White Paper

Success Multiplied: Launch Excellence for Multi-Indication Assets

How to capture the full potential of a pipeline in a product

MARKUS GORES, Vice President, EMEA Thought Leadership, IQVIA
KIRSTIE SCOTT, Consultant, EMEA Thought Leadership, IQVIA

MERCK EX1220
Merck Sharp & Dohme LLC v. The Johns Hopkins University
IPR2024-00240

Table of contents

Introduction	1
Multi-indication launches: Opportunities and challenges	2
Indication roll-out: Sequencing and speed	3
Performance consistency when launching multiple indications	10
Promotional investment strategies for multi-indication launches	12
How to achieve multi-indication launch success	14
References	17
About the authors	19

Introduction

The concept of a 'pipeline in a product' emerged with the rise of specialty care and has become firmly established since. Many specialty products are developed for multiple potential indications, which is possible because their mechanisms of action often target fundamental biological processes and pathways, such as the immune cascade, which underlie a wide range of disease states.

Targeted immunology products launched over the past 25 years, for example, have an average of four indications, while some, like the TNF inhibitors, have many more, with Humira amassing a total of 11 indications to date (see Figure 1).

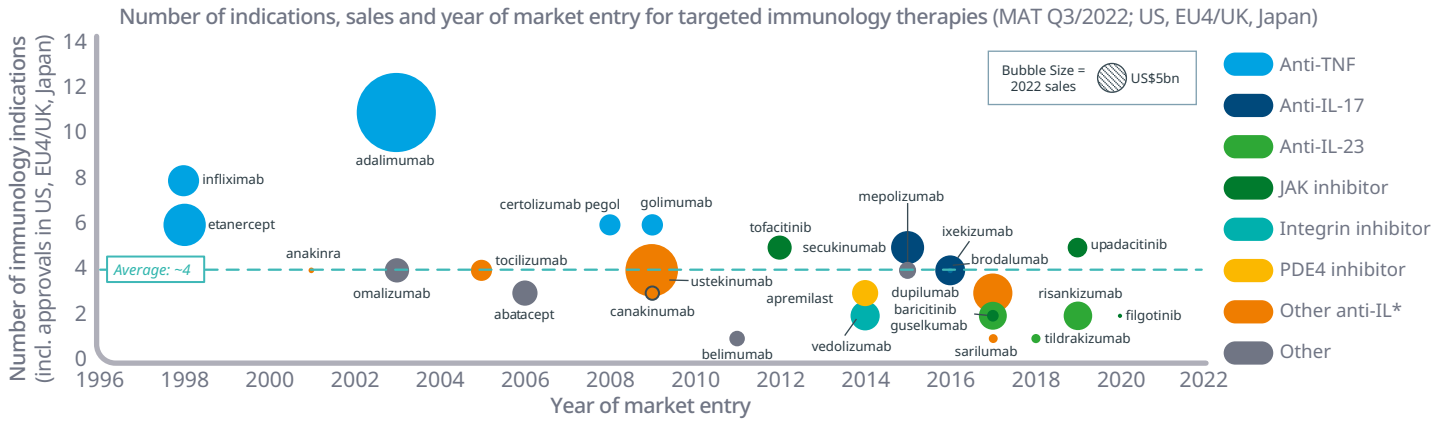
Oncology is another therapy area where multi-indicationality is common. Twenty-six percent of all novel cancer drugs launched in the U.S. between 2011 and 2021 to treat solid tumours were subsequently approved in multiple indications, while this was the case for 34% of all haematological drugs.[1] The checkpoint inhibitors are a case in point, e.g., with Tecentriq approved in 5 indications, Opdivo in 10 and Keytruda in an astonishing 19.[2–4]

Multi-indicationality is a relatively common feature among specialty products, however, it is worth noting that it can also be found in non-specialty products. The SGLT-2 inhibitors, for example, have proven their versatility and have been expanding beyond their initial indication in type 2 diabetes to treat heart failure and chronic kidney disease. Similarly, we are seeing several products originally developed for type 2 diabetes expand into obesity, e.g., liraglutide, semaglutide or tirzepatide.

Unlocking multi-indicationality is therefore critical to maximise the full potential of such assets. While multi-indication assets offer unique commercial opportunities to innovators, they also present formidable strategic and operational challenges.

In this white paper, we will explore the specific challenges that multi-indication launches face, review the different strategies such launches have pursued, and identify critical success factors for maximising the value of multi-indication assets. These insights are derived from a systematic analysis of launches of targeted immunology products, complemented by selected checkpoint inhibitor launches.

Figure 1: Unlocking multi-indicationality is key to success in immunology



* Includes IL-1, IL-4/13, IL-6, IL-12/23
Source: IQVIA EMEA Thought Leadership; IQVIA MIDAS Sales by Disease MAT Q3 2022; SBD targeted therapies only, category of "other diseases" excluded from indication count; all sales for the molecule are included (eg biosimilars).

Multi-indication launches: Opportunities and challenges

A 'pipeline or portfolio in a product' offers several attractive benefits to innovators. Firstly, the inherent, total opportunity potential of multi-indication assets is typically sizable. As such, a single asset can sustain future revenue streams over a longer time horizon as its additional indications are successively launched. Secondly, the scale of the combined revenue across multiple indications provides leverage in payer negotiations, for example, allowing innovators to offer attractive rebates to secure favourable formulary positions for all its indications. Finally, synergies can be realised during both the development and commercialisation of a pipeline in a product, e.g., by developing a deep understanding of an asset's mechanism of action or safety features which are applicable across multiple indications and help accelerate development efforts; by benefitting from potential customer overlap between indications; or possibly by creating a 'halo effect' in the marketplace across indications to drive incremental brand awareness spanning different HCP specialties and other stakeholders, thereby giving the asset a competitive edge.

However, compared to single-indication launches, innovators of multi-indication assets face greater strategic and operational complexity which manifests itself in specific challenges:

- **Indication sequencing:** A key strategic choice for a multi-indication asset is the order in which to develop and launch its different indications to maximise its commercial potential. This involves a number of important considerations, e.g., selecting initial indications where a highly differentiated benefit can be proven to secure an optimal price vs. gaining early access to the largest possible patient population.

- **Co-positioning:** A product with multiple indications which are simultaneously promoted in the marketplace faces complexity in optimally positioning individual indications alongside each other. While messaging needs to reflect a product's specific benefits in each indication and must be tailored to the needs of the relevant HCP specialty and the broader stakeholder audience, collectively, messages must be aligned to reinforce brand equity. This may also involve choosing between a single brand name used across all indications vs. different branding for different indications.

- **Pricing:** The relative value of a multi-indication product typically varies considerably across its different indications, driven by a combination of differences in the product's intrinsic clinical profile, different levels of unmet need and the current standard of care. Defining an optimal pricing strategy that maximises an asset's value involves making some fundamental choices, e.g. setting a single price for the asset vs. indication-based pricing, and it has strong interdependencies with a product's indication sequencing.

- **Performance consistency:** As we have shown in previous IQVIA Launch Excellence research[5], complexity makes it hard to achieve consistency in launch performance, and it is one of the main reasons why launch excellence proves elusive for most. Launching a multi-indication product is an inherently complex endeavour, and the challenge innovators face is how to maintain organisational focus and momentum and execute consistently across the launches of multiple indications.

- **Resource allocation:** Maximising the value of a multi-indication asset depends on optimally resourcing each launch of its different indications.[6] Practically, this means competing for budgets and managing potentially conflicting priorities, while ensuring customer engagement at competitive levels, sustaining a competitive Share of Scientific Voice™ for evidence generation and dissemination[7,8] and capturing synergies at total brand level across all of its indications.

