The pharmaceutical industry's increasing focus on RWE reflects the greater supply of electronic patient-level data and higher stakeholder demand for RWE-based decisions. So why have manufacturers struggled to act? They have been constrained by a limited fact base and isolated case examples, prompting this research. Here, we detail data supply dynamics and over 100 cases studies of actual RWE influence on product decisions.

These quantifiable insights debunk a number of common beliefs:

- RWE's influence on decisions about medicines has increased in magnitude and scale in western markets: more than 100 observed case studies illustrate its evolution beyond pharmacovigilance (PV)
- Payers have applied RWE in assessing value in a variety of ways, including expanding medicines use where warranted: cost containment is not the sole objective
- Although payers are a powerful stakeholder in setting the RWE agenda, proactive pharma engagement matters: manufacturer-generated RWE influenced over 25% of observed decisions
- RWE strategies need a local context but four fundamental market archetypes can focus pharma efforts: pharma does not need a unique approach in every country

This study provides a detailed understanding of market dynamics, consolidating them into four dominant archetypes. It enables manufactures to focus RWE investments via improved internal alignment and gain greater value from stakeholder engagement. The insights it provides are also relevant to policy makers and payers seeking value from RWE.

**RWE MARKET IMPACT RANKING**

1. United Kingdom
2. Sweden
3. Netherlands
4. United States
5. France
6. Italy
7. Denmark
8. Canada
9. Germany
10. Spain
THE STRUGGLE FOR DECISIVE ACTION

The increasing need to obtain better value for healthcare spend has elevated RWE’s importance as a decision-making tool. This is particularly true for medicines. In separate research, IMS estimated that improved medicines’ use could avoid USD300-650 billion of cost worldwide.

Even stakeholders who see the RWE opportunity and its increased use struggle to act on it. Limited, isolated public case studies create a narrow picture of how RWE has affected decisions and misjudge the complexities in the underlying drivers of RWE across markets. The debate is muddied further by different stakeholder perspectives – industry versus payers, health economics versus pricing and market access (PMA).

The result is confusion, misalignment, and even organizational paralysis over what to do about RWE in pharmaceutical companies. Some see RWE narrowly – supporting safety or mandatory submissions – while others see a broad lever to engage stakeholders. While RWE evangelists clash with skeptics wanting proof that RWE matters, they themselves are split between those who see many positive opportunities and those focused on using it to mitigate risks.

FACT-BASED INSIGHT

To forward the debate, we sought an objective demand and supply lens on RWE. This focused on licensed medicines use rather than innovation, PV, or broader payer and provider use such as patient pathway evaluation. Payers, health technology assessment (HTA) experts and clients provided insights in over 50 interviews.

FIGURE 1: RWE APPLICATION CASE STUDIES ACROSS COUNTRIES

Sources of impact
- Label
- Launch Access\(^1\)
- Ongoing Access\(^2\)
- Price
- Use

\(^1\) Launch Access: Agreement for RWE generation for market access at launch
\(^2\) Ongoing Access: RWE used to support access post-launch
To characterize demand, more than 100 non-safety examples were identified in which RWE impacted medicines (Figure 1). Mainly driven by payers, RWE has influenced license (label), access, pricing, and use across countries and therapeutic areas (TAs). Approximately 25% of these decisions reflect industry-generated RWE, demonstrating that pharmaceutical companies influence this evolving landscape.

In addition to demand, we examined real-world data (RWD) supply, focusing on database use rather than (costly) prospective data generation. A proxy for supply, RWE output through peer-reviewed research varied from the thousands of publications in the US and UK to only a few hundred in Germany and France. This difference reflects varying usefulness of electronic data and different stakeholders’ ability to access it. Useful data would have extensive coverage, illustrate the full patient journey, and have high clinical depth and quality. While only selected actors might need this level of data to create value, in practice widespread appropriate access generates more research output (Figure 2).

