Breaking New Ground with RWE:

How Some Pharmacos are Poised to Realize a $1 Billion Opportunity

The pharma industry has invested substantial resources in Real World Evidence (RWE). Differential success rates have been observed, with little consensus on best practice or value potential; the most successful companies have realized substantial value across the product lifecycle through RWE platforms and these RWE leaders are poised to capture sustained value.

What's the conventional wisdom on RWE?

- RWE and patient outcomes are becoming a powerful currency for engagement and demonstrating product value
- Hundreds of examples of RWE-based payer decisions impacting product use seen[1]
- Most pharmacos are making major RWE investments

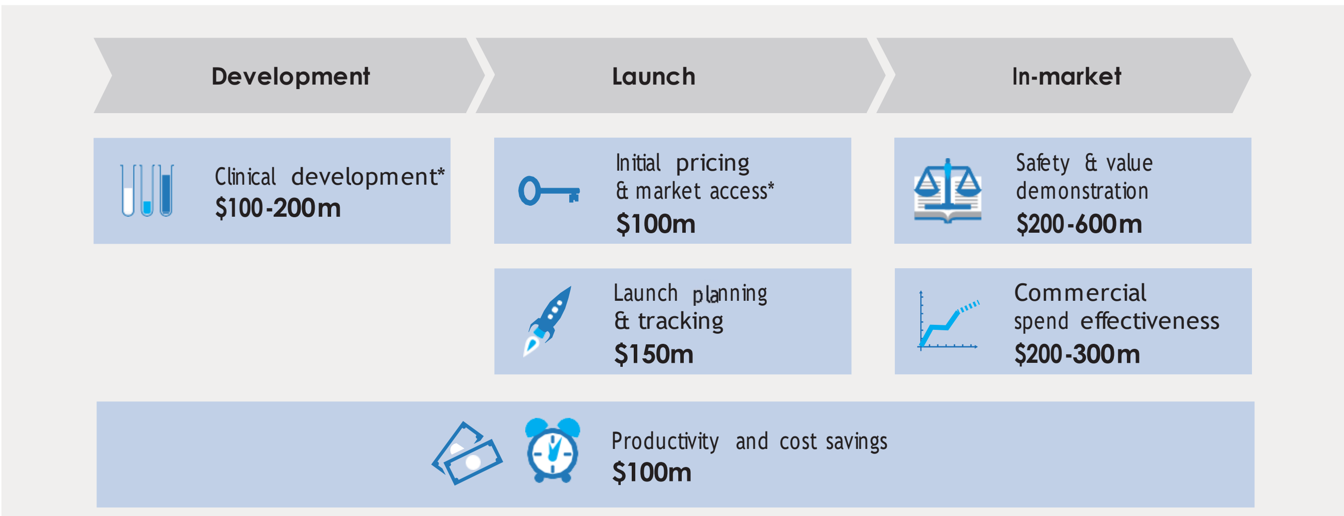
What new RWE opportunities are emerging?

- Demonstrating product value for PMA is only one of six major RWE impact areas
- Extending RWE use, such as to commercial spend effectiveness or launch planning, can realize $1bn in value (Figure 1)
- Platforms enabling on-demand RWE insights are driving value capture and PMR substitution

What are the implications for pharma execs?

- RWE needs commercial leadership and investment beyond immediate business challenges
- Making trade-offs on TAs and market focus accelerates overall impact
- Explicit performance goals, including faster timelines for scientific analyses, is key

FIGURE 1. VALUE CAPTURE FROM RWE ACROSS LIFECYCLE FOR A TOP-10 PHARMACO



*Selected operational opportunities only; excludes increased R&D pipeline throughput and better pricing

[1]Hughes B, Kessler M. RWE market impact on medicines: A lens for pharma. IMS Health Access Point 2013; 3(6): 12-17

The Commercial organization must champion RWE to broaden its value beyond traditional applications and realize its full potential.

