norstella™

Guiding you from pipeline to patient

6 STEP GUIDE

Successfully navigating complexities of drug development

Not only is developing a new drug expensive, but an extraordinarily lengthy and complex process. In fact, some estimate that drug development can cost upwards of $2.8 billion and take 10-15 years.

From the initial stages of drug discovery, clinical trials and regulatory approvals, to pre-and post-launch strategizing and commercialization, pharmaceutical companies face numerous obstacles and uncertainties. The pharmaceutical landscape is highly regulated, and navigating it can be challenging, even for experienced professionals.

If you've never traversed the pharmaceutical landscape before, you'll likely need a guide to succeed. Or, even if you have experience in a particular life cycle stage, you may not have the breadth of knowledge required to make informed decisions at every step.

To remedy this, many manufacturers utilize outsourced help for each development stage.

There are five key steps in the process:

1. Discovery and development
2. Preclinical research
3. Clinical research
4. Regulatory drug review (e.g. FDA)
5. Post-market drug safety and monitoring

Providing insights that span the entire drug development life cycle is critical to successful commercialization and market access especially when it comes to:

- Understanding the competitive landscape.
- Modeling the risk and return of every drug in the market.
- Understanding the global clinical trial landscape, design and develop trials.
- Building pathway strategies to ensure optimal access.
- Smoothing access to patients by helping physicians.
- Understanding the post-launch landscape.

Understanding the competitive landscape

You're likely not the only manufacturer trying to develop a similar drug. There's a massive competitive landscape, and to navigate it successfully, you must employ data to understand where your drug stands.

One way to understand where you fall within the competitive landscape is by benchmarking your drug against previous and current drugs. If you are between different molecules or a molecule has various applications, you may be uncertain about which indication to pursue.

In this scenario, RWD, including payer data and RWE, can aid in benefits and risks of a drug or therapy, predicting future uptake by examining historical trends such as sales volumes, peak sales, and net product value. Additionally, this data and evidence can assist in understanding the reimbursement and competitive landscape across different indications to identify the most suitable one with the least amount of restrictions.

Often, one of the most challenging aspects of this step in the drug development process isn't finding this data or evidence but consolidating it into one space and deriving insights.

> *"We use Biomedtracker and Datamonitor Healthcare from Citeline to gain an in-depth understanding of drugs in late stages of development to choose where we as an organization pursue cost and comparative effectiveness evaluations."*
>
> **– Director of Pharmaceutical Intelligence, Independent Non-Profit**

Modeling the risk and return of every drug in development

Creating a new drug involves significant investment, time, and risk. Therefore, utilizing data and evidence to decrease risk and increase returns is crucial for manufacturers.

When understanding the risk and return, it's essential to determine:

- Is your molecule meeting the unmet needs of patients?
- Is that need consistent or growing?
- Is there enough market potential to justify such a significant capital investment?
- Where can this molecule fit in the target standard of care?

To reduce risk, one of the earliest analyses that must occur is between potential molecules. It's in a manufacturer's best interest to identify and screen multiple drug candidates before moving forward toward development. Choosing the most promising candidates can help to reduce the time and cost of drug development and ensure returns on an often substantial investment.

An additional way to lower risk and increase returns is to use historical evidence and insights on drug approvals to estimate how long it will take to get a drug approved and develop more accurate cost and profit projections. This information can help companies make more informed decisions about which drugs to pursue and allocate resources effectively.

Finding the answers to these questions isn't always straightforward, making working with a partner who uses data and evidence as a guide is invaluable.

Understanding the global clinical trial landscape and developing trials

After determining a need to bring your therapy to market, your next step toward launch is designing and executing a clinical trial. And with 90% of clinical trials failing, meticulous and strategic planning is necessary.

Manufacturers can be more strategic by leveraging real-world data (RWD) sources, such as (closed) claims, lab, and EHR data, when designing clinical trials.

For example, by using RWD, you may find that relapsing patients of a particular subtype benefit from therapy. Not only does it help them clinically, but it also reduces their expense to health systems, making these patients ripe for recruitment. This type of information lends to a robust trial enrollment strategy and is the key to success, considering that meeting enrollment targets is a common struggle for clinical operations teams.

It's difficult for clinical operations team when, after moving through phase 1, they suddenly need hundreds or even thousands of patients to build out their clinical trials. Not only do they need to scale their patient numbers quickly, but they typically need to find more sites that may or may not be within the United States.

In the past, people have relied on contract research organizations (CROs) to run their clinical trials, but nowadays, that often isn't enough. Enabling your clinical operations team to be on time, within budget and recruiting the right patient population to ensure your trial will meet all the requirements ahead of regulatory approval is critical.

Building pathway strategies to ensure optimal access

Finding a drug that meets an unmet patient need, is deemed worthy of investment, and after having proven it to be safe and efficacious, it feels like having run an entire marathon, but when you reach this point, it's almost like your back is at the start line.

