White Paper

Excellent launches are winning the evidence battle

Beyond necessity and nice to have: RWE as a true strategic differentiator

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Introduction

Launch Excellence has acquired an almost mythical quality: pursued by many, found by few, as we have observed in our most recent white paper on this topic.[1] The pharmaceutical industry's quest for launch excellence has spurred a wealth of publications on how to achieve it, yet little has been written on the competitive use of real world evidence (RWE), as a true strategic differentiator, in the launch context.

In this white paper, we will explore the critical importance of RWE as a source of competitive advantage, how excellent launches have utilised it in achieving success and address key questions, such as: What is a competitive level of RWE? How early should RWE generation start? What issues should RWE focus on? And how do the answers to those questions change over the launch lifecycle?

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>
> ***As we have seen, excellent launches have realised this, and they are embracing RWE strategically as a source of competitive advantage."***

A new battle line in the quest for launch excellence

At a fundamental level, a new product must take three hurdles to achieve commercial success:

1. Gain regulatory approval
2. Secure market access
3. Be widely utilised in real world clinical practice

Evidence plays a key role in overcoming those hurdles by convincing relevant stakeholders and decision makers of the benefits and value a new product offers, its safety and by explaining how it fits with current clinical practice and within the existing treatment landscape.

The role of evidence in launch success as such is not new. Generating data via randomised controlled trials (RCTs) has always been a fundamental part of the pharmaceutical industry's new product development model. However, in today's launch environment the evidence burden continues to rise, as stakeholders demand more information, as well as increasing levels of 'proof', along the entire product lifecycle:

- Health care systems faced with increasing budget pressures want to be sure they are getting value for money – and continue to get value relative to alternative options as the treatment landscape keeps evolving.

- Innovation in areas of high unmet patient need has led to earlier regulatory approvals based on less mature data, for example from single arm, phase 2 trials, using surrogate endpoints.[2] This creates uncertainty among healthcare stakeholders beyond regulators, especially for payers and healthcare professionals, who want to be reassured that a new product's early value proposition holds under real world conditions and delivers clinically relevant outcomes.

- With innovation shifting towards specialty care, including advanced therapy medicinal products (ATMPs), new treatments are becoming scientifically more sophisticated and complex. Consequently, healthcare professionals require additional information, for example, about the underlying science and how it translates into patient benefits, or how to navigate an increasingly crowded treatment landscape, with guidance on how to correctly use a new product, in which sub-populations and how to identify those in practice.

Real world evidence (RWE) is uniquely suited to address those demands for additional information. Its distinctive feature, of capturing patient-level observations in routine clinical practice, allows RWE to bridge the evidence gap left by RCTs, due to their inherent limitations, such as being highly controlled and thus unrepresentative of real world patient populations.

At the same time, initial scepticism about the robustness of RWE has given way to the appreciation by healthcare stakeholders of the value RWE brings in addressing their needs.[3,4,5] Therefore, in today's launch environment, RWE has an invaluable role to play in eliminating uncertainty and guiding healthcare stakeholders' decisions across the board.

Crucially, the need for evidence is no longer confined to discrete events in the development path, such as regulatory approval, pricing decisions or health technology assessments, given the nature of today's pharmaceutical innovation and because healthcare stakeholders now continuously scrutinise the value of a new product against a fast-evolving competitive landscape. Instead, it is now necessary to generate a continuous flow of evidence and to keep polishing the value proposition of a product along its entire lifecycle.

As companies are thus competing for 'news flow', inevitably, RWE is emerging as a key battle line in the pursuit of launch excellence.

RWE as a true strategic differentiator

The importance of RWE as a key part of the evidence mix is generally well recognised today. However, its full strategic potential is often not appreciated. In our experience, RWE is still largely seen as a combination of necessity and nice to have, rather than as a true strategic asset and a source of competitive advantage.

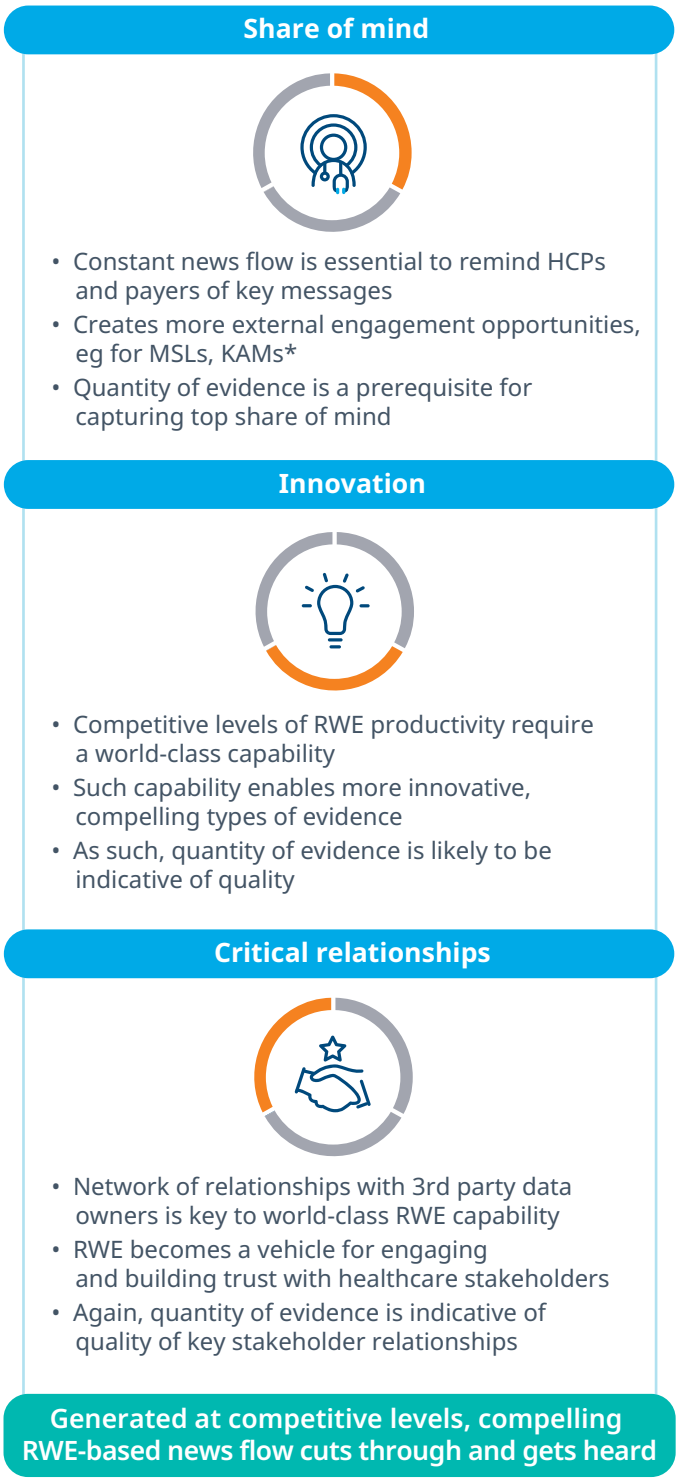
For example, few companies approach RWE generation with the same strategic mindset as they would, for example, building a competitive promotional in-field presence that sets them apart in a crowded market place. Yet in today's launch environment, success depends very much on generating *competitive levels of RWE,* with its focus strategically aligned with stakeholders' evolving needs.