Innovators must address all of these challenges and show enduring commitment to staying the course of what will inevitably be a 'long launch', which we elaborated on in our earlier publication IQVIA Launch Excellence VI[9], to unlock the full potential of a pipeline in a product.

Indication roll-out: Sequencing and speed

Defining the optimal sequence in which to launch its different indications is one of the first major strategic decisions to make for a multi-indication asset. Innovators have a fundamental choice between two sequencing strategy archetypes (see Figure 2): 'narrow first' vs. 'broad first'.

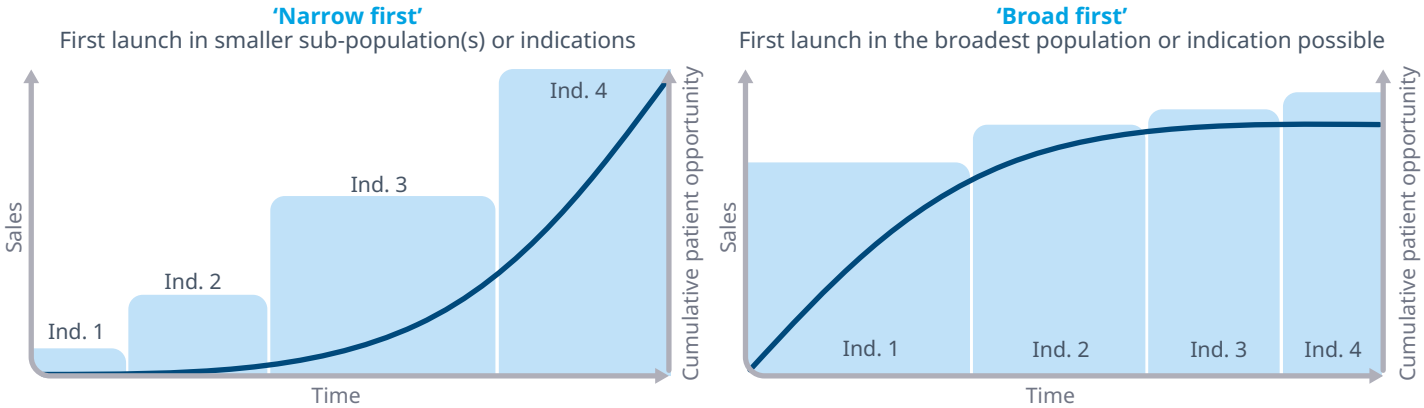
Narrow first

This sequencing strategy is based on the key premise of achieving maximum differentiation by launching first in an indication where the product shows the highest benefit, supported by compelling clinical evidence, which is typically limited to smaller, well-defined patient (sub)-populations, especially when products are approved on less mature data.

This approach has the benefit of reassuring regulators and payers by addressing concerns about both potential outcomes and budget impact uncertainty, while allowing to generate additional, supporting real-world evidence (RWE) along the way to substantiate the asset's value proposition. Furthermore, it allows innovators to secure a favourable price for the initial indication that reflects the superior outcomes, while budget impact is limited due to the small target patient population. As additional indications are launched, this initial price provides a favourable reference point for any price negotiations of future indications.

However, the flipside of this strategy is that the early commercial opportunity is limited by the small, initial target patient population, followed by a long road to capture the full potential of the asset's other, larger indications. Furthermore, the launch environment is becoming increasingly unforgiving, which poses additional, competitive risks for a 'narrow-first' strategy. As recent IQVIA research[10] has shown, over the past decade the typical speed of competitors entering the market has increased significantly, from one every three years to one per year. Consequently, only the first three products in several major therapy areas now capture 10% or more of the market each, on average. Therefore, a 'narrow first' strategy potentially risks being beaten to the market by competitors before it can seize the later, bigger prize.

Figure 2: Sequencing strategy archetypes for multi-indication launches



- Focus on well-defined sub-population(s)*/indication in product's 'sweet spot' to demonstrate superior outcomes
- Reassures regulators, payers by addressing outcomes, budget impact uncertainty, esp if RCT data less mature
- Superior outcomes create opportunity to lock in favourable price points for later indication expansion
- Enables HCPs to gain hands-on clinical experience
- Needs clear expansion strategy from the outset

- Launch first in the broadest patient population or indication possible, followed by smaller ones
- Maximises early revenue opportunity/NPV – in principle
- Requires limited outcomes uncertainty: proven effectiveness via RCTs, RWE
- Risk of challenge on price and access: budget impact, inconsistency of patient outcomes due to size, heterogeneity of patient population

* Eg via biomarker, CDx, clear clinical patient profile, can be identified in routine practice
Source: IQVIA EMEA Thought Leadership.

Case example: Keytruda's narrow-first success

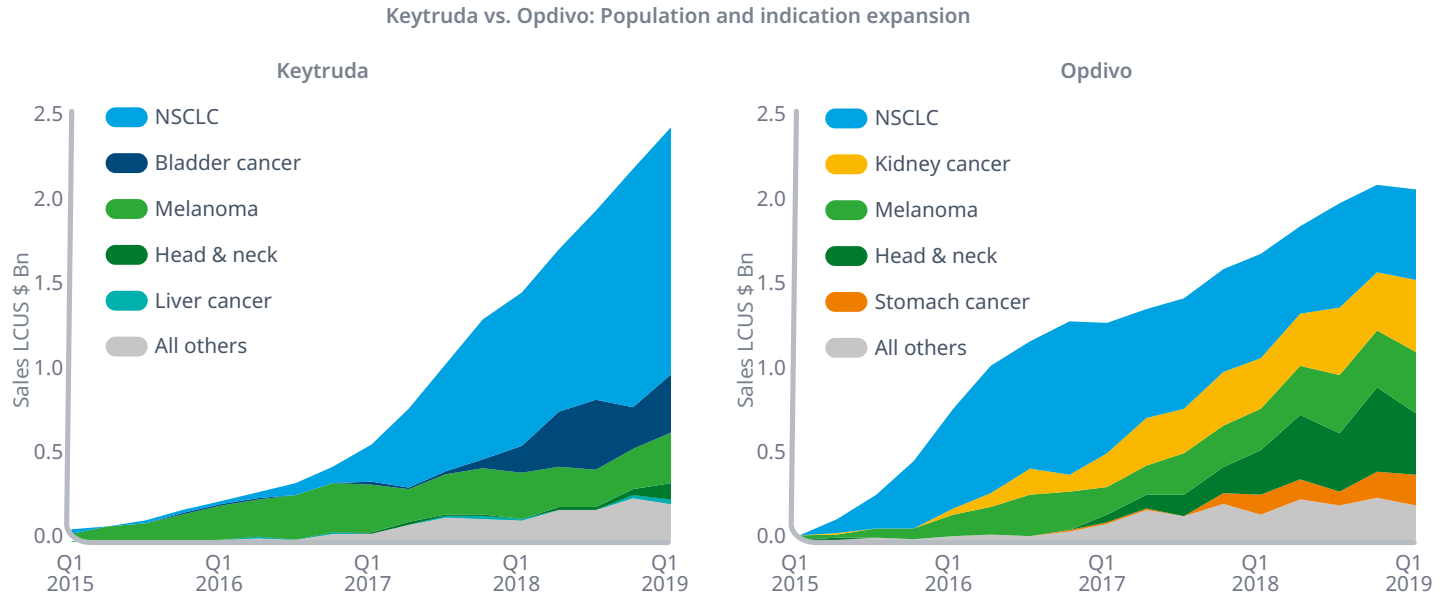
Keytruda is a case in point for a tremendously successful 'narrow first' strategy, in which the PD-L1 biomarker played a crucial role.[11] When launching Keytruda, Merck chose a highly targeted approach, focussing on second-line NSCLC patients with high PD-L1 expression who should see the greatest benefit. Conversely, Opdivo launched with a broad strategy, targeting all second-line NSCLC patients regardless of PD-L1 expression.

