Early Adoption of an Integrated Product Development Strategy will Reap Dividends

With both the cost and time to bring a drug to market ballooning, the importance of an integrated product development (IPD) strategy is gaining traction. This multidisciplinary approach to drug development brings key stakeholders together, breaking down barriers to an efficient and cost-effective path to market. But while more organisations are adopting an IPD strategy, a recent industry survey found most aren't doing so early enough. Frédéric Pailloux, Senior Director, Head of Integrated Product Development and Consulting at PharmaLex examines the IPD journey.

The response to COVID-19 demonstrated how quickly and effectively new drugs can be released. While the circumstances were exceptional – nothing mobilises forces like a global pandemic – companies that embrace transformational strategies in drug development can also reduce timelines and costs.

Key to this is the early adoption of an integrated product development (IPD) strategy, a multidisciplinary approach designed to improve efficiencies from start to finish.

Unlike the long-established approach to drug development, which is phase driven with functions working in silos, IPD uses a holistic framework that integrates all functional teams, including clinical, regulatory and commercial.

Biopharma companies are increasingly recognising the ability of a strong IPD strategy to transform drug development, inviting participation from internal and external stakeholders across different platforms for the greater good.

In a recent survey commissioned by Pharmalex and conducted by Censuswide, almost half of the 107 senior leaders from US pharmaceutical and biotechnology companies polled had already implemented an IPD program or were conducting a pilot. Another third expected to roll out an IPD program within the next year.

The respondents work across a range of fields, at all sizes and stages of development, including biostatistics, clinical, regulatory affairs, patient safety, market access, medical affairs and CMC (chemistry, manufacturing and controls).

Almost all (98%) believe IPD is integral to their ability to innovate across research and development (R&D).

Indeed, innovation is essential in an industry that has seen the price of bringing a drug from conception to market double in a decade – a journey that takes more than 10 years and costs almost $2.6 billion.[1]

Those who have already invested in IPD and are starting to measure their returns believe the strategy will reap dividends in three key areas:

- Compressing time to market
- Increasing productivity
- Delivering on innovation

Over the next 12 months, industry leaders say they plan to bolster their IPD strategies, with the development and implementation of target product profiles (TPPs) or end goals; improved management of timelines, costs and resources; and the creation of more detailed strategic and operational plans to underpin a robust IPD.

But while companies are clearly warming to the value of a cross-functional approach that dismantles silos and promotes an agile and decisive response to myriad challenges, the data shows that most are starting their run too late.

Only a third believe IPD should begin early in clinical development, while almost half (48%) believe IPD should start at Phase 3, or after they have received regulatory approval.

This is despite an overwhelming number of those already in the process of implementing IPD believing that the strategy will help them meet key milestones (96%) and to identify where therapies could be marketed earlier (94%).

By pushing the adoption of IPD later in the drug development phase, companies are making it harder to capitalise on those key areas, which represent potentially huge savings in both time and money.

Creating a Road Map for the Future

When leaders from different disciplines and departments are brought together to form a cross-functional team at the start, a road map encompassing all areas of drug development can be created.

By inviting input from all parties, companies develop a clearer understanding of potential pitfalls at each stage of development, as well as a multidisciplinary approach to finding solutions. This, in turn, means decision makers are not stuck in silos, where counter-intuitive steps can be taken without knowledge of what is happening outside their self-imposed walls, but have a clear picture of the broader development program. This enables activities and decisions to be conducted in parallel across different functions, thus improving efficiencies.

Waiting until after regulatory approval to create an IPD strategy puts companies at risk of missing opportunities to change or adapt processes that could prevent budget or deadline blowouts.

Implementing an IPD strategy early in clinical development can help determine important points along the drug development journey, including:

- Data required to address pharmacology, safety and toxicology further downstream
- The best global regulatory strategy for client and business

objectives, as well as meeting agency expectations
- Suitable countries for clinical trials from a regulatory standpoint, global data acceptance and clinical cost perspective

While almost half of respondents say they plan to make their target product profiles (TPPs) a priority during the next 12 months, they should be identified early and referred to regularly.