A few leading companies have broken new ground in driving a systematic – rather than opportunistic – approach to RWE. They're implementing RWE platforms that move beyond narrow study-based approaches to create sustained value across the product lifecycle and disease franchises. Applied systematically, RWE could realize $1 billion in value for a top-10 pharmaco.

Companies that have not experienced the breadth and depth of RWE applications firsthand may find this figure astounding, particularly if they view RWE as a tool primarily to support market access and demonstrate product value. Leaders, however, regard this figure as an achievable target based on the value realized from their own RWE platforms.

What have leading companies (some claiming to be capturing ~$500 million as they strive to reach $1 billion) done differently? Their experiences suggest Four Golden Principles of RWE transformation:

1. **RWE capabilities should converge in a platform.** Leaders consolidate budgets and make longer-term investments in information, technology and analytics tools to open up a range of uses not possible with registry-style or study-by-study RWE approaches.
2. **Narrow precedes broad.** Leaders focus on select therapeutic areas and markets to ensure that their investments lead to differential value.
3. **Commercial leads the charge.** While medical/HEOR departments may lead *implementation*, the Commercial organization must champion efforts to broaden RWE's application and value.
4. **Speed is a goal.** Leaders seek speed to insight, and can perform end-to-end scientific studies in weeks. In their vision of on-demand insights, quality and speed are harmonious, not trade-offs.

Other companies can benefit from these lessons if they move quickly to compete with leaders who are constantly uncovering new opportunities and improving their own approaches.

Shaking free of traditional thinking on RWE and making meaningful, wise investments can capture dramatic, sustained value – even $1 billion annually for each of the largest companies.

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Real-World Evidence (RWE) has long been heralded as a "game changer" for the life sciences industry. As outlined in IMS Health's paper RWE market impact[1], its impact in pricing and market access decisions is proliferating.

RWE is drawn from robust anonymous patient-level data using sound scientific and commercial analytics. It is not about amassing "Big Data" so much as performing targeted analyses on ever expanding healthcare datasets.

While RWE is known to complement data from Randomized Clinical Trials (RCTs), its real potential is in moving decisions away from perceptions and broad extrapolations to the actual facts about patient journeys and outcomes. With innovations in data and technology, RWE is replacing other information sources such as non-behavioral primary market research (PMR), standard market reports, consumption/market data purchases, observational studies, and even selected spending on RCTs.

RWE is delivering deeper insights about patient care, treatment pathways, and drug effectiveness than previously thought possible. Companies are using RWE to support clinical development, improve launches, and drive better commercial results in physician targeting, detailing, and promotional activities. Indeed, commercial spend effectiveness is emerging as one of the biggest sources of RWE value.

Quantifiable RWE Capture: Exemplary Companies Aiming for $1 Billion Potential

Two examples of the journeys that leading companies have taken with RWE help demonstrate how this promise can be realized across an expansive set of opportunities and functions.

CASE STUDY 1: SCALING ACROSS FUNCTIONS

One company started its RWE journey in a typical way: a need to demonstrate the value and safety of one of its products, a $1 billion oncology therapy. A challenge from the Food & Drug Administration (FDA) and potential label changes put up to $500 million of revenue directly at risk. It developed an RWE platform to avoid that risk and then extended its use to improve commercial spend effectiveness and, most recently, clinical development.

Built platform in response to safety challenge for $1bn product

- Developed RWE platform with "off-the-shelf" claims data
- Partnered with providers to enrich platform with outcomes data
- Put brand challenges to rest rapidly including FDA response in <2 weeks

Extended platform to Commercial, improving physician segmentation

- Based highly targeted marketing campaigns on observed patient pathways, doubling sales growth
- Shared forecasting and disease progression models with providers for use in service planning

Increased data depth to enable clinical development

- Enhancement of the platform continues with the addition of linkage to tissue samples
- Enables more effective Ph II-III design translations

[1]Hughes B, Kessler M. RWE market impact on medicines: A lens for pharma. IMS Health Access Point 2013; 3(6): 12-17