"We use Evaluate pharma data as our go-to 3rd party source to see trends and development of the pharmaceutical market - specifically individual accounts and molecules. We then look at revenue projections and investigate the most important accounts/customers. With this data, we can better understand business process workflows and how that translates to relevant KPIs that can be measured. It also allows us to function with more of an integrated mindset and think about CapEx investments and the prioritization of scarce resources. All of these insights are coming from Evaluate."

- Customer Insights Sr. Manager, Premier Biopharma Company

Just because a drug is safe and effective doesn't mean payers will cover it or health systems will make it available. Manufacturers must build effective strategies to ensure commercialization success in the marketplace and patient access.

Common barriers to patient access include:

- High costs.
- Existing reimbursement structures.
- An evolving pharmaceutical landscape.
- Identifying providers who are treating these patients.

To ensure optimal access, it's important to find a partner who helps you understand the context around these potential barriers by providing you with comprehensive insights and analytics such as historical coverage trends for therapies similar to yours, physician prescribing trends, and patient patterns.

Smoothing access to patients by helping physicians

A large part of ensuring patient access is communicating with the right providers so they feel confident to prescribe your therapy or treatment. Naturally, a common roadblock is not knowing who to speak with and where these providers are located.

One way to accomplish this is through lab data. This data will show you which physicians have ordered lab tests are a clue that a provider might be on a path to diagnosing a condition your product will treat. Once you've identified your target healthcare professionals (HCPs), it's crucial that they are aware of the safety and efficacy of your medicine and ensure they actually have the product available.

The right partner will help you create a robust commercialization plan including marketing distribution, dispensation, and patient services plans to help you identify and get in front of providers and ensure they can dispense your product to patients.

Understand post-launch landscape

Even after your product is ready to go to market, you still need to consider a post-launch environment.

You and your team will need to ask yourselves:

- Is this the right indication?
- Are there other indications we should look at?
- Have we launched it in the right region?
- Is it being sold at the right price?
- Which competitors should we watch?
- Has anything in the competitive and product landscape changed?

"The partnership with MMIT has been critical to our success. We recently changed our go-to-market model to be more in-line with a traditional pharmaceutical model - contracting with PBMs and payers - to improve access to our products to reach as many patients as possible. We used MMIT's foundational platform to segment our customers and prioritize where we wanted to invest the majority of our time from a targeting perspective. We also utilized other MMIT solutions to help with a payer marketing campaign. Our commercial access footprint has really grown, and we rely on a dashboard that gives us a heat map of good / poor access in various states so that we know where to focus our efforts."

- Sr. Director Market Access, Pharmaceutical Company

To answer these questions, companies can leverage payer data to monitor and enhance strategies to ensure long-term coverage. Payer data also helps to identify potential hurdles.

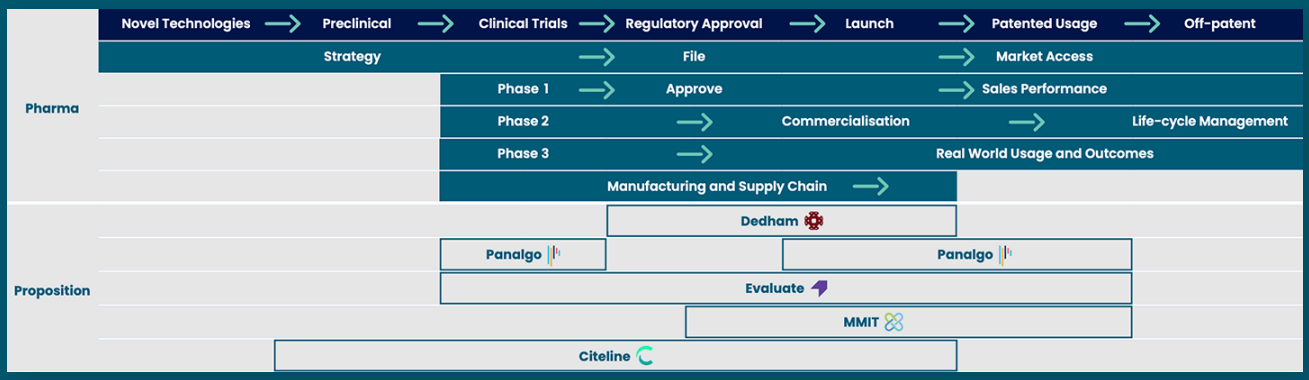
For example, some payers may require a step through existing treatments, which limits access. You may have to run a study comparing your molecule and another treatment head to head as a first therapy in the treatment pathway.

While this doesn't always happen, leveraging rich data sources to anticipate these issues, you can prepare and plan.

