DEFINITIVE HEALTHCARE
Discover opportunity

Optimizing your pre-launch activities to impact time to peak sales

A Definitive Healthcare special report

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The commercialization process is increasing in complexity

Advances in science, technology and artificial intelligence are revolutionizing the way that we diagnose and treat disease. Pharmaceutical and biotech companies continue to innovate around new manufacturing and commercialization approaches, enabling them to create and deliver more effective therapies for the patients who need them.

The use of new technology and methodologies has prompted a shift in the industry. Previously, most organizations focused on population health drugs, for which large markets and easily understood intervention points made the path to successful commercialization relatively straightforward.

Now, biopharma companies are increasingly building therapies for more targeted patient populations with historically poorly treated diseases. In fact, roughly a third of all private investment made in life sciences in 2021 (nearly $68 billion) went to companies developing cell and gene therapies.[1]

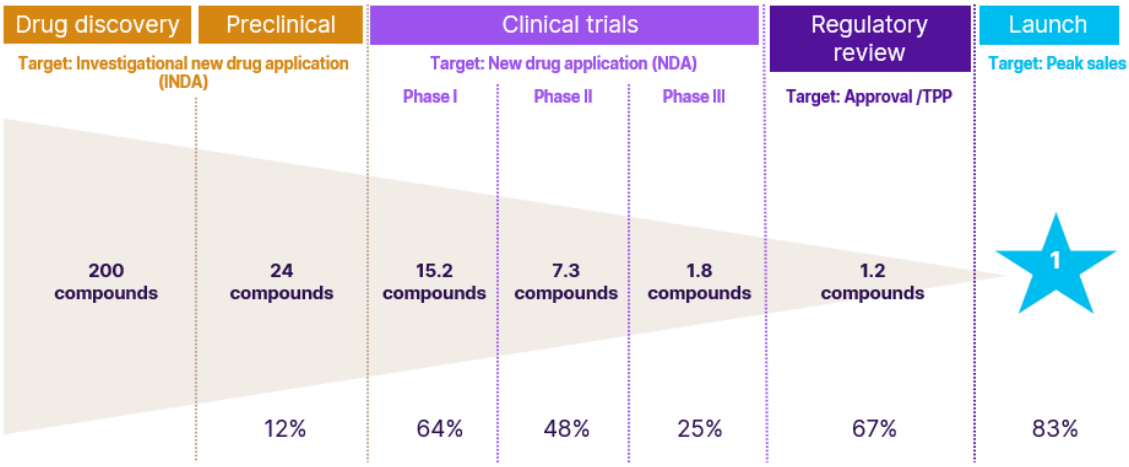
As companies shift to target smaller, more complex patient populations, they face some challenges inherent to commercialization of more complex therapies. In this biopharma industry brief, we'll examine some of the key challenges that exist, particularly in the early phases of commercialization, and review some of the ways organizations can address them. Chief among these challenges is the identification of treatment-ready patients and appropriate intervention points.

The impact of accelerating commercialization phases

With a total timeline of more than 10 years[3] and an estimated investment of up to 2.8 billion dollars[4], the stakes for approval are high, and biopharma organizations have a large incentive to "get it right". Success means that life-changing therapies reach the patients who need them, while a failed launch means a disappointing end to multiple years' worth of work and investment—and possibly the end of the line for the brand or company.

It is estimated that as many as 90% of drugs that enter clinical trials fail to gain approval for clinical use[5]. When looking at the commercialization process up close, we can see that the first phases are where a potential drug candidate is likely to fail.

MOLECULAR ENTITY SUCCESS RATES BY STAGE[2]

