacturing and packaging requirements such as the manufacturing/packaging site, package design and regulatory submissions.

Phase III to Commercialization Considerations

Several considerations can help save cost and time for launch and can be initiated in Phase III:

STABILITY
While having vial stability at -20°C might work for clinical trials, it's important to think about the move toward commercialization, as there are additional cost impacts and supply chain challenges of going to market with a -20°C product. Can you distribute to remote countries, and will those countries have proper cold chain capacity? The cost can be considerable for the supply chain and reinforces why stability testing at different temperatures is essential.

There are also packaging considerations: some products require specialized or specific packaging materials, which often require a longer lead time. By determining your products stability across a range of packaging formats early you will be able to shave commercialization costs and simplify your supply chain.

TOOLING
Phase III trials can be conducted by purchasing commercial tooling up front. If you're looking to scale over time, perhaps because first-year volumes are low with a small patient population to start, tooling for Phase III may be adequate for the first year. You can later scale up to increased volumes and larger-scale equipment. If you have a smaller patient population for the duration of your commercialized product, you'd need to purchase the tooling only once.

SHIPPING STUDIES
Additional shipping studies may be needed for different temperatures. As we saw during the pandemic, some products for COVID-19 went to market, often to remote areas, at -60°C, with others at -20°C. These products are now being tested to eliminate these requirements. In a more traditional launch timeframe, you would have adequate time to conduct the additional studies. Conducting shipping studies early on saves time and

money moving into the commercialization process. The cost savings and simplification of the supply chain greatly depends on product viability and key learnings from the studies.

PLACEBO SUPPLIES

It's a good idea to produce some additional placebo supplies while running a Phase III trial to conduct engineering trials later. It is particularly important with biologics, to save on cost and time. Often, it costs less to manufacture the placebos during Phase III. Once the run is set up, it is much more cost effective to create whatever quantity you need and put them aside for later.

If you're working with safety syringes or autoinjectors, creating additional supplies during Phase III will eliminate the need for a production run later. Many organizations that fill syringes don't want to do a one-off, nonactive run, and it can be costly to jump into the schedule later to do so.

SCALABILITY

As you go through your planning process, it's important to think about whether you will launch with a fully commercialized model that serves the long term, or whether you just need a model to get through the early years. It's essential to understand your organization's tolerance for risk versus the level you want to scale up.

Package Development

One of the most common mistakes when it comes to package development is getting locked into a package design that looks great and works well for patients but can't be produced efficiently on standard commercial equipment. Often pharmaceutical companies will have a package designed by an advertising agency that isn't as familiar with the equipment needed for production.. When this is then given to a supply chain outsourcing partner to manufacture the packages on an assembly line, they discover how difficult and costly it is. There is an opportunity to make these changes during Phase III to ensure the commercial packaging is feasible at scale. Other important packaging considerations at this stage include:

HUMAN FACTOR TESTING

The most time-consuming part of the design process is human factor testing, in which the package is tested for overall feasibility, child resistance and/or ease of use by seniors. Is an autoinjector, for example, working properly? Do patients like it? Would it work for at-home use versus in a hospital setting? Are you overengineering the package or under-engineering it? These studies typically take two to six weeks, so conducting them early is key. If the package proves unsuccessful in testing, more time will be needed to adjust it and test again, pushing out the launch timeline.

PATIENT COMPLIANCE

Early planning to create a package that fosters patient compliance often has benefits beyond just ensuring that patients adhere to their dosing schedule. You may very well see higher sales because patients are getting results with the product when taken as indicated and thus promptly refilling their order the next month.

BARRIERS TO ENTRY

Creative packaging with unique attributes is a great way to provide market differentiation and barriers to competitors. Premium packaging costs may deter generic competition from entering the market. The same concept can be used to enable product line extensions by introducing new modes of administration to extend patent life.

RAPID PROTOTYPING

There is a lot of lab-scale equipment that can create packages for marketing studies, which helps marketing teams determine the commercialization strategy. Consider leveraging package development laboratories that use this kind of equipment to create prototypes quickly.