- Akin to share of voice in the commercial setting, there is such a thing as share of mind even in the scientific world of evidence. A constant news flow is essential in reminding HCPs and payers of key value messages for a product. Furthermore, the more evidence is generated, the more engagement opportunities this provides, for example, for MSLs to talk to KOLs or payers and build relationships.
- Secondly, to achieve competitive levels of RWE productivity, a world-class evidence capability is required, such as an evidence platform.[6] Such world-class capability will have access to unique data assets, and therefore is highly likely to generate more innovative, compelling and timely evidence. In this context, ultimately, quantity does correlate with quality.
- Finally, related to the previous point, a world-class evidence capability is underpinned by a portfolio of unique data assets drawing on a network of relationships with third party data set owners. Many of those are key stakeholders in the local healthcare system, and thus the evidence capability becomes a collaboration vehicle for building deep relationships and trust.[7,8] Again, quantity of evidence ultimately says something about the quality of a company's relationships with key stakeholders.

Used strategically, RWE proactively addresses key stakeholders' information needs as they evolve over the product lifecycle, while overcoming the three hurdles to launch success, i.e. approval, access and real world utilisation. Generated at competitive levels, such highly relevant, RWE-based news flow stands out from the crowd, cuts through and gets heard.

As we shall see in the next section, our systematic analysis has shown that this is precisely how excellent launches are embracing RWE – as a true strategic differentiator.

Figure 1: Why competitive levels of RWE matter



* MSL: Medical Science Liaison, KAM: Key Account Manager
Source: IQVIA European Thought Leadership

How excellent launches are using RWE

To understand the role and impact of different RWE strategies in achieving launch success, we performed a volumetric analysis, for each given launch, of all relevant RWE published until December 2019, based on pragmatic publication searches in PubMed & Embase.

We acknowledge the limitations of analysing published RWE. Firstly, many companies today generate 'invisible' RWE, which is not published externally and serves the sole purpose of informing internal strategic and operational decisions. Secondly, published RWE volume alone only tells part of the story. Any impactful evidence must be of the highest quality, too: robust, compelling and relevant. Nevertheless, we believe published RWE is undoubtedly a good, measurable indicator of a company's commitment to evidence generation, and it also reveals which issues it deems relevant to engage external healthcare stakeholders on.

Our publication searches focused on launches in three, highly competitive therapy areas: diabetes, immunology and immuno-oncology. Specifically, we have included launches in the following drug classes, to be able to investigate particular competitive dynamics:

- **Diabetes:** GLP-1 receptor agonists; SGLT-2 inhibitors.
- **Immunology:** Interleukin inhibitors, including IL-12/23, IL-17, IL-23, IL-4/13; PDE-IV inhibitors and JAK inhibitors.
- **Immuno-oncology:** checkpoint inhibitors, including PD-1 and PD-L1.

The results from our pragmatic publication searches were then analysed for patterns of RWE generation, including:

- Total volume (i.e. number of relevant search 'hits') over the full product lifecycle, normalised for the number of FDA approved indications and their time on the market
- Annual volume over time, at different points in the product lifecycle
- Annual volume over time *and* by focus of evidence, with publications allocated to seven categories based on information in each abstract: effectiveness, safety, quality of life (QoL), clinical practice, disease characteristics, patient characteristics and health economics

Finally, we overlaid the launch type on the findings from this volumetric analysis, i.e. excellent vs. non-excellent, based on the well-established definition of 'Excellence' from our reputable IQVIA Launch Excellence series[9]; and first-in-class vs. follower.

This systematic analysis has revealed intriguing patterns of RWE generation in the context of launch and allowed us to identify RWE strategies adopted by successful launches. It provides answers to key questions, such as: How much evidence is needed for competitive levels? What issue(s) should evidence focus on? And how does this change over the product lifecycle?

The following key findings have been observed across the three therapy areas we examined.