By demonstrating superior outcomes in its narrow initial population, Keytruda secured subsequent approval for first-line NSCLC patients with tumours expressing high levels of PD-L1, opening up the larger first-line market opportunity. At the same time, the FDA expanded use of Keytruda to all second-line NSCLC patients regardless of level of PD-L1 expression.

Thus 'narrow-first', followed by strategic indication expansion, provided the path towards broad use of Keytruda and, ultimately, its dominant market position (see Figure 3).

Today, most multi-indication oncology products pursue a narrow-first indication sequencing strategy, a reflection of the growing number of approvals based on less mature data, an increasingly crowded and competitive oncology landscape which payers use to their advantage, and the reality of significant differences in products' relative value in different indications.

Figure 3: Keytruda: a successful example of 'narrow first'



Source: IQVIA EMEA Thought Leadership, MIDAS Q1 2015 – Q1 2019, LCUS $, Global Sales.
Indication Split: IQVIA Oncology Dynamics Q1 2017-Q1 2019, Patient Level Oncology Survey, EU5, JP, CN, KR, Oncology Analyzer Q1 2015- Q1 2016, EU5, JP, CN, KR *Patient Split from said countries applied globally to predict sales by Indication.

The findings of an analysis by Michaeli et al of 25 multi-indication cancer drugs across 100 indications corroborate the dominance of the narrow-first strategy in oncology:

For the sample of analysed products, the average incremental quality adjusted life-years (QALYs) and life-years (LYs) gained *decreased* for successive indications launched, while the average disease prevalence *increased* for successive indications, clearly showing that multi-indication oncology products are first launched in small indications with high clinical benefit, before expanding into larger indications with comparatively lower benefit.[12]

Broad first

Conversely, launching first in the broadest possible patient population or largest indication seeks to maximise the early revenue opportunity, and thus asset NPV — in principle. Early focus on the largest opportunity also minimises the risk of missing out on an asset's full potential by being beaten to the market by competitors when only the early entrants tend to capture a sizeable share.

However, this rationale is somewhat simplistic for the harsh realities launches face today, for example, budget and resource constrained health systems, post-pandemic macro-economic headwinds, a raft of cost containment measures being put in place across many countries, and intense scrutiny of value by payers and HTA bodies.[13] Consequently, going broad first faces the risk of payer push back on price and restrictive market access, driven by budget impact concerns due to the size of the potential target population and questions around the consistency of patient outcomes across a large, typically heterogeneous patient pool.

Therefore, to be successful, a 'broad first' strategy requires the product to have proven, consistent patient benefits in its initial launch indication, which are supported by strong and mature clinical trial data, further substantiated via RWE and compare favourably against both the standard of care and the broader competitive context.

Today, most multi-indication oncology products pursue a narrow-first strategy, reflecting a lack of mature data at launch in an increasingly crowded and competitive market and the reality of significant differences in products' relative value in different indications.

Case example: Targeted autoimmune therapies — going broad first

The order in which the different indications of targeted autoimmune products were launched strongly correlates with their respective market size, i.e., larger indications were typically launched before smaller ones. This pattern applies across a basket of targeted autoimmune products comprising all major mechanisms of action (MoA), including anti-TNF, IL-inhibitors, JAK inhibitors and others, which were launched over the past two and a half decades. It has also endured over time and holds true when we look at the subset of products with newer MoAs, excluding the TNF inhibitors (see Figure 4).

Interestingly, we found 'broad first' as the prevailing strategy for immunology assets at large. Leading multi-indication products for treating allergic inflammation conditions, for example Dupixent or Nucala, also follow the indication roll-out pattern we observed for their autoimmune counterparts, starting with larger indications followed by smaller ones.

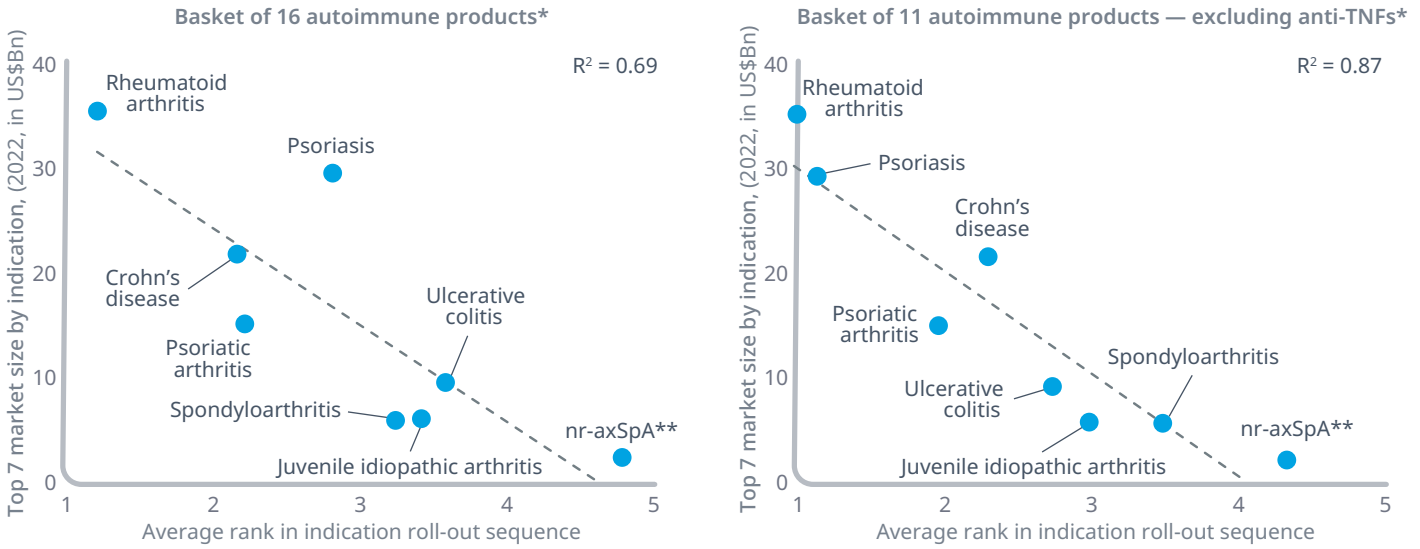
In stark contrast, no such correlation between the order of indication roll-out and relevant market size exists for checkpoint inhibitors at the tumour-indication level.

SPEED OF LAUNCHING ADDITIONAL INDICATIONS

Once the indication sequence has been defined, the speed of executing its roll-out represents the next degree of freedom for unlocking a pipeline in a product.