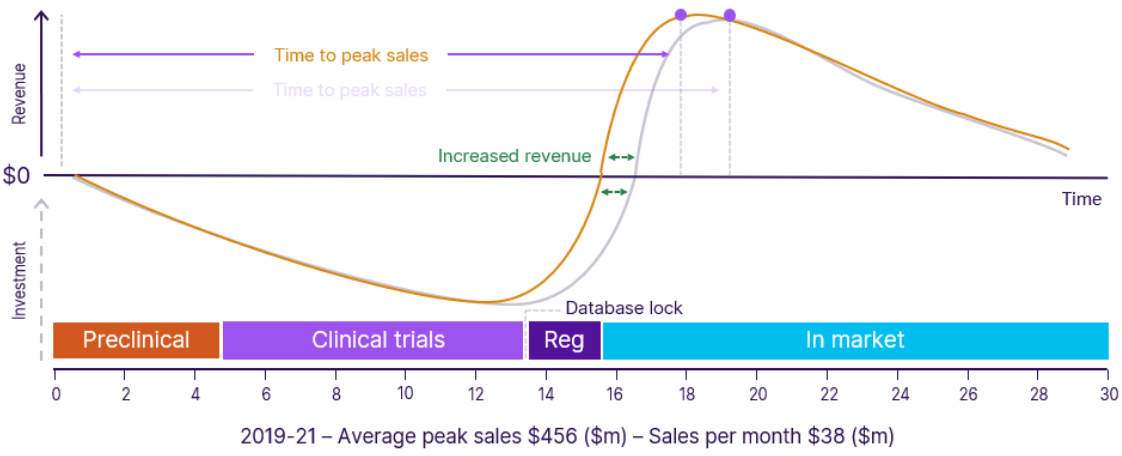


5 year rolling average New Molecular Entity Success Rate — 14/20 Top pharma 2010/15

With such high failure rates, lengthy timelines and massive investments, competition is fierce. As a result, being first to market is key—especially as the industry moves to target smaller, more niche populations. A 2014 study on first-mover advantage from McKinsey & Company supports this. According to the study, the "first-mover advantage is more pronounced in specialty areas with small numbers of prescribers and patients.[6]"

As illustrated in the chart below, not only does being first to market provide a competitive advantage; it also translates into significant revenue potential for an organization. With average monthly sales equaling $38 million, even shortening launch timelines by one month can have a real impact on a business.

IMPACT OF ACCELERTING PRE-LAUNCH ACTIVITIES[7]



5 year rolling average New Molecular Entity Success Rate — 14/20 Top pharma 2010/15

It's clear that biopharma organizations need to move as quickly as possible to reduce their financial risk. Yet, as illustrated above, each step in the commercialization pathway represents a significant likelihood of failure. Companies must utilize all tools available to increase their chances of receiving FDA approval and subsequent commercial launch.

Identifying and addressing data silos across clinical and commercial teams

In the biopharma world, medical affairs operates as the bridge between a company's R&D and commercial functions. Ideally, all three teams work together to identify, understand and develop market and clinical opportunities.

The insights and analyses collected by each team inform and drive commercialization across the organization. As targeted patient bases become more nuanced and complex, organizations are increasingly seeking greater collaboration and integration between teams' data and insights.

To achieve greater efficiency and discover opportunities faster, organizations can (and should) utilize a unified dataset to create a single, shared source of truth. Providing cross-functional teams with access to a single data source not only removes data silos, but also creates alignment as all teams can create reporting using the same underlying set of data.

By bringing together formerly siloed datasets and insights, companies can more easily anticipate and respond to ongoing market movements and behavioral shifts. As market conditions develop, pre- and post-commercial teams can address common challenges in real time using patient and physician data to perform critical tasks like:

- Design trials around target patient diagnosis, procedure and prescription data
- Identify ideal trial sites based on patient acquisition success rates and other factors
- Monitor incoming and external data to modify trials as they're being executed
- Inform more personalized communication to providers and potential key opinion leaders

The applications for a comprehensive, unified dataset are only as limited as a team's imagination. Let's dig a little deeper into one of the key uses in our next pre-launch activity: trial site identification.

Optimizing trial site and principal investigator selection

Clinical trials are tough nuts to crack. The aforementioned ~90% failure rate is driven by a few key factors:

Many trials have a drop out rate of up to 20%[8], 86% of trials do not meet enrollment timelines[9], and 30% of all Phase III trials fail due to enrollment challenges[10]. Luckily, biopharma companies can mitigate some of these issues by using data to more effectively drive patient recruitment.

20%
Trial dropout rate

86%
Trials do not meet enrollment timelines

30%
Of Phase III trials fail due to enrollment challenges

As more organizations revisit historic enrollment estimates versus actual performance, it's becoming clear that many investigators overestimate their capability to attract and retain patients. Organizations can leverage payor claims data to identify the right patients and involve those patient groups in the development of their trials. This ensures participants' voices are heard, leading to greater efficiency and, ideally, higher retention.