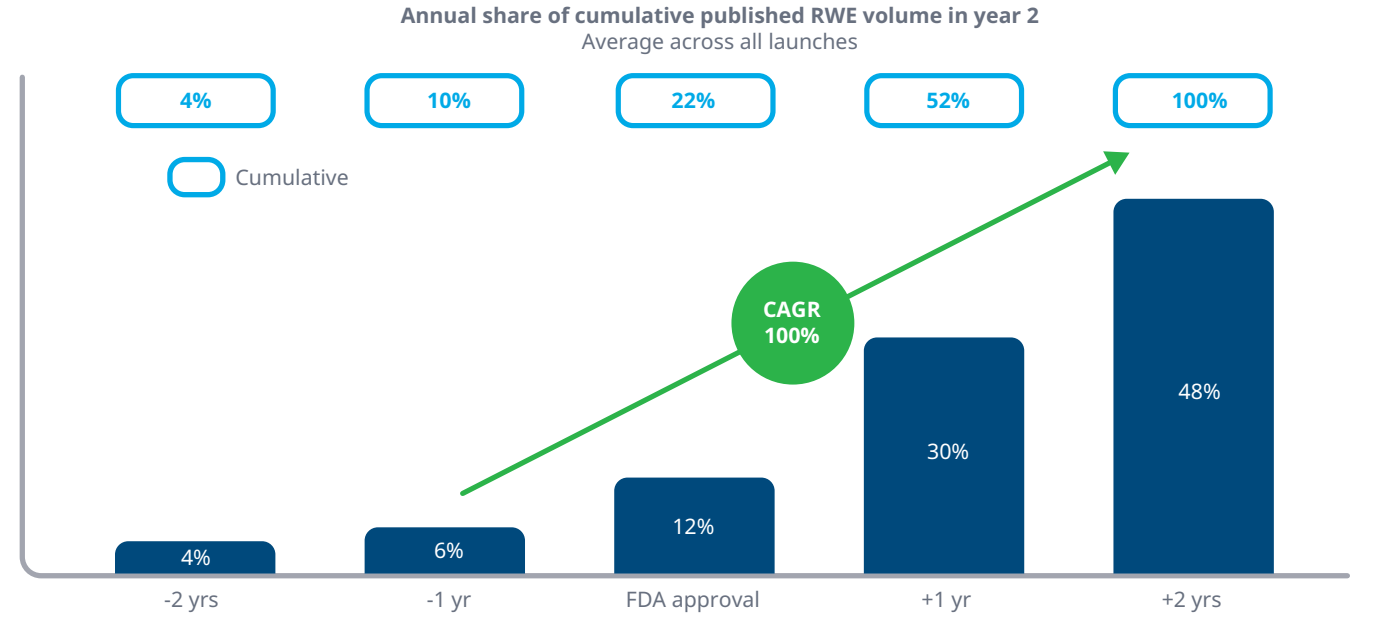
I. RWE DISSEMINATION RAMPS UP SHARPLY ONE YEAR BEFORE APPROVAL

The first set of questions we wanted to answer were 'What does the typical RWE volume trajectory for a launch look like? When does it start to ramp up? And how fast?'

To allow for cross-product analyses, we normalised both timelines and published RWE volumes. First, we converted absolute time points into relative timelines anchored on a product's FDA approval, looking at the period from 2 years before approval until 2 years after approval. Annual published RWE volumes for each launch were normalised as a share of its total absolute published RWE volume generated over this period.

Across our universe of launches, we found a broadly applicable pattern: Typically, RWE dissemination already starts 2 years before approval, albeit at very low levels, which continues at low levels until 1 year before approval. However, the RWE volume trajectory then starts to ramp up sharply, with published RWE volumes roughly doubling year after year, which equates to a compound annual growth rate (CAGR) of

Figure 2: Typical RWE volume over the product lifecycle

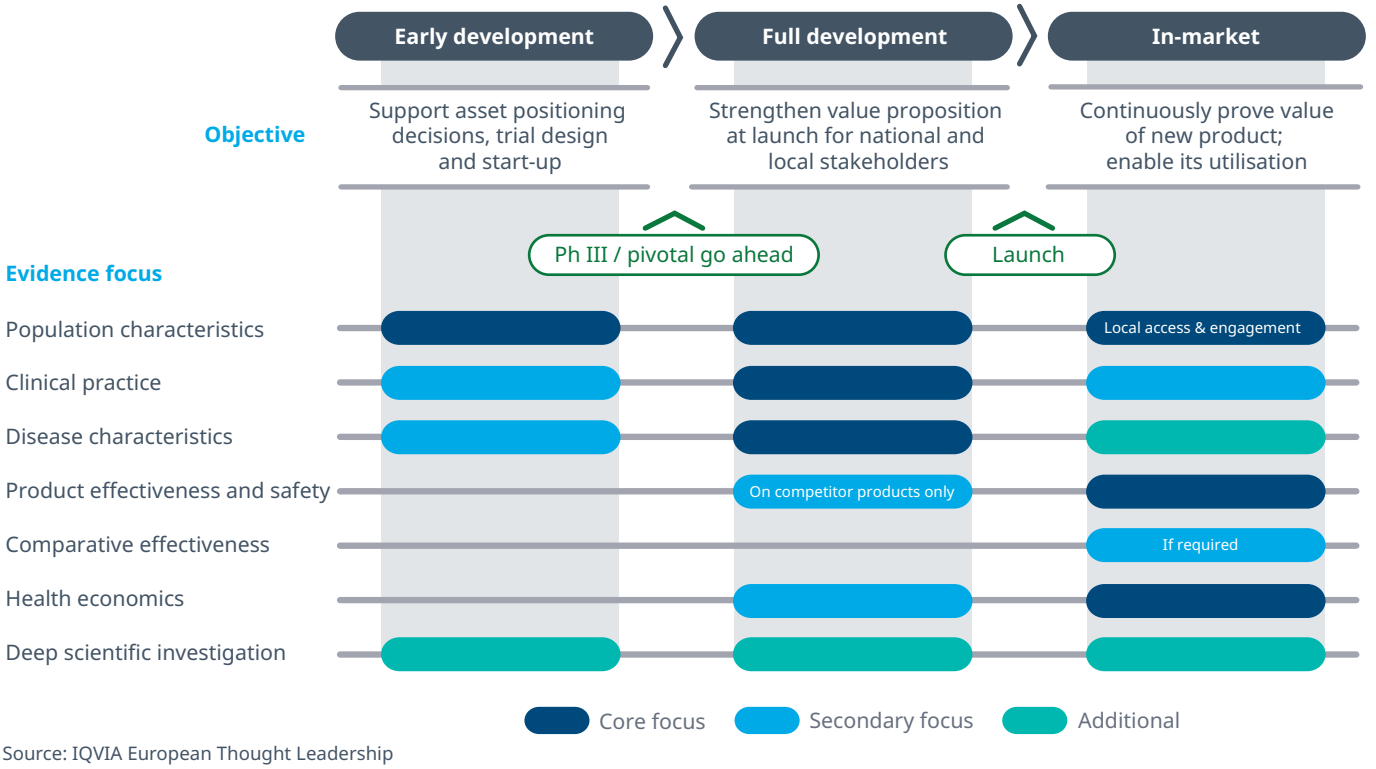


Source: IQVIA European Thought Leadership

100% for the period spanning 1 year before approval until 2 years after approval.

One immediate implication from this observed pattern is the need for a comprehensive, pro-active approach to evidence generation. To be able to deliver those RWE volumes on time, systematic evidence planning must start early, at least 2–3 years before approval, with anticipation of stakeholder needs, given the typical 12–18 months lead time for generating RWE output.

Figure 3: Systematic RWE planning must start early and anticipate future needs



Source: IQVIA European Thought Leadership

II. EXCELLENT LAUNCHES GENERATE MORE RWE, FASTER

The key question at the heart of this white paper is 'How do excellent launches utilise RWE?' To answer this question, we compared excellent and non-excellent launches using two metrics:

- Normalised RWE lifecycle productivity: This is the total published RWE volume over a product's entire lifecycle, divided by the number of its approved indications that have been on the market for at least 6 months; and normalised for the time those indications have been on the market.
- Growth in annual RWE volume over the product lifecycle: Here we examined the 2-year CAGR in annual published RWE volumes for two time periods, 2 years before approval and 2 years after approval, respectively.