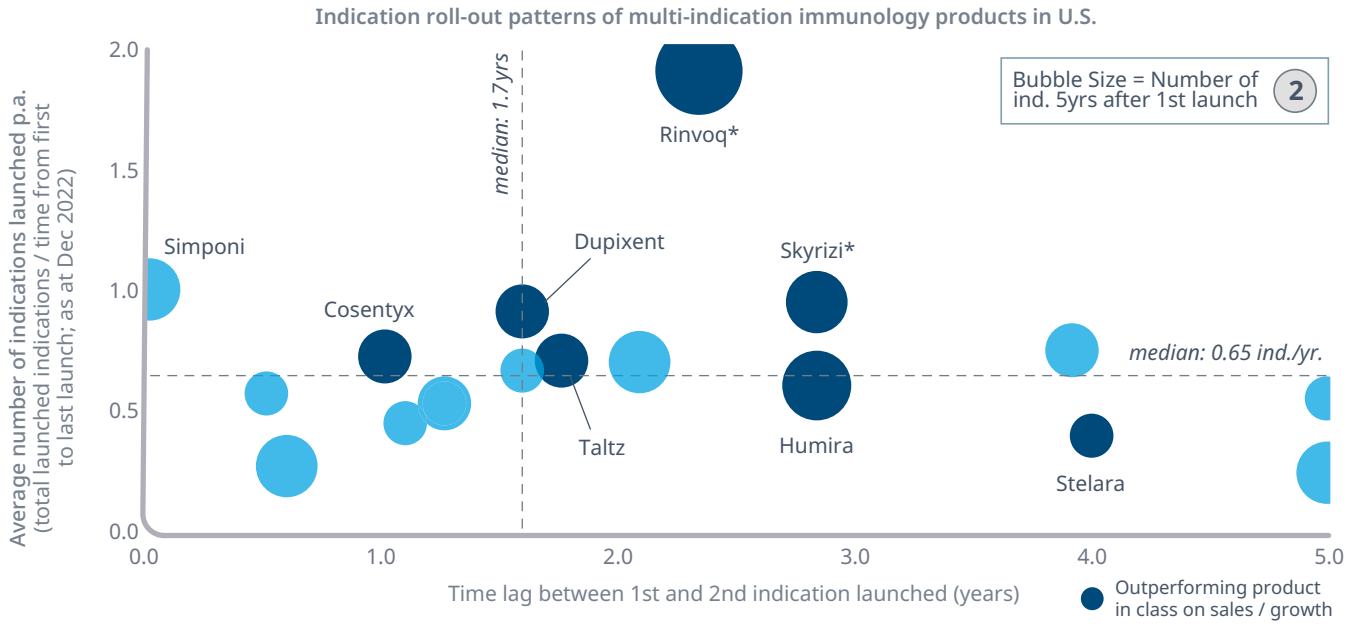
To understand how innovators have approached this issue, we analysed the indication launch patterns of a basket of 18 leading multi-indication immunology products in the U.S. Specifically, we focussed on three metrics: the time lag between the launch of successive indications; the average number of indications launched per year, defined as total number of all launched indications divided by the time from the first to the last indication launched; and the number of indications on the market five years after the initial launch (see Figure 5).

Figure 4: Sequencing autoimmune indications: typically going 'broad first'



*Includes abatacept, adalimumab, apremilast, baricitinib, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tofacitinib, upadacitinib, ustekinumab, vedolizumab; the second analysis excludes the 5 TNF inhibitors from this group; indication rank based on FDA approval dates. **Non-radiographic axial spondyloarthritis.
Source: IQVIA EMEA Thought Leadership; secondary research; FDA; market sizes according to IQVIA Forecast Link 2022.

Figure 5: Speed of indication roll-out



* Product has been on the market for <5 years; total number of indications for bubble size estimated based on latest pipeline information
Note: Analysis based on a basket of 18 immunology products: abatacept, adalimumab, apremilast, baricitinib, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tofacitinib, upadacitinib, ustekinumab, vedolizumab, dupilumab, mepolizumab.
Source: IQVIA EMEA Thought leadership; FDA, company reports, press releases; IQVIA MIDAS Sales by Disease MAT Q2 2022.

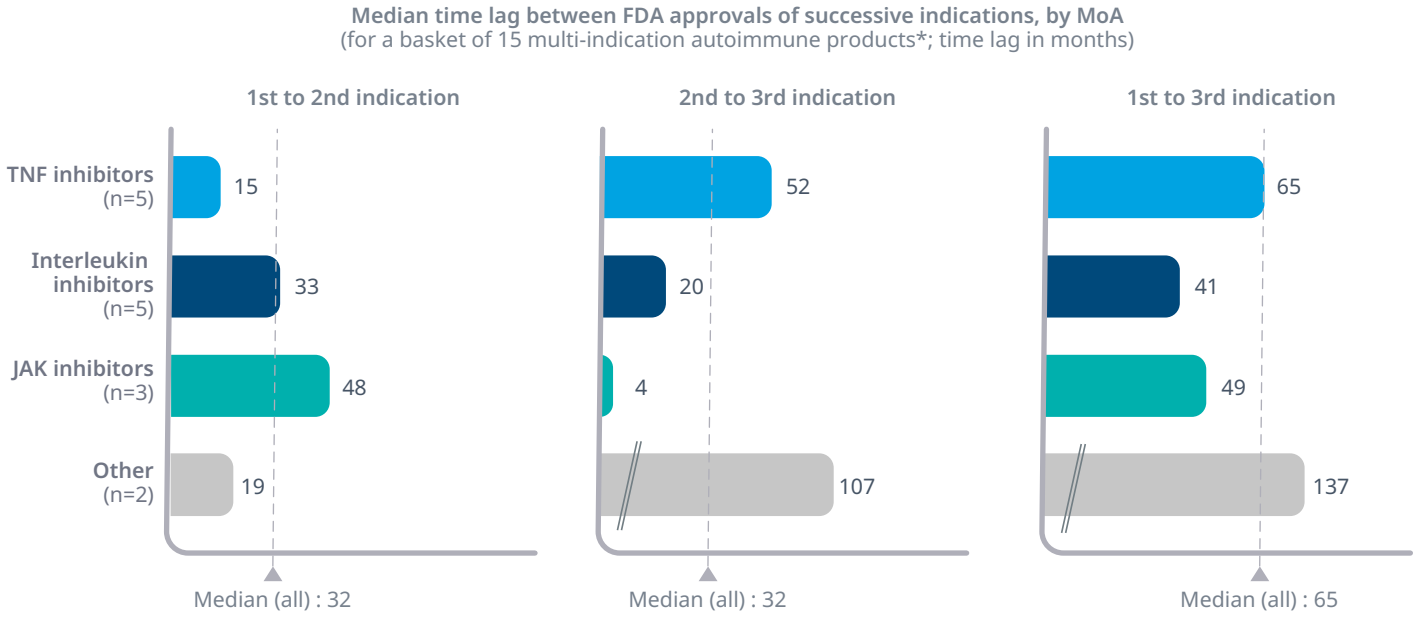
Across our sample of leading immunology products, we found a median lag of 1.7 years between the launch of first and second indication and a median of 0.65 for the average number of indications launched per year. Five years after the launch of their initial indication, 70% of the immunology products in our sample had 2–3 indications on the market.

Against those benchmarks, we observed great variation in the indication roll-out patterns between individual immunology products, for example:

- Stalwart Humira launched 5 indications during its first five years on the market, while adding, on average, 2 new indications every 3 years over its entire lifecycle. Humira sustained this rate over a remarkable 18-year period from its first to the most recent indication, but it took comparatively long, just under 3 years, for its second indication to be launched.
- In contrast, fellow TNF-inhibitor Enbrel launched its second indication just half a year after its first, while Simponi secured simultaneous approval of its first 3 indications.
- Rinvoq, one of Humira's key successors in AbbVie's immunology portfolio, has already amassed 6 indications within 3 years from initial launch, and it is poised to reach 8–9 indications after 5 years on the market.

A more detailed analysis of the speed of indication roll-out by mechanism of action (MoA) for a basket of leading autoimmune products found that the older class of TNF inhibitors were faster than classes with newer MoAs, i.e., IL inhibitors, JAK inhibitors, in adding a second indication, taking a median of just 15 months vs. 33 months and 48 months, respectively.