"Panalgo's IHD platform is very intuitive, straightforward and flexible. It requires no internal infrastructure built to conduct analytics, from descriptive to hypothesis-testing, quickly. Panalgo has the most responsive and knowledgeable customer support staff. The new foundational learning program, along with the on-site training, and customer support really triangulates the onboarding process to get staff up to speed quickly and efficiently."

- Sr. Director, Drug Safety & Pharmacovigilance, Leading PharmaCompany

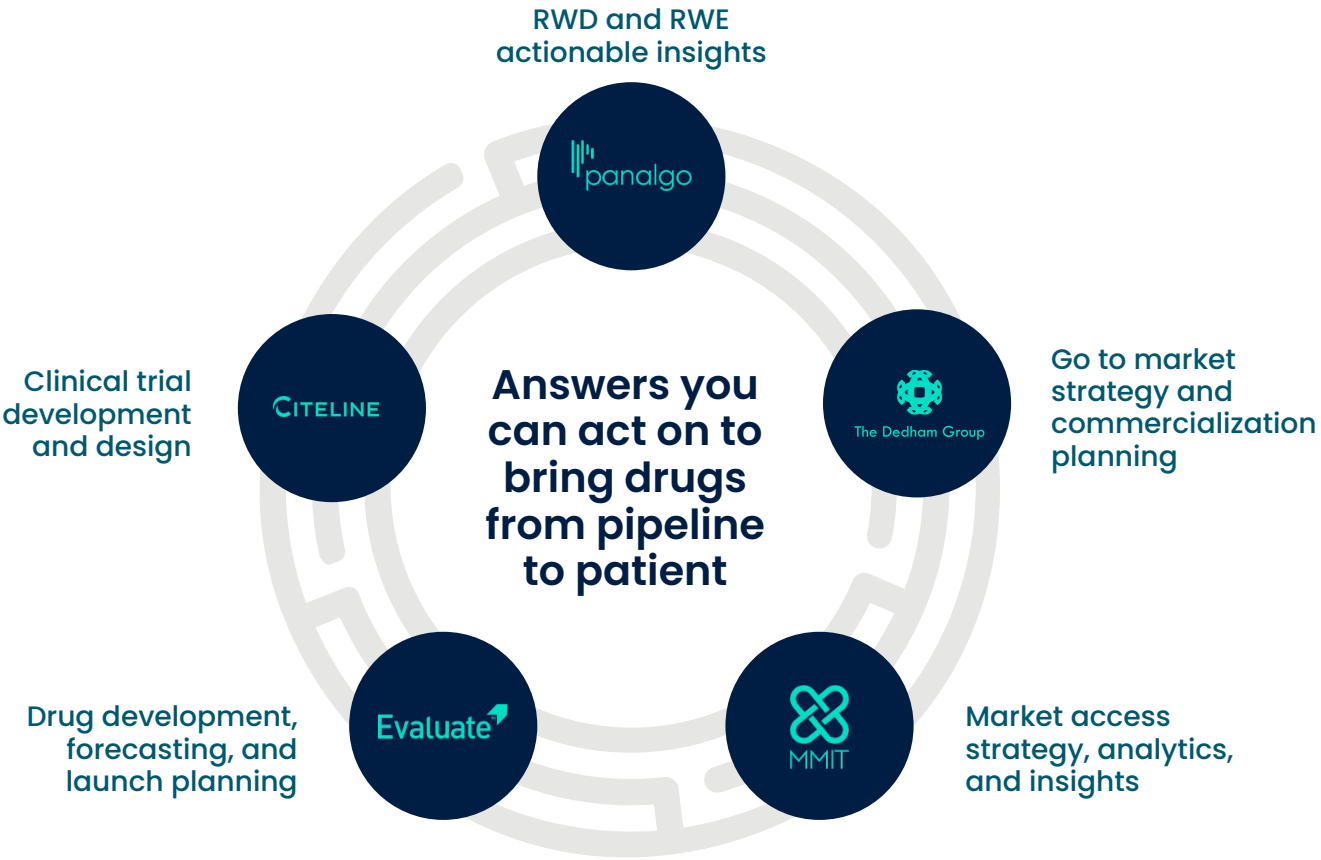
At Norstella, each of our brands offers unique solutions to help inform and guide client decision-making all the way from preclinical to post-launch.



Our cutting-edge data solutions and expert advisory services, paired with RWE, and advanced technologies to support insight generation such as machine learning and predictive analytics, help guide manufacturers through the complexities of drug development.

Norstella provides pharmaceutical manufacturers with the answers to the questions that keep them up at night. Answers that help them get the right treatments to the right patients at the right time.

> *"With so much change and noise, it's hard to focus our people and resources. No one is closer to the customer than The Dedham Group, which gives us a huge competitive edge on a daily basis."*
>
> **- VP, Oncology Franchise**



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Get answers to your most pressing questions