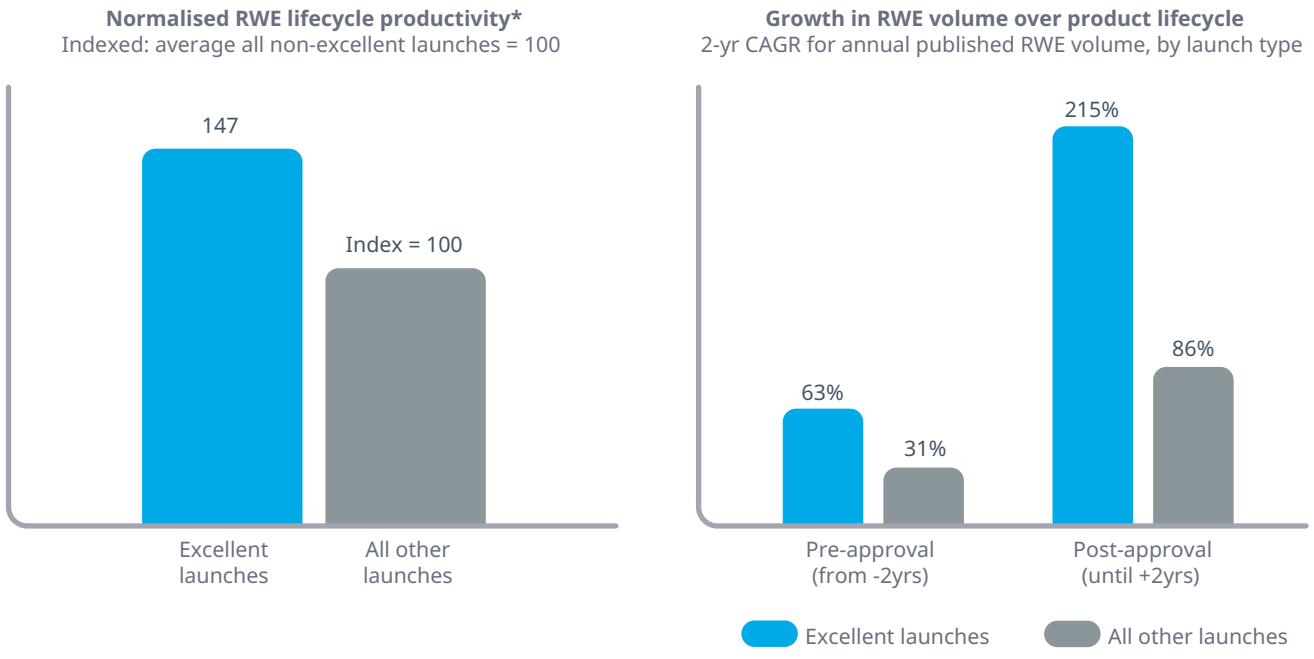
Our results were unequivocal: Excellent launches generate more published evidence than non-excellent ones. And they do so faster, with steeper trajectories of published RWE volume, both during the pre- and post-approval 2-year periods.

This finding has a number of important implications:

- Firstly, it suggests that excellent launches are much more ambitious in their use of RWE, but also more disciplined in starting their evidence planning early, to create a robust lifecycle evidence roadmap that underpins such steep trajectories.
- Secondly, they follow through with competitive levels of investment in evidence generation, to be able to execute such an ambitious evidence strategy.
- Finally, a traditional approach to evidence generation based on one-off studies is insufficient to sustain such high levels of RWE productivity. Instead, innovative approaches that enable efficiencies, flexibility and speed are needed, such as evidence platforms and 'secondary data first'. Judging by their steep RWE volume trajectories, excellent launches appear to embrace such innovations.

Clearly, excellent launches are indeed winning the evidence (volume) battle!

Figure 4: Excellent launches generate more RWE, faster



* Total number of publications / number of indications approved >6month ago / normalised for time on market
Notes: Excellence defined according to the IQVIA Launch Excellence criteria (Launch Excellence VI and prior publications)
Source: IQVIA European Thought Leadership

III. EXCELLENT LAUNCHES SHOW CONVICTION

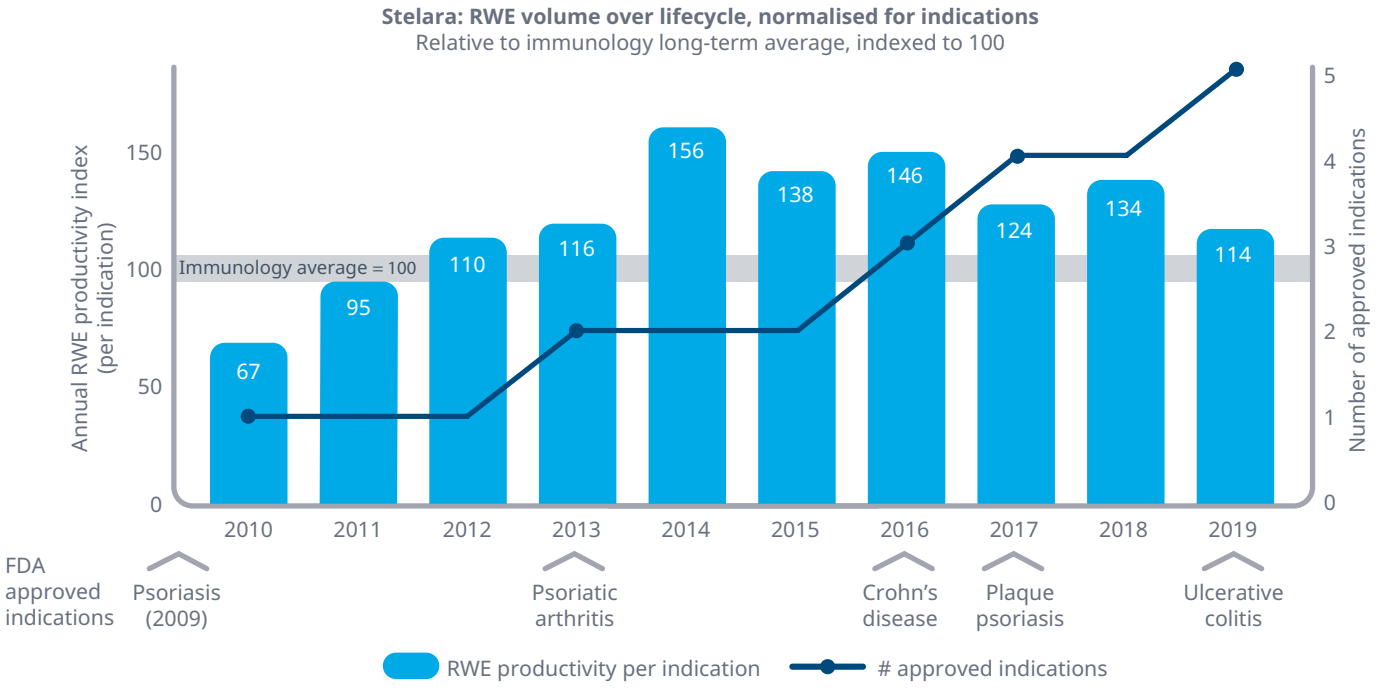
The ambitious approach towards RWE by excellent launches does not end 2 years after approval. In fact, we found that excellent launches show conviction in their commitment to RWE. They maintain competitive levels of published RWE productivity many years after launch, well into the mature stage of their lifecycle.