Figure 6: Speed of indication roll-out by MoA



*Includes abatacept, adalimumab, apremilast, baricitinib, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tofacitinib, upadacitinib, ustekinumab.
Source: IQVIA EMEA Thought Leadership; FDA; company reports, press releases.

Conversely, classes with newer MoAs were faster to expand beyond their second indication, at a median time lag of 20 months and 4 months between second and third indication for IL inhibitors and JAK inhibitors, respectively, compared to a median of 52 months for the class of TNF inhibitors (see Figure 6).

Importantly, although faster indication roll-out alone does not guarantee greater overall commercial success, we found that most outperforming immunology products tend to launch an average number of indications per year equal to or greater than the median of 0.65 for our sample (see Figure 5).

This pattern also holds among checkpoint inhibitors, but the observed overall speed of indication roll-out is much faster. Specifically, outperforming products Keytruda and Opdivo have launched an average of 3.3 and 2.1 indications per year, respectively, compared to a median of 1.7 for the checkpoint inhibitor class, while the median time lag for the class between first and second indication launched is a mere 4 months.

While faster indication roll-out alone does not guarantee greater overall commercial success, most outperforming immunology products launch an average number of indications per year equal to or greater than 0.65, the median for our sample.

KEY CONSIDERATIONS FOR DEFINING THE INDICATION ROLL-OUT STRATEGY

Getting the indication roll-out right is of paramount importance and a major determinant of the overall success of commercialising a multi-indication asset. When defining their indication roll-out strategy, innovators must consider the following key questions:

- What is the level of unmet need in each indication? And how does it compare between indications?
- How differentiated are the asset's benefits in each indication relative to the current SoC, and the broader competitive context, including likely future therapy options?
- How robust and compelling is the supporting evidence to prove differentiated clinical benefits to both regulators and payers?
- When will we have 'good enough' evidence in each indication that is sufficiently mature and compelling to convince key stakeholders?
- What competitive intensity will we face in the marketplace when launching each indication?
- Will some indications take us into novel markets where we don't have any prior presence, experience or stakeholder relationships vs. being a continuation of our existing business?
- What is the trade-off in patient population size/ commercial opportunity between different indication sequencing scenarios?
- Should all indications be launched under a single brand name or would separate branding for some indications maximise the opportunity?

Getting the indication roll-out right is of paramount importance and a major determinant of the overall success of commercialising a multi-indication asset.

It is important to consider these questions in the context of the broader healthcare system, because the regulatory and policy environment matters.

For example, the U.S. Inflation Reduction Act (IRA) will have implications for manufacturers' pipeline and portfolio choices.[14,15] Faced with potential Medicare price negotiations 9 years and 13 years post approval for small molecule drugs and biologics, respectively, innovators of multi-indication cancer drugs may now choose to launch the largest indication first. This way they avoid starting the clock on when price negotiations could begin with a smaller, initial indication of limited commercial potential, and thereby, to their detriment, limiting the time available for capturing the full opportunity of subsequent, larger indications.

However, such change in indication sequencing in turn has profound ramifications for the go-to-market approach, for example in larger indications launches would face far greater competitive pressures and payer scrutiny, precisely the kind of challenges that a 'narrow first' strategy seeks to avoid.

Performance consistency when launching multiple indications

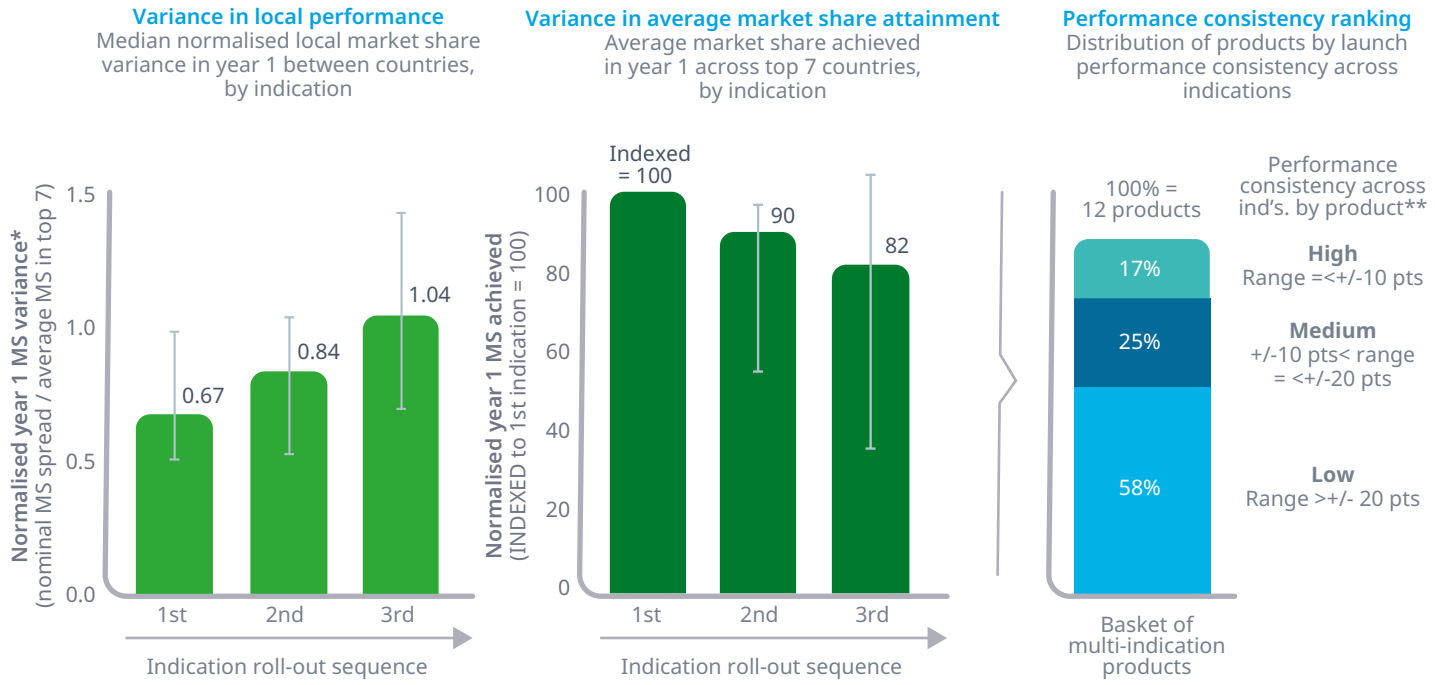
In our very first Launch Excellence publication[16] in 2007 we already identified wide variations in the local performance across countries as a key challenge for the vast majority of launches, which at the time were predominantly single-indication products.

As we elaborated earlier, launching a multi-indication product is considerably more complex and therefore compounds the challenge of delivering consistent performance across the multiple launches of its different indications.

To systematically explore this challenge, we analysed a basket of 12 multi-indication products, comprising immunology brands and PD-(L)1 inhibitors, using two metrics to assess their performance consistency:

- **Variance in average market share attainment:** How does the market share average achieved across the top 7 markets (US, EU4/UK, Japan) one year after launch compare for a product's first, second and third indication, respectively?
- **Variance in local performance:** How does each indication perform in gaining market share in each of the top 7 markets, measured as normalised variance in first year local market share, again for the first, second and third indication, respectively? This metric is defined as the nominal spread in local market share attainment one year post launch between the highest and lowest performing country for a given indication, divided by the average market share that indication achieved across the top 7 countries at the year 1 time point.[5]

Figure 7: Performance consistency challenge for multi-indication launches



* Equals nominal market share spread between highest / lowest performing country divided by average market share achieved across all countries for a given indication of a given product.
** Measured as range in average market share achieved by a brand in its 2nd / 3rd indication vs 1st, with 1st indication indexed to 100; range expressed as points difference of high/low around indication average.
Notes: Error bars indicate interquartile ranges; launches have sales in at least 3 of the top 7 countries (US, EU4/UK, Japan); basket of multi-indication products includes 8 immunology brands and 4 PD-(L)1 inhibitors.
Source: IQVIA MIDAS Sales by Disease; IQVIA Forecast Link 2022; IQVIA EMEA Thought Leadership.

