White Paper

Re-defining OPEX Modelling for a Competitive Future

How life sciences companies should rethink their approach to OPEX to maximize the value of investments, and drive success in launch.

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Introduction

When evaluating assets and launching products, pharma companies invest significant resources into forecasting revenues. But what about the other part of the profit equation? For operating expenses (OPEX), many pharma leaders rely on outdated assumptions, such as "OPEX spend should be 15-20% of revenue". It's one of the many outdated strategies embedded in the launch process that are no longer applicable.

In today's evolving post-Pandemic landscape, companies cannot simply rely on past launch outcomes to predict future results. Average launch sales in the first six months are still down versus pre-Pandemic benchmarks . Factors such as shifting portfolio mix, higher frequency and complexity of product launches, increasingly complex patient journeys, higher barriers to access, and changes to customer expectations for engagement with pharma companies are all changing the launch environment.

In response, pharma companies are building more targeted asset strategies and commercial plans to address the unique needs of patients, health systems, payers, and healthcare professionals (HCPs) in a fragmenting market. However, many are failing to adapt their OPEX plans to align with these strategies. This can cause overspend on activities that won't deliver value, missed opportunities to win greater market share, and failure to unlock OPEX resources early enough to get the launch off the ground. These missteps often force medical, access, and commercial teams to play catch up in the early critical months of a launch.

Companies are also lacking precision when evaluating and prioritizing early-stage assets for acquisition or progression through clinical development phases, which introduces avoidable obstacles to commercial success.

FIND YOUR BALANCE

To maximize launch potential in this environment, OPEX spending must be rebalanced to accommodate, and more accurately reflect, shifting trends. This requires a pro-active approach based on up-to-date industry benchmarks and insights regarding market dynamics and stakeholder needs. Modelling and predicting OPEX with greater accuracy aligns teams on true drivers of success. It enables smarter decision making and prioritization for optimal asset or franchise value.

To achieve this precision, many pharma companies work with partners, such as IQVIA, to inform their investment and launch strategies. Combining data assets with deep market expertise and practical experience in commercial strategy and launch helps IQVIA create robust asset, franchise, and enterprise-level OPEX models as the basis for smarter plans and data-driven investment decisions.

NOTE: In this article, we are defining OPEX as sales, marketing, and medical spend associated with a brand, excluding R&D expenses relating to registrational studies.

The launch environment is changing — it's time to adapt

Pharma companies launching new products in today's environment are facing increasing costs and complexity (cf. Figure 1).

With more than twice as many new active substance (NAS) launches occurring today compared to five years ago, competition is intensifying and markets are fragmenting across many disease areas. The new generation of treatments are generally more complex, often featuring innovative mechanisms of action (MOA) targeting the needs of more specific, smaller patient populations. These treatments require sophisticated development and manufacturing processes, which introduces new complexities into the production environment. As a result increasing R&D expenditure and cost of goods sold (COGS) have significantly outgrown sales, causing margins to tighten.

On the customer side, patients, payers, and HCPs are shifting preferences and expectations for how and when they want to engage with pharma companies, to reconsider their go-to-market models and channel mix.

All of the above factors entail major implications for launch and commercialization strategies, with knock-on effects on the size and distribution of OPEX investments. In today's launch landscape, pharma companies need to proactively plan how much and when to invest, and to determine which activities and investments will deliver the greatest future value. A more robust approach to OPEX modelling can help them create more targeted asset plans that better align with the complexities of the current healthcare environment.

Figure 1: Increasing cost and complexity of launches

INCREASING FREQUENCY OF NEW LAUNCHES (NUMBER OF NAS LAUNCHES, '21 VS. '16)[1]

2x

Increase in New Active Substance launches (84 in '21 vs 41 in '16)

GROWTH OF INNOVATIVE MOAs AND ORPHAN LAUNCHES (SHARE OF FIC AND ORPHAN LAUNCHES, '21 VS. '18)[1]

+18% & **+10%**

Increase in share of first-in-class drug launches — *Increase in share of orphan drug launches*

RISING PRESSURE ON MARGINS & INTENSIFIED COMPETITION (CAGR, '15-'19)[2]