Stelara, Janssen's interleukin 12/23 inhibitor for the treatment of autoimmune disorders, is a case in point. Stelara was first approved in 2009 in psoriasis. Since then, Stelara has expanded its number of approved indications, adding psoriatic arthritis in 2013, Crohn's disease in 2016, plaque psoriasis in 2017 and ulcerative colitis in 2019. Furthermore, we identified Stelara as an excellent launch in our IQVIA Launch Excellence V publication.[10]

Not only has Stelara outperformed competitors on early RWE productivity benchmarks, Stelara has sustained competitive RWE productivity levels throughout its lifecycle: Average annual published RWE volume generated per indication remains well within a competitive range, even as the number of its approved indications increases over time. A more detailed analysis shows this is the case even in its first approved indication.

> *"Excellent launches maintain competitive levels of RWE productivity many years after launch, well into the mature stage of their lifecycle."*

Figure 5: Stelara has sustained competitive levels of RWE productivity over its lifecycle



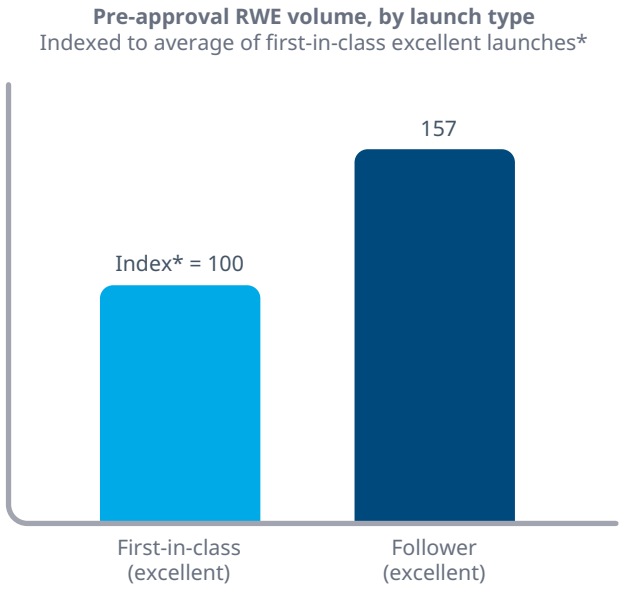
Source: IQVIA European Thought Leadership

IV. EXCELLENT 'FOLLOWERS' TEND TO MAKE GREATER USE OF EARLY RWE

Excellence is not the only dimension for segmenting launches. Order of market entry is an equally important feature that determines many aspects of launch strategies.

In the context of published RWE, we found a striking difference among excellent launches between first-in-class products vs. followers. These two launch types differ in the relative distribution of their respective, cumulative published RWE volumes over the product lifecycle, specifically, between the pre- and post-approval periods.

Figure 6: Excellent 'followers' tend to make greater use of early RWE



* Within a given TA, average pre-approval volumes of published RWE were compared for excellent first-in-class launches vs. excellent followers, the former were indexed to 100; graph shows average across TAs.
Source: IQVIA European Thought Leadership

Excellent followers tend to make greater use of early RWE. We can find a plausible explanation for this strategy by looking at the benefits of early RWE uniquely applicable to followers.

- Followers can generate insight on incumbents already on the market which they will compete with head-to-head, for example, on their current real world performance.
- Followers can use a deeper understanding of patient segments, clinical practice, burden of illness and unmet needs to identify opportunities currently not addressed by incumbents and highlight those to healthcare stakeholders.
- Such insight enables followers to fine tune their launch strategy, for example, optimal competitive positioning, which sub-populations to target or how to seamlessly fit with current clinical practice.

Since followers will launch into a market place that is already busy, to varying degrees, with in-class competition, they have a greater need to optimise their differentiation and place within the treatment landscape than first-in-class launches. Excellent followers appear to resort to early RWE to inform those key strategic choices, with indisputable results.