Based on these measures, launch performance varies considerably across indications for our sample of products, while the consistency challenge increases with the number of indications launched (see Figure 7).

Successive indications achieved lower average year 1 market share compared to a product's initial indication, at 90 and 82 index values for the second and third indication launched, respectively, vs. 100 for the indexed year 1 market share of the first indication. At the same time, the range of observed market share values for our sample widens from first to third indication launched.

Furthermore, the variance in local performance that an indication launch achieved also widens for successive indications, with the median value of the normalised local year 1 market share variance increasing from 0.67 to 0.84 and 1.04 from first to second and third indication, respectively.

Importantly, this variance in market share is predominantly a reflection of companies' launch performance and not simply the result of differences between countries, such as different healthcare systems, HTA requirements or timelines for achieving favourable market access. We did not find any obvious or consistent patterns with regards to particular countries driving significant out- or under-performance that might explain the observed variance in launch performance.

Ranking the multi-indication products in our basket by launch performance consistency across their respective indications highlights the extent of the challenge: Only 17% performed within a narrow range of less than 10 points in average year 1 market share attainment between first, second and third indication; 25% performed within a range of 10 to 20 points, while for a majority of 58% of products the average year 1 market share values varied by more than 20 points between their three indications.

Furthermore, achieving launch consistency is a challenge faced across the performance spectrum. We only observed a soft correlation between a product's overall sales and growth performance and greater consistency across its individual indication launches. Out-performing products achieved moderately better consistency, i.e., falling into both the high and medium categories of launch performance consistency in our analysis, but even they still exhibited considerable variation in performance across both indications and countries.

Promotional investment strategies for multi-indication launches

Launch success for any type of asset critically depends on optimal resourcing and investment, e.g., to ensure effective market preparation and customer engagement to establish a competitive presence.

Multi-indication assets face a number of additional complications, such as launches of their different indications competing for budgets, managing potentially conflicting priorities, while maximising pan-indication synergies.

For a sample of five, multi-indication PD-(L)1 inhibitors, we found that capturing synergies between indications is indeed a hallmark of typical promotional investment strategies for this class. To illustrate this point, we compared the U.S. promotional investment profiles along each product's indication roll-out sequence. The underlying metric for this analysis was the total promotional spend in the U.S. for each brand, excluding DTC, at the respective year 1 timepoint after each new indication received FDA approval, divided by the number of a brand's approved indications at that point in time.

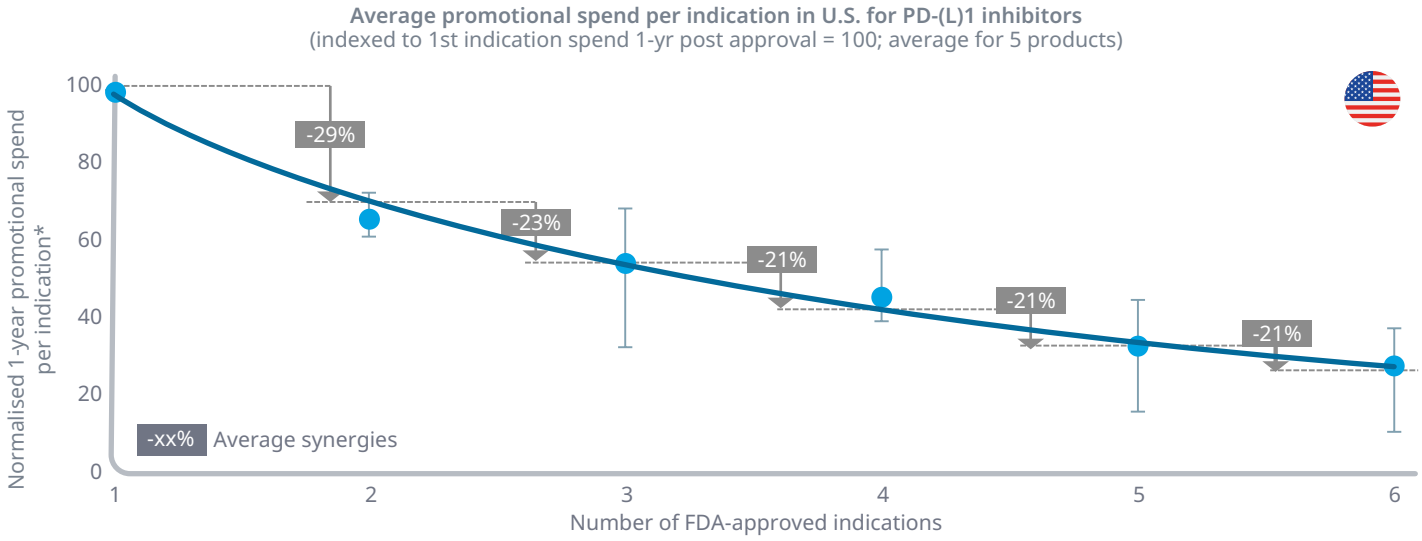
To allow cross-product comparisons, the spend profile for each brand was normalised by indexing its first indication to 100.

The result is a surprisingly consistent promotional investment profile across the five analysed PD-(L)1 inhibitors, with the average spend per indication following a downward sloping, almost exponential trendline along the indication roll-out sequence. Specifically, this finding implies that, on average, promotional investment synergies of 21–29% were realised for each new indication added for this class of products (see Figure 8).

A more differentiated analysis of the promotional investment patterns for a basket of nine multi-indication immunology products highlights two different ways in which cross-indication benefits may be realised:

- **Synergies,** in the traditional sense, which arise because of customer overlap between indications. For example, an autoimmune product approved for rheumatoid arthritis (RA), ankylosing spondylitis

Figure 8: Multi-indication promotional spend profiles: PD-(L)1 inhibitors



Note: Error bars show min/max values;
* Total US promotional spend (USD) at year 1 timepoint after each new FDA indication approval, excluding DTC, divided by number of approved indications; 1st indication indexed to 100;.average products: n=5 for indications 1-3, n=3 for indication 4–6.
Source: IQVIA Channel Dynamics Jan 2023; IQVIA EMEA Thought Leadership.