+6.2% vs. **+3.9%**

COGS — *Sales*

FUNDAMENTAL CHANGE TO HCP ENGAGEMENT (SHARE OF REMOTE ENGAGEMENT)[3]

12% & **51%**

2010 — *2022*

Yet many companies still plan OPEX with traditional assumptions such as OPEX = 15-20% of peak sales

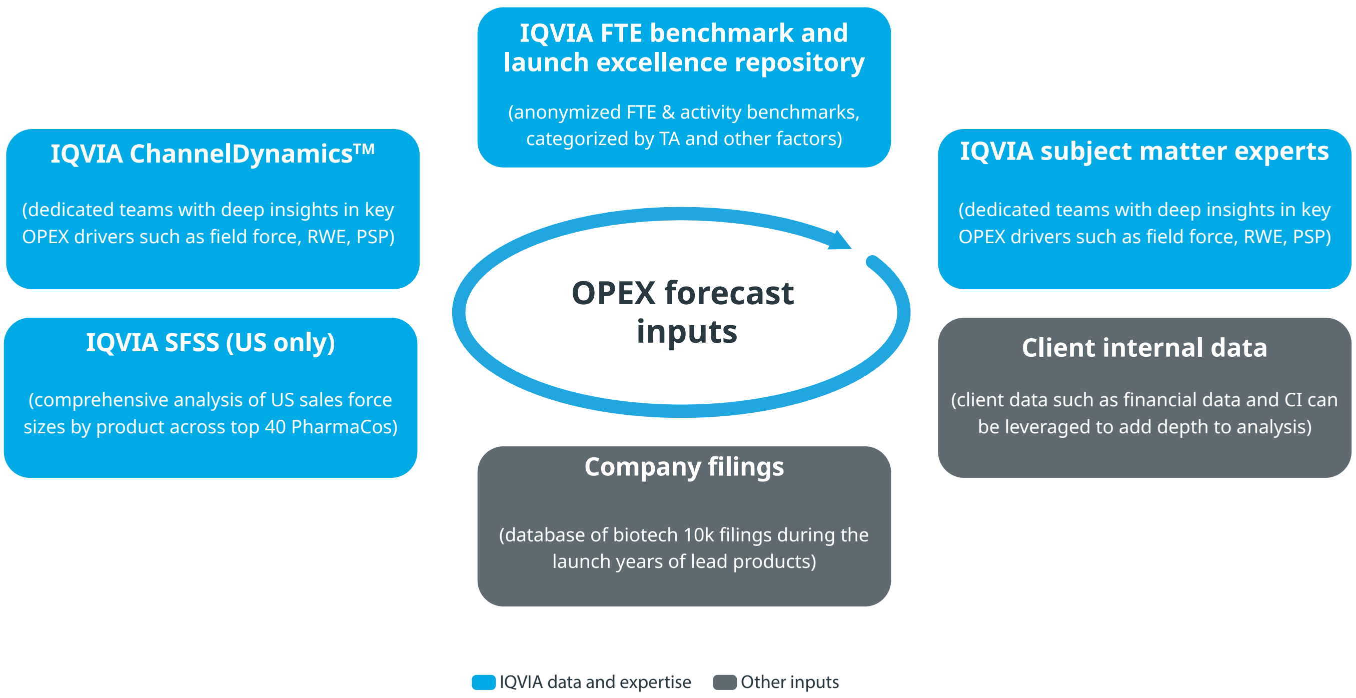
1) Global Trends in R&D: Overview through 2021. IQVIA Institute Report, 2022
2) Editing the DNA of Pharma Go-To-Market Models. IQVIA EMEA White Paper, 2021
3) IQVIA ChannelDynamics™; IQVIA analysis
FIC: First in class

An insights-led approach to OPEX

IQVIA has one of the largest healthcare data sets in the world backed up by its partnerships with leading pharma and biotech companies. Our approach to OPEX modelling builds on proprietary data assets, such as IQVIA ChannelDynamics™, and Sales Force Structures and Strategies (US), along with repositories of full time equivalent (FTE) benchmarks and costs associated with launch excellence (investments into Real World Evidence, Patient Support Programs, etc.). Our IQVIA approach is based on deep knowledge and extensive experience from supporting launches for many pharma companies (cf. Figure 2).