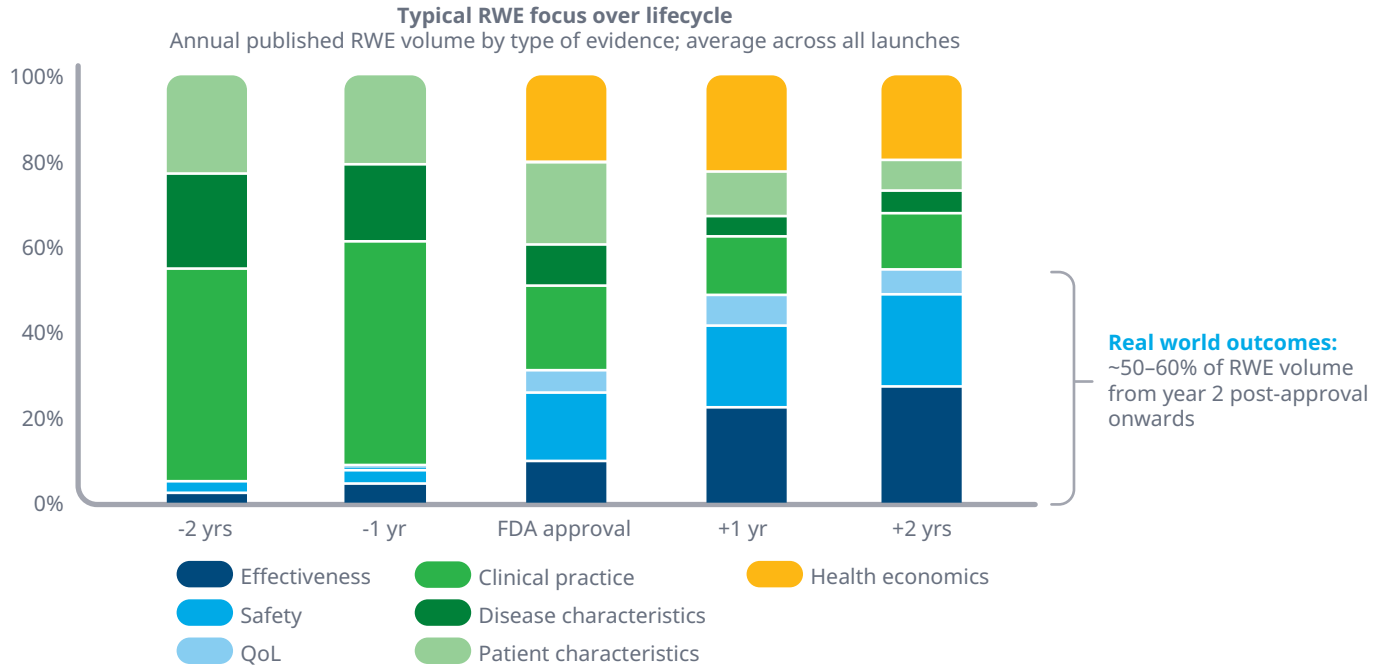
V. THE FOCUS OF RWE EVOLVES OVER THE PRODUCT LIFECYCLE

Besides the question about competitive levels of evidence, there is another important dimension to its impactful use: What issues should RWE focus on? And how does this focus evolve over the product lifecycle?

To answer those questions, we categorised RWE publications using seven different focus areas: effectiveness, safety, quality of life (QoL), clinical practice, disease characteristics, patient characteristics and health economics. We then compared their respective relative shares of a product's annual RWE volume, over the period from 2 years before approval until 2 years after approval.

As a typical pattern across our launch universe, we found that in the pre-approval period RWE focus is directed towards market and disease insight categories, such as patient characteristics, disease characteristics and clinical practice. After approval, once the new product is on the market, health economics and real world outcomes move into focus, including (comparative) effectiveness, safety and quality of life (QoL). From 2 years after approval onwards, real world outcomes become the single largest combined category, accounting for just over half of the annual published RWE volume.

Figure 7: The focus of RWE evolves over the product lifecycle



Note: Absolute, published pre-approval RWE volumes are generally much lower than post-approval
Source: IQVIA European Thought Leadership

This shift in focus reflects the need to address ongoing stakeholder scrutiny and demonstrate value under real world conditions, once a product is on the market.

Clearly, a lifecycle evidence strategy is essential for maximising the impact of RWE. Used strategically, the focus of RWE dynamically aligns with evolving stakeholder needs over time, thereby ensuring continuous relevance. As we pointed out earlier, given the typical lead times for generating RWE, early planning with anticipation of stakeholder needs is crucial, to ensure relevant evidence is available at the right time.

Interestingly, 'Excellence' turned out not to be a meaningful driver of variations in RWE focus, as we could not observe any consistent pattern differences in RWE focus between excellent and non-excellent launches. However, we found other intriguing variations, which we will elaborate on in the next section.

"Used strategically, the focus of RWE dynamically aligns with evolving stakeholder needs over time, thereby ensuring continuous relevance."

THERAPY AREA-SPECIFIC TRENDS

Beyond those broad trends described so far that we have seen across the different launches we examined, we have also identified some aspects of marked differences between therapy areas, including unique, therapy area-specific, patterns.

Immunology

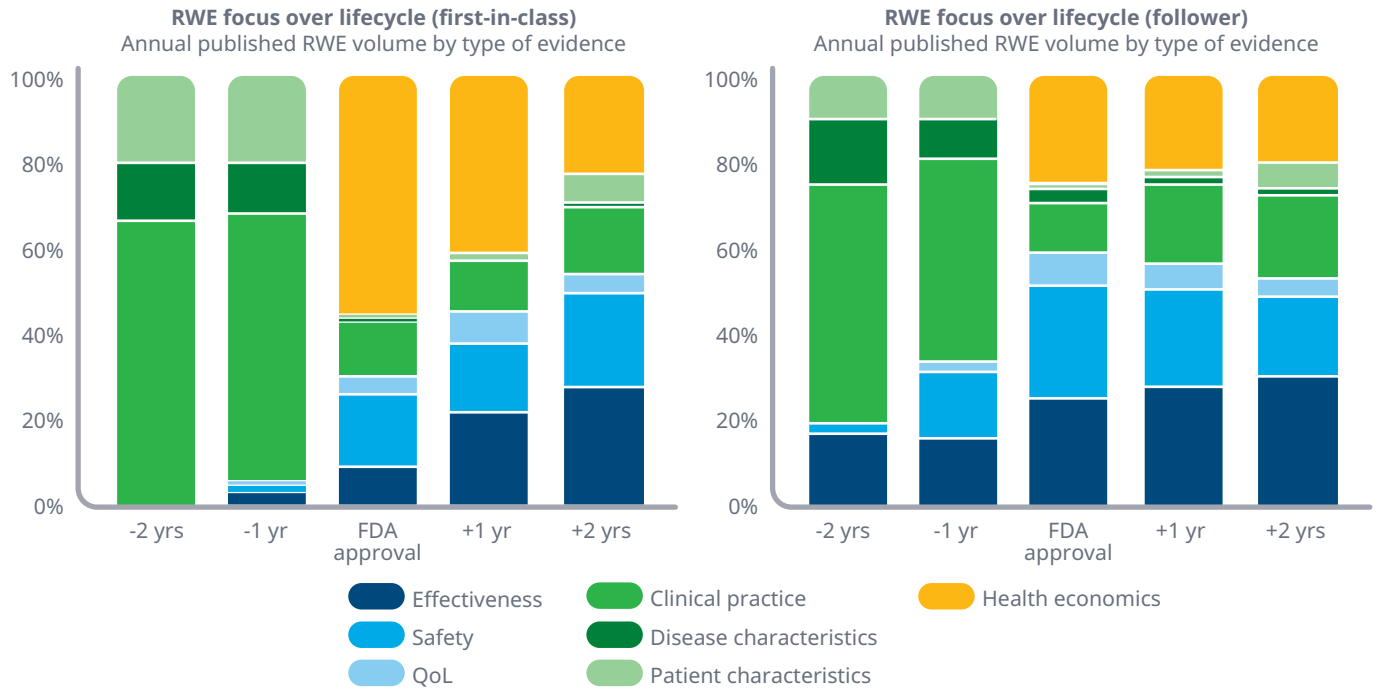
Amongst immunology launches, we found consistent, distinctive patterns of RWE focus for first-in-class launches vs. followers. The respective patterns differ significantly from 2 years before approval until 1 year after approval, but they start to converge around 2 years after approval.