The TPP is critical to the strategy because it forms the foundation for all the steps needed to move a drug through development and requires input from internal and external stakeholders, including regulatory and market experts.

While it will naturally evolve with the project, the earlier the TPP is incorporated into a company's IPD program, the better equipped the multidisciplinary team will be in an increasingly competitive landscape. It provides important context for the drug's position in the clinical setting, as well as the marketplace.

Moreover, when the early adoption of an IPD strategy is closely aligned to business objectives, industry leaders can:
- Align all stakeholders with the end goal – ensuring new therapies can be released without delays or budget over-runs and reducing duplication, such as repeated studies.
- Determine changes that will drive greater efficiency – this includes promoting more innovative clinical trial designs, as well as collaborative and integrated processes

Bringing Everyone Along for the Ride

Those respondents already implementing an IPD strategy report a strong focus on team alignment, efforts supported by cross-functional technology infrastructure (62%) and the contribution of cross-functional teams (58%).

While most involve all the key departments that support a drug's development, the degree to which certain functions are included in the multidisciplinary team depends on the company's size and stage. Only about a third reported involving patient safety, medical affairs and CMC.

Industry leaders should consider all functions and stakeholders when developing an IPD strategy to maximise the chances of a successful drug rollout and minimise waste and cost blowouts.

An IPD strategy that is stage appropriate, with the right subject matter experts at hand at the right time, will be more adaptable and better equipped to deal with new challenges.

For example, CMC is often overlooked as part of the strategy but a cross-functional model that involves CMC can help ensure adequate product supply and prevent bottlenecks at the launch stage.

Similarly, an early understanding of the regulatory environment and how it might affect a drug's development can provide a smoother path to approval.

It is also critical that functions associated with the end of the cycle, such as commercialisation, be brought into the planning room from the start of clinical development.

More than half the respondents already implementing IPD have identified commercial considerations as integral to the strategy, with 56% reporting that market access, pricing and reimbursement strategies were in scope.

However, to be truly effective, commercial considerations need to be incorporated from the get-go. While even the best-case scenarios can fall short, and clinical trials can still fail, a comprehensive risk-benefit analysis provides companies with more surety for the return on their considerable investment.

Overcoming the Biggest Hurdle

Industry leaders cited several obstacles to implementing IPD, including budget constraints and operational limitations.

One way around this is to form strong partnerships with like-minded external organisations, an approach that more than half the respondents have already adopted.

But what is seen as the biggest hurdle to an effective IPD strategy is the same across all organisation types, stages and sizes, with almost 40% identifying culture as the main impediment to transformational change.

When an organisation has traditionally operated in silos, with each department staking out its territory and fiercely defending it from perceived attacks on capability, accountability or performance, it is even harder to break down those walls.

The incentive to work together as a team is also seen to be hindered by overly complex processes (32%), the inability to keep plans current as factors change (32%) and the lack of technology to collaborate (30%).

With the push for change needing to come from the top, leaders can help initiate a shift in entrenched culture by:

- Cultivating the sharing of information and ideas, to show that integration is not only beneficial to everyone but rewarding
- Creating a cross-functional team that can be assembled and disbanded based on deliverables
- Empowering functional teams and the core program team, with each being positioned as the primary decision maker on specific deliverables
- Encouraging early input from internal and external stakeholders, including investigators and patients
- Designing processes that don't require an extended or laboured chain of approvals

While it requires considerable commitment from leadership, it is clear an IPD strategy is a powerful tool for changing both culture and outcomes.

By driving new ways of thinking, and encouraging the dismantling of silos, industry leaders can build a multidisciplinary framework for current and future challenges in drug development, helping to lower costs and improve the chances of commercial success.

The earlier this holistic approach is adopted, the more likely the integral pieces will complete the puzzle – and bring life-changing therapies to those in need in the safest, most efficient and cost-effective way.

Frédéric Pailloux

Frédéric Pailloux, PharmD, Senior Director, Head of Integrated Product Development and Consulting, at PharmaLex. He has extensive experience in regulatory science and quality assurance, both within the pharmaceutical industry and as a consultant

Email: frederic.pailloux@pharmalex.com