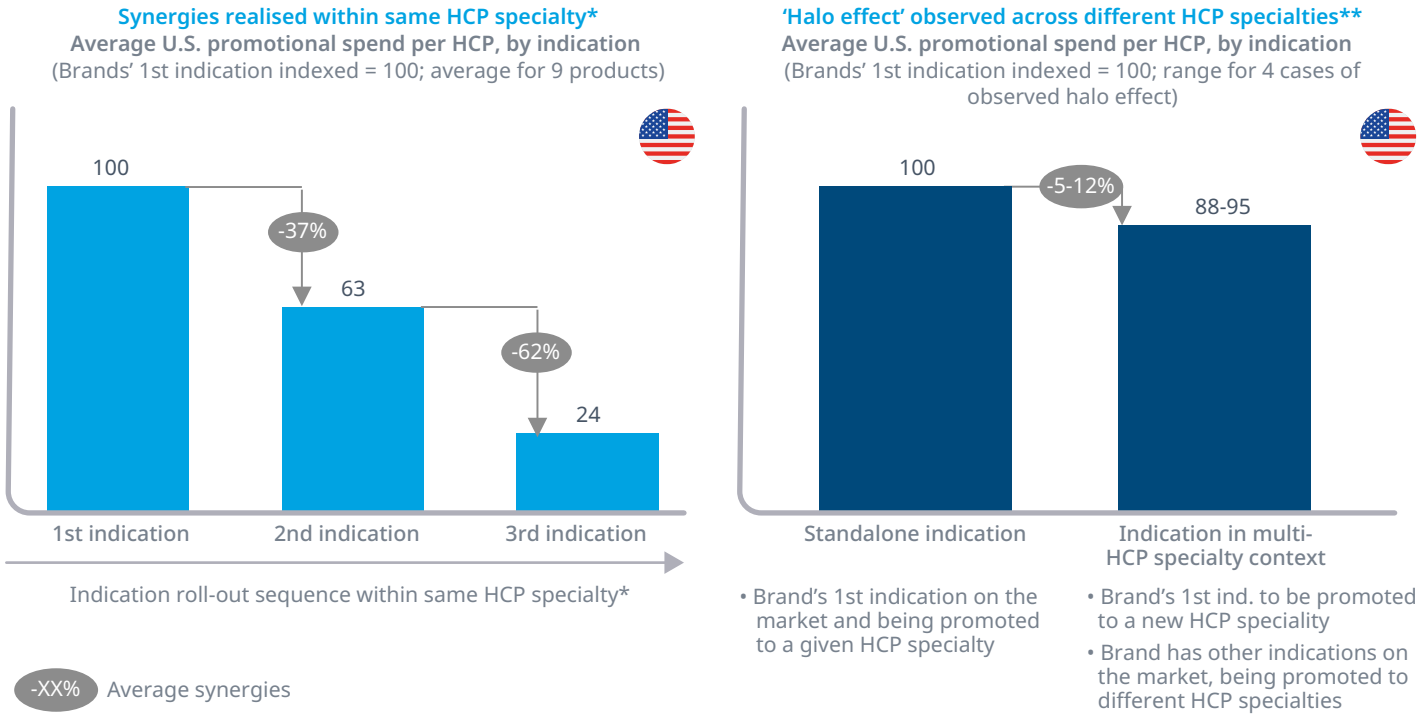
(AS) and non-radiographic axial spondyloarthritis (nr-axSpA) shares the same prescriber specialty between its indications, i.e., they are all promoted to rheumatologists.

- A **'halo effect',** which results from spill-over of overall brand-level awareness and perceptions across different prescriber specialties. Consequently, it manifests itself between a product's different indications which are promoted to different prescriber specialties. For example, an autoimmune product approved for rheumatoid arthritis and Crohn's disease would be promoted to rheumatologists and gastroenterologist, respectively. Despite the absence of customer overlap between its indications, the product may still see cross-indication benefits which a single-indication product would not, because seemingly unrelated promotional efforts contribute to the overall brand equity.

To systematically explore this issue, we analysed differences in the average promotional spend per prescriber in the U.S. for relevant specialties, including rheumatologists, gastroenterologist and dermatologist, at the respective year 1 timepoint after each new indication received FDA approval for our sample of multi-indication immunology products.

This analysis shows average synergies of 37% were realised from customer overlap when a second indication was launched into the same prescriber specialty already targeted by a product's first indication. When adding a third indication, incremental synergies of 62% were realised on average (see Figure 9).

Figure 9: Promotional synergies and 'halo effect': immunology launches



Note: Average promotional spend per HCP equals U.S. promotional spend 1-yr post approval for each indication targeting a given HCP specialty, divided by the universe size of that HCP specialty in U.S; 1:1 detailing channels only; brands'1st indication indexed = 100; values in chart are averages across products.
* Only includes a brand's successively launched indications that share the same HCP specialty, eg RA, AS, nr-axSpA all promoted to rheumatologists.
** Based on a cross-brand comparison, looking at average spend per HCP benchmarks for 1st indications only targeting a given HCP specialty vs. later indications targeting the same specialty but which are a brand's first indication for that HCP specialty while the brand has other on market indications promoted to different HCP specialties.
Source: IQVIA Channel Dynamics Jan 2023; IQVIA OneKey; IQVIA EMEA Thought Leadership.

The existence of a 'halo effect', as defined above, was more difficult to demonstrate. Its magnitude should be expected to be smaller than traditional synergies from customer overlap, due to its more indirect nature.

Nevertheless, while not a universal pattern, we found a modest 'halo effect' among a select sub-set of immunology products in our sample, all with single branding across their respective indications. When these products launched an indication into a new prescriber specialty for the first time, while already having other indications on the market which were promoted to different prescriber specialties, we observed a beneficial 'halo effect' of 5–12%. This manifested itself as lower promotional spend per prescriber compared to typical benchmarks for launching the same indication standalone. Importantly, this benefit did not come at the expense of launch success for these indications.

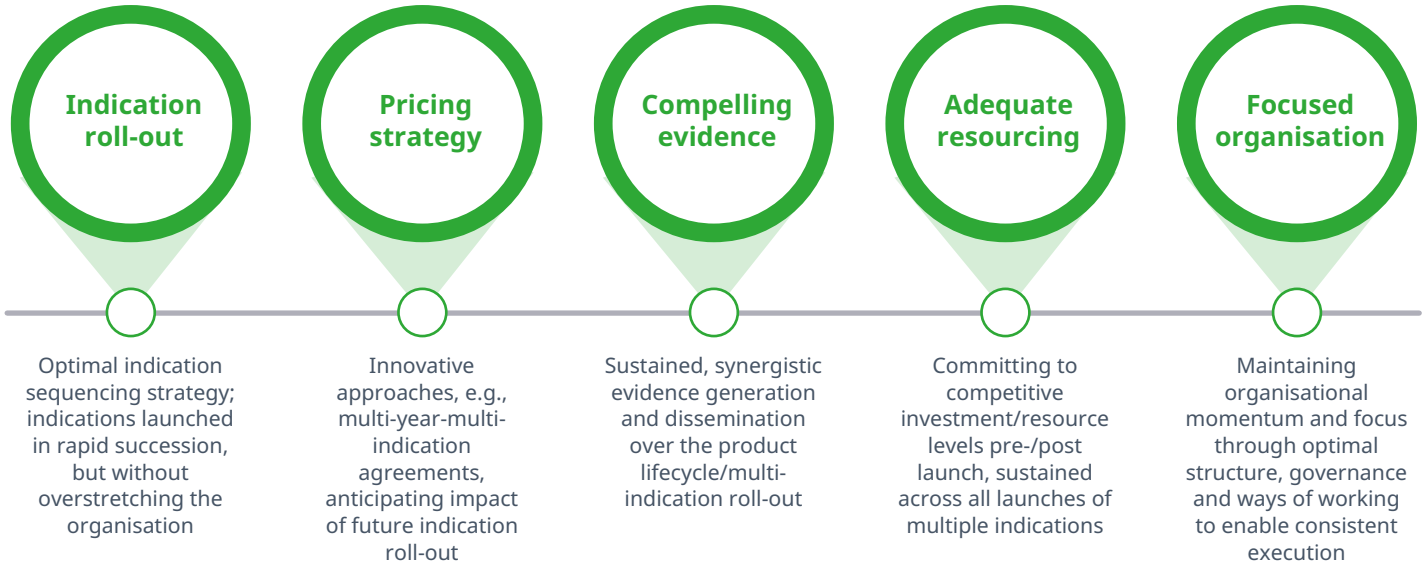
Pan-indication benefits derived from both capturing traditional spend synergies and building overall brand equity are an important lever for maximising the value of multi-indication assets, which few brands exemplify as strikingly as the $20 billion Humira mega-franchise.