Specifically, our analysis found the following, distinctive patterns of RWE focus.

First-in-class launches:

- Pre-approval: Evidence focus is on clinical practice, patient characteristics and, to a lesser extent, disease characteristics. This could help generate insight, for example, into the treatment landscape or to understand unmet patient needs.
- Post-approval: Initial evidence focus is dominated by health economics, which subsequently shifts towards real world outcomes, to become the largest combined category.

Figure 8: Distinctive RWE focus patterns: first-in-class vs. followers - *Immunology launches*



Note: Absolute, published pre-approval RWE volumes are generally much lower than post-approval
Source: IQVIA European Thought Leadership

Followers:

- Pre-approval: In addition to the categories identified for first-in-class launches, followers also show some early focus on real world outcomes of competitors already on the market. As we explained earlier, one likely reason behind this is that followers benefit from better understanding the opportunity and optimising their competitive positioning vs. in-class incumbents.

- Post-approval: Compared to first-in-class launches, followers show greater evidence focus on real world outcomes vs. health economics, while focus on clinical practice is also relatively more pronounced, albeit at an overall moderate level. Again, this may help followers optimise their differentiation and competitive positioning in the market place.

Furthermore, we also observed drug class-specific patterns within immunology, which directly reflect particular issues that RWE needs to address in those products.

The JAK inhibitors are facing concerns about increased rates of thrombosis and embolisms, which has led the FDA to add black box warnings to the three approved JAK inhibitors, Xeljanz, Olumiant and Rinvoq, suggesting the FDA is treating such risks as a class effect.[11] Therefore, it didn't come as a surprise to find that for JAK inhibitors, post-approval, safety-focused RWE accounts for more than twice its average share of published RWE volume amongst all immunology launches.

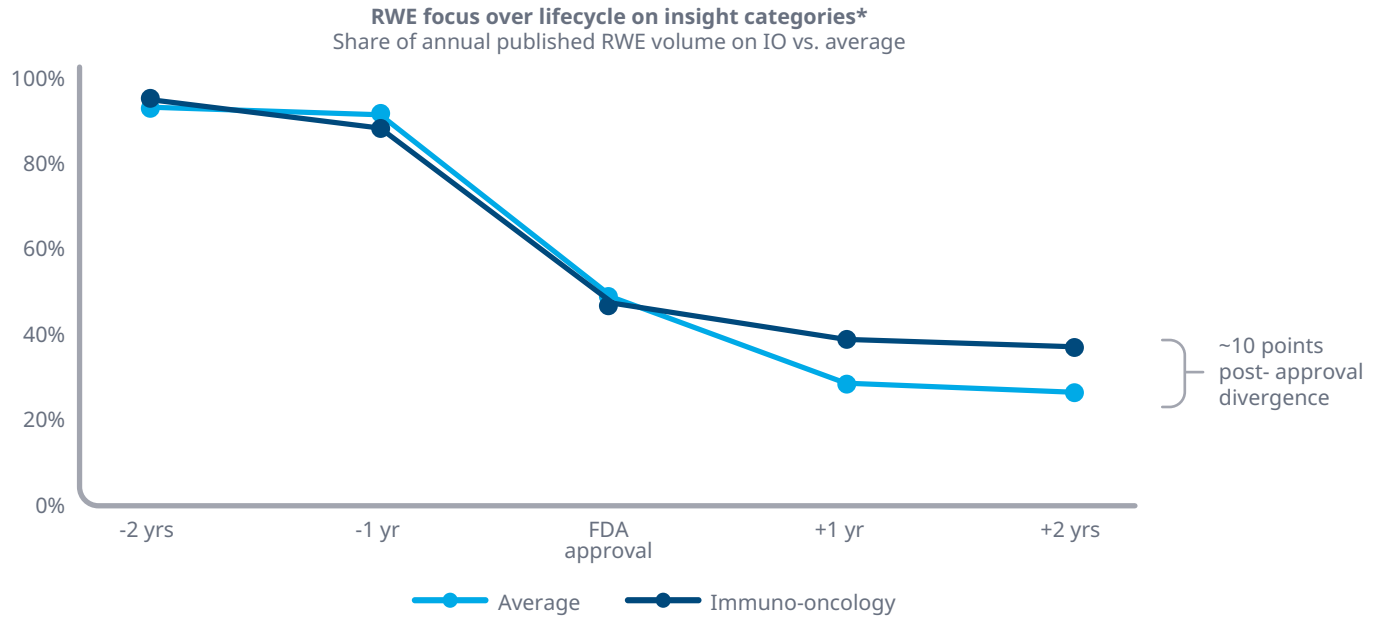
Immuno-oncology

Compared to the broad trend in the evolution of RWE focus over the product lifecycle, we observed that immuno-oncology launches maintain greater focus on insight categories, which include patient characteristics, disease characteristics and clinical practice.

During the 2-year post-approval period, we found that immuno-oncology launches diverge by about 10 percentage points in annual RWE volume share for insight categories, above the average trend line for all launches. This divergence comes largely at the expense of the health economics category.

