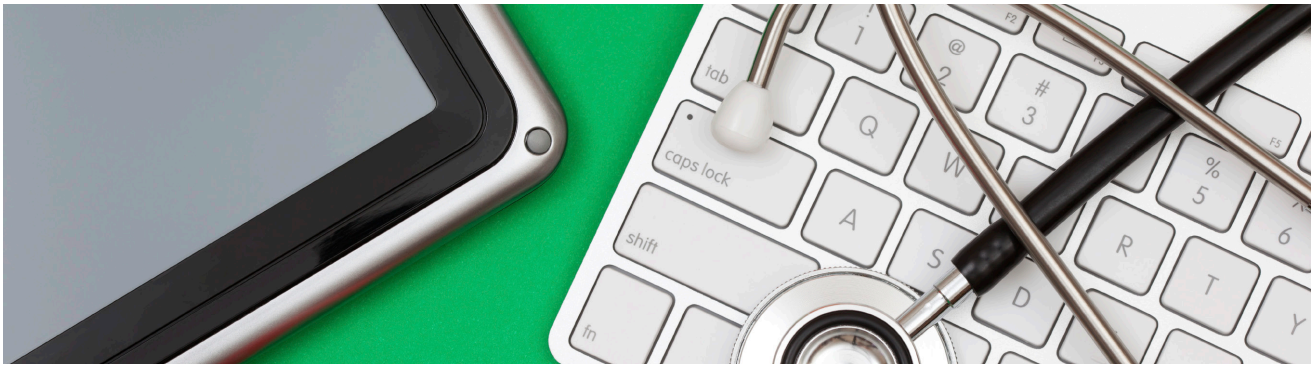
IT insights



How can pharmacos take advantage of the real-world data opportunity in healthcare?

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Article at a glance

Why is this important?

The proliferation of information technology at the point of care and the improvement of payor data sets creates a significant increase in the availability of real-world data (RWD) in healthcare.[1] Pharma customers and regulators are eager to mine such data for any insights that can drive down cost and protect patient safety. Over the longer term, we expect analysis of RWD to be a cornerstone of value-based pricing methods that may redefine the basis of competition and access. Meanwhile, pharmacos can use RWD to generate advantage across the value chain, from sharpening the understanding of diseases and treatments, to informing the design of products and trials to address those opportunities, to gaining and defending market access. Our clients are actively engaged in projects across these areas to win and build sustainable capabilities.

What do I need to know?

The availability of RWD is rapidly advancing and has reached pockets of critical mass. National and large private payors have improved their data infrastructures to enable more pointed research into the total cost of care and the therapeutic context of the drug regimen, forcing pharmacos seeking access to build the capability to respond. Analyses from third parties, such as academic medical centers with access to clinical data, are shaping the discussion, too—with research methodologies that may be debatable. Pharmacos will increasingly need to actively mine RWD to stay ahead of potential news and dismantle dubious challenges. The case for urgency in building these capabilities is rising as strong analytical talent and critical data partnerships are constrained resources likely to provide advantage to early movers.

How do I make it happen?

To take advantage of the emerging opportunity, pharma companies need to evolve their health economics and outcomes research (HEOR) capabilities by refreshing their data strategies (to access new RWD sets) and internal operating models, based on product pipelines and strategic objectives. With an eye toward partnerships and building internal capabilities, we believe the winners will also define asset-level plans for using RWD. Internal challenges will not be insignificant; many organizations believe they are "already" pursuing RWD. In our assessment, however, these efforts are at a nascent stage, and ad hoc in nature; most are not building RWD analytics capabilities at scale, or with sufficient attention to talent development, governance decisions, and the many legal unknowns. We see the opportunity for select pharma companies to play a central role in shaping the standards and public policy that govern how this topic evolves, including how to measure clinical effectiveness and how to create a viable model for data access that upholds the tenets of patient privacy.

What is it worth?

The acute traction point for RWD in the near term is in gaining or defending market access: building a scalable capability can support access for products in key markets—this is becoming a near-requirement in some markets such as Germany and France. Additional value comes from using RWD to identify patient subsegments with superior product performance, optimize R&D portfolios decisions (shaping the product), and negotiate for value-based pricing agreements.

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1 This paper uses RWD to define claims databases and clinical records primarily, though the definition extends to lab, patient registry, and genomic data, as well. Analysis of RWD, or "real-world research," is implied in our use of the term "RWD." Real-world evidence is the post-analysis byproduct of this data, as an article or retrospective study, with a definitive insight.

Why is this important?

Customers, regulators and competitors have begun forming RWD strategies

Across geographies, gaining control over healthcare costs is an undebatable imperative of payors and governments. In large developed markets, payors and regulators are moving toward systematic reviews of RWD on in-market pharma products to confirm product safety and comparative effectiveness versus incumbent products. The more progressive healthcare systems are using this data to determine product cost-effectiveness and value, and fast approaching pricing and reimbursement decisions, in part, based on RWD. Notable recent advances by the public payors in the United States, France, and Germany are moving those markets toward the already established role of health technology assessors in the United Kingdom, Australia, and Sweden. Private payors in the United States are navigating carefully, initiating partnerships and joint studies with pharmacos to "understand" product value, but those partnerships will very likely evolve into new standards for what is expected in the dossiers that accompany market access appeals.