FIGURE 2: RWE SUPPLY FROM DATABASES SOURCES

Overall, no country has an ideal data supply, with usefulness of or access to data constraining supply to different extents. In access-led countries (above the arrow), improving supply focuses on usefulness, such as the UK’s national CPRD\(^1\) linkage program. Companies play a role too, such as IMS’ US strategy of developing sophisticated HIPAA-compliant\(^2\) linkage technology. In usefulness-led countries (below the arrow), debates are ongoing to improve access, such as to payer data in France. Meanwhile individual companies are engaging directly with physicians and patients for consent to lever data for research.
This new fact base is not complete without market-making mechanisms or frameworks. Enabling demand, these detail how decision making could include RWE. Examples include evaluation mechanisms (e.g., HTA, reimbursement processes, clinical guideline development), dissemination, and measurement (e.g., prescriber incentives, payment for performance, quality indicators). This complete framing can help pharmaceutical companies, payers, and policy makers alike derive the fuller potential of RWE.

**RELATIVE MARKET COMPARISON**

To highlight markets’ individual characteristics, we created an RWE assessment scale based on supply and demand. Data supply and demand frameworks were each scored out of five, and application was scored out of ten to reflect the importance of observing RWE demand in practice. This reveals major differences in RWE impact, with countries scoring between 2 and 11 of a potential 20 (Figure 3). The maximum score of 11 reflects that no country has the ideal conditions for RWE use in a scalable manner and highlights RWE’s infancy. Lower scores indicate that RWE is relatively less available or more costly to generate with less consistent or transparent use in decision making. But even in markets with lower scores, RWE is still relevant.

In terms of data supply, the US scored highest, with a commercial market ensuring data availability for research needs, enabling research output greatly surpassing other countries. The US did not score a maximum five as ongoing linkage efforts are yet to achieve their potential, and underlying Electronic Medical Record (EMR) data capture is lower relative to other countries. Conversely, countries such as Spain score low given limited pockets of usable data.

**FIGURE 3: RWE MARKET IMPACT SCORES (OUT OF 20)**
On demand frameworks, the UK is closest to the ideal because RWE is used in systematic review for most evaluation processes (HTA, reimbursement, clinical guidelines). Stakeholders can disseminate RWE directly to prescribers, and RWE-enabled payment-for-performance contracts encourage appropriate prescribing. Even the UK can go further: for example, RWE-enabled prescribing indicators are still limited. Conversely, countries like Denmark and Spain lack clearly defined roles for RWE in decision frameworks.

In terms of application – where RWE has informed decisions – all countries are distant from the ideal. Consistent, transparent use of RWE in decision making is lacking across therapeutic areas and patient populations. Case studies from the UK suggest the most extensive application, given the number, variety, and breadth of resulting decisions relative to the entire health system. Conversely, in countries such as Germany, public case studies of RWE application are rare.

**MARKET CLUSTERS AND STRATEGIES**

The analysis explains markets through RWD supply and RWE demand (clear frameworks and application to decisions). These dimensions and scores segment markets into four groups: Pioneers, Traders, Explorers, and Laggards (Figure 4).

**FIGURE 4: MARKET SEGMENTATION FOR PHARMACEUTICAL INDUSTRY STRATEGIES**

**Pioneers**

Stakeholders in Pioneer markets use their relatively notable RWD supply to inform drug decisions. Countries in this group – the Netherlands, Sweden, and the UK – all have strong national HTAs, suggesting an impact from concentrated decision making. In these markets, pharmaceutical companies should set high ambitions for RWE plans, demonstrating value and engaging stakeholders based on a variety of real-life views (e.g., disease, product, class, cross care settings, long-term outcomes, payer-relevant quality of care indicators). They must fully exploit RWE beyond traditional evaluations to enable commercial strategy, leverage outcomes-based marketing, and use innovative evidence tools with local health systems.
For example, one ground-breaking manufacturer developed a mobile (iPad) evidence platform to support its diabetes drug launch in the UK. It used RCTs and various RWD sources to build models of prescribing patterns, cost and outcomes for general practices. Trained sales representatives engaged prescribers by adjusting the pre-loaded parameters of the model (e.g., patient numbers, prescribing profile, cardiovascular risk factors) to discuss prescribing from the clinician’s perspective. As RWE becomes an accepted dialogue with payers and clinicians in Pioneer markets, companies without these capabilities will be disadvantaged against or unable to respond to more innovative competitors.