A review of the information provided in the relevant publication abstracts suggests that immuno-oncology launches generate real world insight to address a range of fundamental disease and clinical practice related questions, for example:

Figure 9: Immuno-oncology launches maintain greater focus on insight categories



* Includes clinical practice, disease characteristics, patient characteristics
Source: IQVIA European Thought Leadership

- Effective use of biomarkers and companion diagnostics (CDx) in routine clinical practice as predictors of disease progression or responsiveness to immuno-oncology therapy
- Fit of immuno-oncology products within the existing treatment landscape, e.g. how to use them in combination with other agents, or sequencing different regimens in lines of therapy
- Handling of dosing and titration of immuno-oncology products, especially in combination regimens, under routine clinical practice conditions
- Understanding the natural history of disease in different sub-populations and how this impacts treatment decisions for different patient profiles

Given the highly innovative nature of immunotherapy, which represents a true step-change in cancer treatment, it is not surprising that there remain more fundamental questions to be answered, especially once a new product enters routine clinical practice, than in the case of relatively incremental innovations. The continued, disproportionate focus of RWE on insight categories for immuno-oncology launches appears to reflect these particular challenges.

Diabetes

Diabetes launches broadly follow the general pattern of how RWE focus evolves over time for the respective 2-year timeframes before and after their initial approval. However, later in the lifecycle of the drug classes that we analysed, i.e. GLP-1 receptor agonists and SGLT-2 inhibitors, we found interesting shifts in the focus of published RWE.

During a period spanning 2 years before label expansion to include cardiovascular (CV) benefits until up to 5 years after, significant RWE focus is dedicated towards two categories, real world effectiveness and patient characteristics. The respective volume shares for these categories increase to more than twice the average we have observed across all launches in the typical 2 years or more after approval.

With cardiovascular causes a major contributor to diabetes mortality, controlling cardiovascular risk while lowering glucose levels is central for an integrated approach to diabetes management. The discovery of CV benefits for GLP-1 agonists, and especially for oral SGLT-2 inhibitors, was therefore greatly welcome.

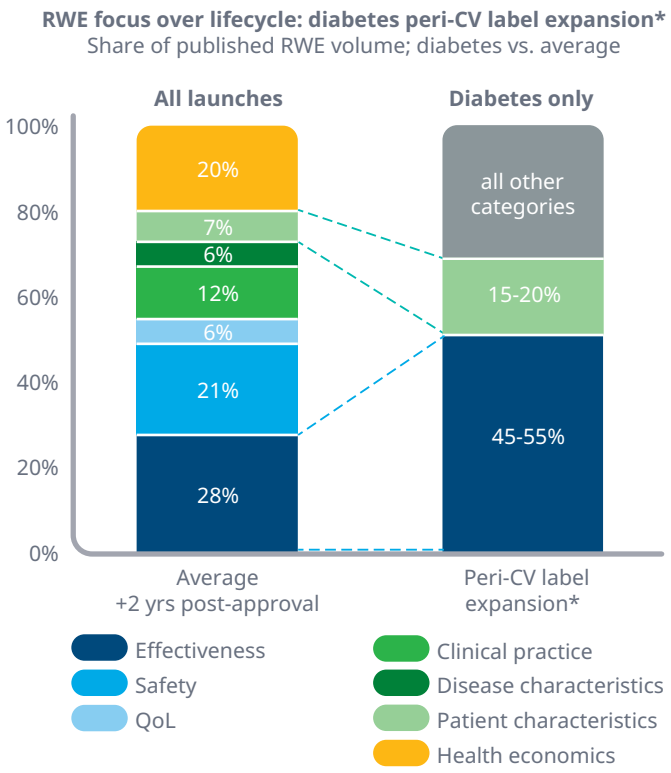
As a typical primary care condition, diabetes affects a huge global patient population, in the order of

several 100s of millions. Hence, the generalisability of results from cardiovascular outcomes trials (CVOTs), with their tightly controlled patient cohorts, to the wider, more complex diabetes population poses a real challenge. This is where RWE can play to its strengths, to complement and substantiate RCTs, by representing a broader, more diverse population of diabetes patients actually seen in routine practice, while exploring a wider range of outcomes, over longer follow-up periods.

This is precisely what we observed, with major diabetes players extensively utilising RWE alongside their CVOTs, including large-scale, landmark real world studies evaluating 100s of thousands of patients, for example, AstraZeneca's CVD-REAL[12], or Boehringer Ingelheim's/Lilly's EMPRISE.[13]

Their efforts are well placed: The invaluable role of RWE in bridging the evidence gap between CVOTs and real world practice is increasingly being recognised by regulators, HTA and guideline setting bodies alike.[14]

Figure 10: Focus on outcomes and patients stepped up around label expansion - *Diabetes launches*



* Spanning period from 2 years before CV label expansion until up to 5 years after
Source: IQVIA European Thought Leadership

Conclusions

In today's launch environment, RWE has emerged as a new battle line to become a strategic differentiator. As we have seen, excellent launches have realised this, and they are embracing RWE strategically as a source of competitive advantage.

To unlock the full strategic potential of RWE for their launches, pharmaceutical companies need to change the way they approach evidence:

1. Evidence generation needs to be elevated to a strategic level that resonates with senior commercial and general management audiences, who tend to have ultimate responsibility for launch success and are often key stakeholders in relevant decisions on investment in evidence.
2. Companies must approach evidence generation with a competitive mindset – how to stand out from the pack and win the battle for share of mind in a crowded market place.
3. Companies need to develop comprehensive, integrated lifecycle evidence plans, starting early with anticipation of stakeholders' needs, and ensure RWE focus aligns dynamically with evolving needs over time, while bridging the evidence gap left by RCTs.
4. Companies must also show conviction in their commitment to RWE, following through with competitive levels of investment to execute their lifecycle evidence plans and sustain differentiating levels of RWE productivity for many years after launch.
5. As a prerequisite to delivering and sustaining competitive levels of RWE productivity, companies need to establish a world-class RWE capability, such as an evidence platform, participate in health system evidence networks and embrace innovations in evidence generation, for example, 'secondary data first' or novel study designs.[15]

By moving beyond regarding RWE simply as a combination of necessity and nice to have, and instead embracing it as a true strategic asset and differentiator, pharmaceutical companies will unlock a novel source of competitive advantage. This will serve them well in their quest for launch excellence.

Final thoughts

While this white paper has focused on volumetric analyses of published RWE, at no time were we implying that large quantities of evidence alone are sufficient.

Any impactful evidence must be of the highest quality, too: robust, compelling and relevant. Furthermore, its high quality needs to be matched by the profile of the dissemination channel, for example, highly reputable journals or prestigious conferences.

Even then, high quality evidence will only have impact if it is communicated effectively by credibly engaging external stakeholders. This requires a highly skilled and adequately equipped in-field organisation, which in our experience represents a considerable capability gap that many companies still have to close. But this is a topic for a future white paper.

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