

The Evolution of Product Launch

Within the Life Sciences industry, pre-launch activities and market dynamics are a critical determinant of a therapy's ultimate success in the market.

Launching a new biopharmaceutical product or indication requires detailed planning and enormous coordination across scientific, commercial, medical, access, and delivery teams in the years leading up to approval.

Over the past several years Vynamic, an Inizio Advisory company, has experienced first-hand how launch strategy and operational execution have evolved to paramount importance. This evolution of product launch has been spurred by five key trends that are affecting Life Sciences organizations and the healthcare industry at large:

1. Increasing product approvals

The catalyzing force shaping the launch space over the past several years is the sheer volume of trials and approvals occurring in both US and global markets, leading to more market competition, especially in specialty and targeted therapy areas.



2. More approvals equal more competition and greater risk

The increase in product approval volume continues to shape the launch market by spurring activity in the 'co-promote' space, igniting talent acquisition battles and creating a market for specialty vendors to assist with optimizing key components of launch activities.

3. A changing regulatory landscape adds to launch complexities

One of the greatest shifts in the global regulatory ecosystem has been the development of pathways to safely streamline the approval process for exciting new therapies, such as the US FDA's Accelerated Approval Program. The use of these pathways has been on the rise for several years.



4. Drug development cost continues to rise

Although there is a greater access to investment dollars today, the rising cost of R&D is still something that a Life Sciences organization must be aware of. The estimated cost to bring a new drug to market is roughly \$2.6B, with that number expected to grow an estimated 3% year over year. Increasing pricing pressure and the cost of a clinical trial are two factors influencing this rising cost.

[Resource for \\$2.6B number here](#)
[Resource for 3% YOY growth here](#)

5. Outsourcing is going mainstream

To help manage regulatory complexity, streamline cost, and mitigate launch risk, more Life Sciences organizations are choosing to outsource certain aspects of product launches to strategic partners.

Given the variety of factors impacting launch activities today, Life Sciences organizations need to start early and operate within a structured yet flexible operating model that takes full pipelines into account. Leaders will need to be thoughtful about establishing clear team structures and goals to ensure that their cross-functional teams are moving in lock step as products approach regulatory approval.



To learn more, listen to Vynamic's Trending Health Podcast on the Evolution of Product Launch [here](#).