**Explorers**

Explorers, such as France and Italy, have a significant demand-side vision but limited RWD supply. France’s bold vision includes using RWE for cost-effectiveness assessments and regular class reviews without detailing how extensive data in the health system can be accessed or levered. In Italy, there is widespread use of pay-for-outcomes or Coverage with Evidence Development (CED), but how these schemes inform coverage or pricing decisions based on the captured data remains unclear. While manufacturers can react to these limited demands for RWE, the more innovative ones might place a bet that the markets will expand RWE use over time. There is no crystal ball, but this RWE demand could signal an evolution to pioneer style markets. Either way, pharmaceutical companies must develop some RWE capabilities for payer’s current focus areas.

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For example, one inventive company has “gambled” on developing a high quality evidence platform in France. With no access to payer data, it has partnered with commercial vendors to use innovative and cost-effective approaches to maximize the value of existing EMR and Ministry of Health datasets. Using these as an initial platform, the company is gathering supplementary data to develop a high quality reference cohort in a chronic disease. In addition to classic RWE, this generates process-of-care indicators, setting a benchmark for understanding patient outcomes.

**Traders**

The US is the only country representing the Traders, though other countries not in scope could have a similar model. Owners of RWD share it without stipulating how it should be used beyond ensuring individual privacy. Most US insurance companies and providers sell data and only use it to support specific analyses about their own populations. Thus, pharmaceutical companies have broad data access to drive performance, from trial design through commercial support. Successful US strategies involve evidence platforms and tools that support multiple internal stakeholders. However, without clear frameworks, the channels for external engagement are more nuanced. Only selected payers engage readily on RWE, and FDA regulations on RWE dissemination are more restrictive than in Pioneer countries. A differentiated engagement approach is needed, requiring creative thought and investment.
One leading company, for example, developed a rich platform in one priority therapeutic area rather than a ubiquitous platform across TAs. Over several years it linked all relevant datasets (Rx, Claims, EMR, registries, RCTs, observational studies, biobanks) and developed different internal customer tools to exploit it. This asset supports traditional RWE and multiple peer-reviewed publications. More impressively, it generates hundreds of internal standard reports even improving sales forecasting accuracy. This capability enhances external engagement too, as the manufacturer is now a reference for local prevalence estimates or characterizing local unmet patient needs.

**Laggards**

Finally, there are the Laggards who may use RWE more in future but face significant hurdles today. The Laggards in this study are Canada, Denmark, Germany, and Spain, all of which illustrate different challenges (e.g., strong data privacy, fragmented healthcare landscapes). In these markets, pharmaceutical companies benefit from engaging directly with selected stakeholders willing to lead on RWE. Markets with strong regional payers may see that leadership from those regions, such as Cataluña in Spain or Ontario in Canada. In Germany, some sick funds have expressed willingness to partner on RWE.

Given the limited resources of these stakeholders and the large number of manufacturers, developing a clear value proposition and local RWE capabilities are essential to becoming a preferred partner. Innovative companies have long been in dialogue with regional stakeholders, quietly making co-investments in research capabilities to further all parties’ goals.

**FROM INSIGHT TO ACTION**

How can senior executives lever these insights for actionable RWE strategies? The emphasis and insights can be used to engage their teams to determine

- **Where** will additional investments in RWE create most value for our portfolio (e.g., market types, therapy areas, stakeholders, phases of the lifecycle)?

- **What** changes to brand evidence plans or stakeholder engagement approaches on evidence can capture the RWE potential in each of the four market types?

- **How** should our RWE generation capabilities be reinforced, such as scalable platforms, targeted stakeholder engagement, or deployment of innovative channel tools?

While franchise and brand teams naturally drive questions on the where, increasing leadership from PMA is required on the what, as is leadership from HEOR, epidemiology, and other evidence functions on the how. Senior executives may need to personally champion cross-functional RWE discussions given the strategic issues involved and given organizational hesitancy around perceived RWE risks even at the expense of potential gains.

*For a full view of country by country dynamics, detailed case studies and methodologies, please request the extended white paper from the authors.*
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Acknowledgments

The development of this work has been a collaborative effort from many individuals across a range of backgrounds and settings. The authors would like to sincerely thank the contributions from numerous payers, clients, members of the global HEOR team at IMS and others for their expert knowledge and insights, which were invaluable in the development of this work.

Websites

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