Using advanced analytics and AI technology like natural language processing, biopharma companies could potentially process data within electronic health records to match more of the right patients to the right trials faster.

Good commercial intelligence offers other ways to understand opportunities for improvement and bring patients closer to pre-commercial efforts. Patient-level data and real-world evidence can enable more effective referral mapping, demystify the patient journey and highlight more efficient intervention points for complex patients who would otherwise be misdiagnosed or not considered for a trial. They also offer insight into the providers who have capacity and expertise to take on a trial, and into the thought leaders who can communicate your successes to the larger medical community.

Engaging the most impactful key opinion leaders

Working with more complex patient bases and therapy areas require greater levels of expertise at every level. When it comes to identifying the external experts best suited to spread the word about trial results or other developments, it's helpful to accurately quantify the know-how and industry impact of any potential candidate.

Moving past the one-size-fits-all model of medical expertise requires an understanding of the individual's persona, skills and additional areas of focus beyond their therapeutic area. It also helps to know who has a preference for trials, speaking skills or experience developing trial guidelines. Claims and profile data make it possible to quantify and compare these factors from candidate to candidate.

These data also allow organizations to react to changes in expert activity according to commercial milestones. Early on, the ideal expert may be someone who can inform trial design or provide advice and consultation, but as commercialization nears, the right expert may be an exceptional speaker, someone with an expansive collaborative network or a deeper reach into a particular therapeutic area.

By quantifying expertise and analyzing expert profiles at scale, organizations can develop real competitive intelligence:

- Who else is an expert working with?
- What are they focused on?
- What do they value in their professional relationships?

The rise of social media and its usage among healthcare professionals has led many medical affairs teams to seek insights in social media data. Depending on an organization's therapeutic focus and commercialization needs, the ideal expert may need to be a digital opinion leader—a healthcare professional whose influence extends beyond academic journals and medical conferences and into the growing digital landscape. Data such as follower count, social engagement and audience demographics provide additional layers of context around an expert's ability to meet an organization's needs.

Bringing it all together

Today's commercialization efforts demand an integrated approach that is thoroughly comprehensive. No longer can commercial, R&D and medical affairs teams operate in silos and collaborate on a periodic basis. Finding success in complex therapeutic areas with highly specific patient bases requires an organization to operate as an integrated unit. Organizations also need to utilize functional market feedback loops to analyze and respond to real-time data as commercialization progresses.

This isn't a what-if scenario: the tools and expertise to implement and act on this intelligence are available right now, putting a data-driven strategy within reach for any organization with the initiative to capitalize on it. The biggest obstacles that contribute to clinical trials' high failure rates—identifying ideal patients, trial sites and clinical experts—can all be mitigated with a good data strategy.

BIOPHARMA COMPANIES SHOULD MAKE THE MOST OF THEIR PRE-LAUNCH ACTIVITIES BY:

Starting with reliable data

Accelerating clinical trials

Engaging the best KOLs

1. https://www.cellandgene.com/doc/cell-gene-therapies-investment-outlook-in-beyond-0001
2. https://www.researchgate.net/publication/277026797_Recent_trends_in_specialty_pharma_business_model
3. https://go.bio.org/rs/490-EHZ-999/images/ClinicalDevelopmentSuccessRates2011_2020.pdf
4. https://pubmed.ncbi.nlm.nih.gov/32125404/
5. https://www.sciencedirect.com/science/article/pii/S2211383522000521
6. https://www.mckinsey.com/industries/life-sciences/our-insights/pharmas-first-to-market-advantage
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8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4688419/
9. https://repository.upenn.edu/cgi/viewcontent.cgi?article=1004&context=crp
10. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3684189/

About Definitive Healthcare

At Definitive Healthcare, our passion is to transform data, analytics and expertise into healthcare commercial intelligence. We help clients uncover the right markets, opportunities and people, so they can shape tomorrow's healthcare industry. Our SaaS platform creates the path to commercial success in the healthcare market, so companies can identify where to go next.

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