This depth and breadth of insight allows IQVIA to model benchmarks globally and across all disease areas, creating a picture of how much pharma companies have spent on previous and ongoing launches for different product archetypes.

Figure 2: Benchmark driven OPEX modelling



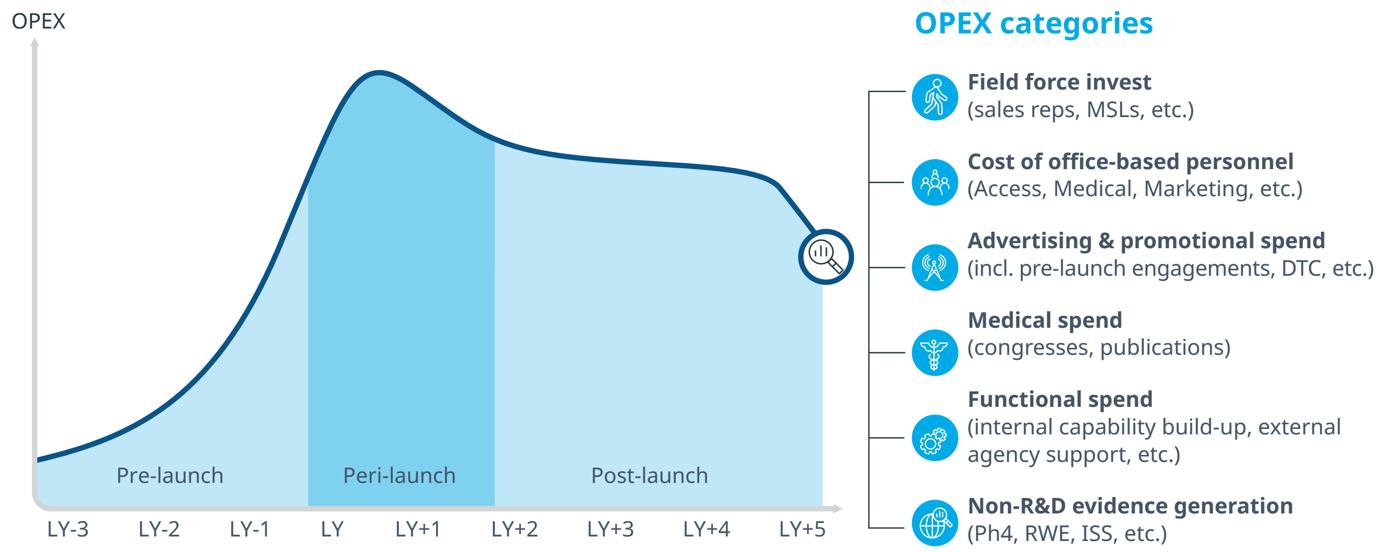
Gaining an understanding of what competitors invested in prior launches and how those investments paid off enables pharma companies to devise their own strategies to compete effectively. This can be particularly valuable where pharma companies have limited experience in the therapy areas, for example small / mid-sized biopharma companies or large pharma companies making forays into new treatment categories.

IQVIA combines this data-driven approach with expert insight, to bring a strategy-led point of view on current market dynamics and their impact on commercial strategies. Such an approach enables a significantly more granular, and better-supported outline of assumptions based on true drivers of launch success.

Decision makers can use these insights to create a tangible strategy for value maximization with a view on where, when, and how to best allocate investment across OPEX categories such as commercial channels, advertising and promotion, direct-to-consumer spending (in the US), medical spend, pre-launch engagements, and RWE generation across the stages of pre -, peri- and post launch (cf. Figure 3).

These insights also allow for war-gaming and comparison of multiple strategies, and enable adjustments to existing OPEX plans based on where additional upside can be gained.

Figure 3: Typical OPEX launch spend pattern and categories



Early analysis delivers better results

The value of OPEX planning is increased when it is carried out early in an asset's development, for example during Phase 2, or at the beginning of Phase 3 trials. Starting this early can be a tough sell for decision makers when it is still unclear whether the treatment will be approved. But if companies wait too long to invest, they could put an otherwise promising launch at risk.

An early, data driven OPEX assessment can help commercial teams convince decision makers to allocate sufficient funds. "Gated" investment strategies can be developed that unlock resources at key milestones in the pre, peri- and post launch environment. In this way, pharma companies can ensure sufficient funds are allocated to set the launch on a course for success, while minimizing investment risk.