How to achieve multi-indication launch success

In this white paper, we have focused on immunology and oncology, the latter represented by checkpoint inhibitors. However, multi-indicationality extends well beyond those two therapy areas and has broader relevance for innovators. For example, products in development for cardio-metabolic health may target several of the associated conditions, e.g., diabetes, obesity, heart failure or NASH. Likewise, mental health assets are often investigated in a number of illnesses, e.g., depression, anxiety or PTSD, while the principles of multi-indicationality also apply to novel technology platforms, such are RNA therapeutics, given their versatility.

As our research unequivocally demonstrates, innovators of multi-indication assets face unique and formidable strategic and operational challenges. They must therefore focus on five critical priorities to achieve multi-indication launch success (see Figure 10):

Figure 10: Critical priorities for multi-indication launch success



Source: IQVIA EMEA Thought Leadership.

1. **Indication roll-out:** Defining the optimal indication sequencing strategy reflecting asset- and TA/market-specific considerations; followed by swift execution to launch the different indications in rapid succession, but without overstretching the organisation.

2. **Pricing strategy:** Optimising price-volume trade-offs, including exploring innovative approaches, e.g., multi-year-multi-indication agreements[17], which anticipate the relative value of future indications and their impact on volume/price, and thus budgets, to accelerate market and patient access.

3. **Compelling evidence:** Sustaining synergistic evidence generation and dissemination over the product lifecycle and multi-indication roll-out to continuously polish an asset's differential value proposition[18] and maintain a competitive Share of Scientific Voice™.[7,8]

4. **Adequate resourcing:** Committing to competitive investment and resource levels, pre- and post-launch, sustained across the launches of multiple indications and reflecting TA/market-specific competitive dynamics and intensity; while capturing cross-indication synergies.

5. **Focused organisation:** Maintaining an organisation's momentum and focus through optimal structure, governance and ways of working, e.g., customer-centric go-to-market models, ringfenced and indication-dedicated teams, balanced with asset-level planning, to enable the consistent execution across the launches of multiple indications.[5]

Multi-indication assets represent a tremendous commercial opportunity, but unlocking their full potential requires careful strategic choices, disciplined execution and sustained organisational commitment to staying the course of a long launch. Innovators blessed with a pipeline in a product have everything to play for.

Multi-indication assets represent a tremendous commercial opportunity, but unlocking their full potential requires careful strategic choices, disciplined execution and sustained organisational commitment.

References

1. Global Oncology Trends 2022: Outlook to 2026; IQVIA Institute: https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicines-2022.
2. Tecentriq approved indications: https://www.tecentriq-hcp.com/
3. Opdivo approved indications: https://www.opdivohcp.com/
4. Keytruda approved indications: https://www.keytrudahcp.com/approved-indications/
5. Launch Excellence: Escaping the Complexity Trap; IQVIA white paper, 2021: https://www.iqvia.com/library/white-papers/launch-excellence-escaping-the-complexity-trap
6. Redefining OPEX modelling for a competitive future; IQVIA white paper, 2022: https://www.iqvia.com/library/white-papers/redefining-opex-modelling-for-a-competitive-future
7. Share of scientific voice, share of scientific impact, and what measurement can tell you, 26April 2018; Pharmaspectra, an IQVIA business: https://www.pharmaspectra.com/resources/features/share-of-scientific-voice-share-of-scientific-impact-and-what-measurement-can-tell-you/
8. Laudano J, Dutton G, Leveraging Medical Affairs Analytics to Enhance Engagement and Demonstrate Value. The Journal of the Medical Science Liaison Society, 19 October 2021; https://themsljournal.com/article/leveraging-medical-affairs-analytics-to-enhance-engagement-and-demonstrate-value/
9. Launch Excellence VI: Launch Excellence in a disrupted world; IQVIA white paper, 2019: https://www.iqvia.com/library/white-papers/launch-excellence-vi
10. Is the launch environment really more competitive now? Pharmaphorum article, 7 October 2022: Is the launch environment really more competitive now? | Pharmaphorum
11. In the Eye of the Storm: PD-(L)1 Inhibitors Weathering Turbulence; IQVIA white paper 2022: https://www.iqvia.com/library/white-papers/in-the-eye-of-the-storm-pd-l-1-inhibitors-weathering-turbulence
12. Michaeli, D.T., Mills, M. & Kanavos, P. Value and Price of Multi-indication Cancer Drugs in the USA, Germany, France, England, Canada, Australia, and Scotland. Appl Health Econ Health Policy 20, 757–768 (2022). https://doi.org/10.1007/s40258-022-00737-w
13. Overcoming Pharma's Launch Performance Problem; IQVIA white paper, 2022: https://www.iqvia.com/library/white-papers/overcoming-pharmas-launch-performance-problem
14. See The Whole Board: The Inflation Reduction Act of 2022, and the complex chess game now in play for pharmaceutical manufacturers; IQVIA white paper, 2022: https://www.iqvia.com/locations/united-states/library/white-papers/see-the-whole-board
15. Pharma earnings outline drug law's looming impact on sales, development; Biopharma Dive, 9 November 2022: https://www.biopharmadive.com/news/pharma-drug-pricing-ira-law-impact-negotiation/636110/
16. Launch Excellence I: Defining global launch excellence; IQVIA white paper 2007
17. Lawlor R, Wilsdon T, Darquennes E, Hemelsoet D, Huismans J, Normand R, Roediger A. Accelerating patient access to oncology medicines with multiple indications in Europe. J Mark Access Health Policy. 2021 Aug 17;9(1):1964791. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8381976/
18. Excellent launches are winning the evidence battle – Beyond necessity and nice to have: RWE as a true strategic differentiator; IQVIA white paper, 2020: https://www.iqvia.com/locations/united-kingdom/library/white-papers/excellent-launches-are-winning-the-evidence-battle

About the authors

MARKUS GORES
Vice President,
EMEA Thought Leadership,
IQVIA

Markus has over 20 years of experience in life sciences, advising clients in all major geographies on a broad range of topics, including real world evidence strategy, launch readiness, go-to-market models, brand and commercial strategies, and building enabling organisational capabilities.

Markus is a frequent speaker on the latest industry trends and regularly engages with senior leadership teams of pharmaceutical companies.

Prior to his current role in Thought Leadership, he has held leadership positions within IQVIA Real World Solutions and QuintilesIMS Consulting Services (formerly the IMS Consulting Group).

Markus holds a PhD in Pharmaceutical Chemistry from the University of Hanover and has completed post-doctoral research at the University of California.

KIRSTIE SCOTT
Consultant,
EMEA Thought Leadership,
IQVIA

Kirstie is a consultant in IQVIA's EMEA Thought Leadership team, based in London. She has experience preparing white papers across a range of priority healthcare topics such as the availability of medicines, the impact of biosimilars in Europe and launch excellence. A particular recent focus is how companies with new launches can overcome the challenging post-pandemic environment to achieve launch success.

Kirstie has over 5 years' experience in healthcare and life sciences, previously working to support industry associations to influence health policy, and providing clinical and commercial competitive insights for pharmaceutical companies. She holds a degree in Neuroscience from the University of Nottingham.

CONTACT US

iqvia.com/contact

© 2023. All rights reserved. IQVIA® is a registered trademark of IQVIA Inc.
in the United States, the European Union, and various other countries.
02.2023.NEMEA