Ensuring a Seamless Transition

To ensure a seamless transition from clinical trials to commercialization, take the needed steps in your late-stage clinical trials. Project management overlap and handoff is key for a smooth knowledge transfer. Ongoing visibility between clinical and commercial teams is also needed. While this doesn't have to occur on every phone call or even during a weekly touch point, schedule higher level meetings to create visibility.

Visibility can also be enhanced by:

- **Cloud-based platforms**, which show you every touch point in the process in real time
- A **master timeline** that tracks important milestones, such as stability study results and package design confirmation — critical to the commercialization timeline
- **Keeping documentation in one location or portal** and/or making sure it is transitioned before the product gets to the end of Phase III.
- **A list of items** that can be generated during trials that could benefit commercial teams. For example, excess clinical inventory available for commercial team use.

It's possible to achieve the corporate goal even if your organization works as separate teams. Experts who liaise between both clinical and commercial teams can guide you through the supply chain considerations at the appropriate points in the product journey. Also, internal planning processes that include stakeholder meetings at key stage gates are helpful. Stage gate meetings with key decision-makers are critical to set up and can help facilitate quick decisions at key milestones. This will help ensure that plans stay on track and your launch moves as quickly as possible.

Getting to Market as Fast as Possible

RAPID LAUNCH TIMELINE

Around 10% of products require a Rapid Launch, which can range from one day to one week from FDA approval.

With products that are smaller volume, such as rare disease, often one lot is enough to get you to market first. In these scenarios, handoffs are critical. Therefore, it is important to conduct a trial run a few weeks before a Rapid Launch. It requires you to be intimately involved with your vendors and to agree on how fast you'll turn around documentation and provide signoffs.
You may also need to work with external vendors for any components being used, such as patient information leaflets. As the last items are approved right before launch, these inserts must be turned around within a few hours in a Rapid Launch and it's crucial to get vendors' commitment to this timing in advance. Having that strong relationship with and commitment from vendors early on is critical to eliminate component risks.

LATE-STAGE CUSTOMIZATION

Often, you may be launching your compound to several countries, and there may not be the volume requirements that support a larger packaging run. A newer option that helps to streamline the packaging as well as reduce costs and wastes is called late-stage customization. This newer technology provides the ability to customize at the time of distribution or approval (including serialization, adding inserts and finishing coding). This allows for the completion of some of the packaging preapproval, to save time later. It also reduces waste because large quantities of a product are not being produced and then destroyed if something changes. Late-stage customization also allows for flexibility so you can label your product specifically for whatever country you are targeting. This tactic provides updated technology, digital printing capabilities and small-scale packaging equipment, making late-stage customization a viable long-term option for many products coming to market.

DIRECT-TO-SITE SHIPPING

Lastly, commercial direct-to-site distribution enables faster speed to market. Being able to ship directly to a pharmacy

warehouse instead of a holding depot, for example, eliminates a step in the process. This also reduces damage to the product from additional shipping and handling and saves on the cost of the second shipment.

In Conclusion

Drug launches can be rife with struggles. The journey from clinical trials through to commercialization will be far more efficient and cost effective for companies with a smooth, seamless handoff from one stage to the next. If you are outsourcing clinical or commercial work, it can help to have a partner provide integrated services throughout the entire product journey. Many times, they can help connect the dots between phases where your own organization may not. Ultimately, early engagement between clinical and commercial teams, due diligence, and careful planning can help keep a launch on time and on budget — resulting in greater revenue recognition while simultaneously removing stress from the launch process.

About the authors Michelle D'Angelo & Tim Roberts

Michelle D'Angelo, Sr. Director of Commercial Sales at PCI Pharma Services, is responsible for the East Coast Sales team and executing PCI's go-to-market strategies. She has over 21 years of pharmaceutical packaging experience including both Clinical and Commercial. Michelle has an entrepreneurial leadership style and a proven track record of revenue growth. Building strategic relationships through trust and value creation is her specialty.

Tim Roberts is Chief Commercial Officer at PCI Pharma Services and is responsible for their global multi-segment Sales team and aligning PCI's go-to-market strategies across Clinical, Commercial and CDMO. With over 22 years pharmaceutical packaging and manufacturing experience and a proven track record of organizational/revenue growth, Tim is highly service-oriented with a firm understanding of the full business equation, client service and consultation.

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