Asset or franchise-level OPEX assessments should not be a one-off exercise. They should be revisited over the asset or portfolio lifecycle, ensuring OPEX plans reflect a changing environment.

ASSESSMENTS FOR EARLY-STAGE ASSETS

When evaluating OPEX for early-stage pipeline (e.g., pre-clinical or Phase 1) or external assets, to make go/no-go decisions or to prioritize indications, developing a full and in-depth OPEX strategy for each asset may not be feasible.

Here, the power of benchmark data can be invaluable: A data-driven benchmarking approach can be used to develop rapid and robust forecast models that predict OPEX requirements based on general product characteristics, such as therapy area or stakeholder universe size. This approach enables systematic and consistent comparison of OPEX needs across early-stage assets, helping pharma leaders to make smarter and more robust pipeline decisions.

Case Study 1: In-depth OPEX planning for new oncology portfolio

A top 20 global pharma company wanted to review their OPEX plans and pressure test the planned investment to stand-up a newly emerging oncology portfolio.

IQVIA supported the client by consolidating a variety of client-internal, IQVIA, and further external data sets, and analyzed them to generate OPEX benchmarks for various analogue products. This benchmark-led approach was complemented by a forward-looking perspective on differentiating capabilities required to build up a competitive new oncology franchise (i.e. 'what good looks like').

The outcome was a combined franchise-level view that pressure-tested the client's budget forecast and the implication on the company bottom-line. The assessment helped senior leadership understand what kind of OPEX investments would be needed to succeed across several tumor areas. It served to refine their investment plans granting increased confidence of planning and launch success, as well as enhanced transparency on the company's operating margin.

Case Study 2: A benchmark-driven approach to model OPEX for early-stage assets

One large pharma client recently sought support from IQVIA to develop a granular, data-driven approach to model OPEX in order to strengthen investment decisions for early-stage assets.

The company had a rich early and late-stage clinical pipeline, but its portfolio was shifting away from primary care and towards specialty and orphan products. They needed a more targeted approach to make go/no-go decisions on early-stage assets, given their OPEX forecasts were inconsistent and relied on high-level assumptions.

In partnership with IQVIA, our client developed a tailored archetyping framework, building a database of OPEX benchmarks and input factors that align with the archetyping criteria for the company's assets. Based on general asset characteristics (e.g., therapy area, HCP universe, market complexity) the model generated a full OPEX forecast based on detailed assumptions, defined with input from IQVIA experts as well as external industry experts.

Today, the model has been adopted across the organization and is used to predict OPEX investments for all early-stage assets, enabling a more consistent and smarter approach to decision-making in asset prioritization and progression to clinical development.

Future proof your launch

Beyond the case studies presented in this white paper IQVIA teams have built detailed projections for everything from rare diseases, to targeted therapies launching in a limited number of markets, to enterprise-level portfolios launched across several disease areas and a wide area of countries. These projections simulate trends in sales, marketing and medical of spend in different OPEX categories across the globe, and test the impact of changes in timing and spend on launch success.

If companies want to succeed in today's changing launch environment, they need to challenge the way they plan OPEX. Leveraging IQVIA benchmarks and launch expertise gives pharma companies the early insight they need to model scenarios and optimize investment decisions for better market results. Once a product launches, these OPEX projections offer an opportunity to re-evaluate progress and pivot strategies as needed.

When combined with Launch Performance Indicators, which bring visibility to success in early market preparation efforts, OPEX modelling is a valuable way to build rigor and consistency into launch planning. It won't guarantee a successful launch, but it can give pharma leaders greater confidence in their investment decisions and go-to market plans, thus minimizing the risk of over/under-investment in an ever-changing environment.

References

1. Launch Excellence VIII. IQVIA EMEA White Paper, 2022
2. Global Trends in R&D: Overview through 2021. IQVIA Institute Report, 2022
3. Editing the DNA of Pharma Go-To-Market Models. IQVIA EMEA White Paper, 2021

For information on how IQVIA can assist you in re-defining OPEX modelling for your early stage portfolio or assess invest requirements for your late stage assets, contact the IQVIA Commercial Strategy team.

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