Opportunities to gain advantage across the value chain

Given the value at stake—potentially direct causation of market access achieved or denied—many pharmacos are accelerating their own capability development. In our recent proprietary research, all of the Top 10 pharmacos we surveyed have initiated RWD projects to inform product development and/or commercial decisions, ranging from better contextual understanding of disease states and treatment patterns to assessing efficacy in sub-populations. A majority are also leveraging RWD in performing safety studies and designing clinical trials, but in far smaller scale. Longer term, we see four primary areas of influence from RWD for pharmacos:

- **Characterize diseases and patient populations:** Understand epidemiology trends, treatment patterns, patient adherence and disease management opportunities.
- **Develop products and therapies:** Assess use of current competitive in-market products, design inclusion/exclusion criteria for clinical trials, perform predictive models on virtual trials, identify patients for recruitment, identify unintended uses/indications (i.e., Phase IV leads).
- **Assess products and therapies in use:** Observe drug safety, compare product effectiveness, assess health economics, and design pay-for-performance criteria.
- T**arget products and services:** Identify underserved patient populations, identify high-cost areas for risk-based product pricing, identify subpopulations with superior product response, and track message effectiveness through prescribing behavior.

What do I need to know?

The availability of RWD is reaching pockets of critical mass

The supply of data to meet the rising demand derives from three primary sources:

- **National payor systems.** For example, in the United Kingdom, the National Health Service's (NHS) General Practice Research Database dataset represents 11 million U.K. patient lives; Sweden's Nationella Kvalitetsregister database captures data across care settings for 9 million patients with any of 70 prioritized diseases. Germany recently announced the intention of opening up large datasets of highly standardized claims information.
- **Private payors and integrated systems:** For example, in the United States, Wellpoint's HealthCore unit has data on 34 million patient lives across 14 states. Similarly, integrated systems like Kaiser Permanente in California or Partners HealthCare in Massachusetts have the critical mass to provide a single data-rich environment. Partners has linked inpatient and outpatient electronic medical records with claims on 8 million patient lives, with multiple studies performed and under way.
- **Clinical IT systems providers.** For example, in the United States, the major clinical systems providers—now expected to be installed in 65% of hospitals and 32% of physicians' offices by the end of 2013—are reaching sufficient scale to make aggregation and commercialization possible. Allscripts and GE both offer access to de-identified clinical datasets on millions of patients in some of their electronic health records systems (albeit with limited longitudinality).

Analyses affecting your products may already be under way

With data becoming more broadly available, some RWD may come to resemble a public commodity—made available by public payors, providers, and/or public-private partnerships—and therefore be more subject to scrutiny from all angles. The FDA's Sentinel Initiative in the United States is a good example of a public partnership for monitoring of RWD for product safety signals. More immediately, however, pharma-sponsored real-world evidence studies continue to be the primary vehicle for comparative effectiveness research, with pharmacos sponsoring 85 retrospective studies of real-world data since 2008.[1] Additionally, multiple examples exist to indicate that payors will proactively scan RWD for opportunities to limit products or otherwise bend the cost curve. Whether from competitor or payor, regulator, or rogue "independent," pharmacos should expect challenges to come from any direction as RWD studies become more commonplace. Our clients need to know how they'll respond and proactively prepare to do so—they cannot sit still until a controversial study is made public.

1 ISPOR Posters 2010, Google Scholar & PubMed 2008-2011; McKinsey analysis

The capability will be difficult to build and take time to refine

There are challenges to building a RWD capability at scale, both in the broader market and within a given client environment. We see the barriers to progress in five categories:

- **Technical:** Though select data sources are reaching pockets of critical mass, it's still difficult to integrate data sets or build linkages across them to create patient-level longitudinal data.
- **Market:** Establishing data standards and consistent definitions of analytical guidelines/quality (e.g., what defines "superior efficacy") have been much discussed but remain unresolved.
- **Legal/regulatory:** Legal and regulatory policies regarding protection of patient health information have erred on the side of conservatism.
- **Organizational:** Particularly in the traditionally independent silos of a pharma company, clients will need to address governance decisions regarding data ownership and internal sharing; investment decisions may require collaborative approaches across brands and functions.
- **Talent: A** related challenge is scarcity of talent—existing internal resources are limited and there are few people available in the market with significant skill and experience on the uniqueness of RWD.

How do I make it happen?

Fortunately for our clients, the rules of competition in RWD are still being written. Pharmacos need not stand by and watch the market evolve. A few pointed strategies should be top of the agenda:

- **Ensure strategic alignment:** Align senior leadership on the value at stake in associated brands, assets, and projects, and create a clear articulation of the enterprise approach to RWD. Appoint a visible senior leadership team to lead cross-functional efforts and build out the talent of the responsible teams. Determine the strategic focus of an RWD effort—R&D, commercial, safety, or all of the above.
- **Evolve the internal HEOR capability and operating model:** Aggregate fragmented efforts and pilots under the responsibility of a central organization—typically HEOR, informatics, or the equivalent—and define a governance model that coordinates enterprise strategies. Design an operating model and associated processes for that body to interface with individual internal stakeholder groups.
- **Determine asset-level RWD strategies:** Review the product portfolio for key decision points and commercial milestones, and the role that RWD can play in defining or defending safety, efficacy, or cost-effectiveness arguments. Identify the partnerships that provide appropriate data access (e.g., by geography, therapeutic area, and analytical capability) to build the argument.
- **Assume a seat at the table to shape industry standards and policies:** Pharma leadership teams need to engage in industry dialogue to determine standards for what defines clinical effectiveness and policies regarding data access and patient privacy. Decisions or de facto precedents in these areas are highly likely in the near future, and as in other industries, may follow a first-mover standard, versus a thorough deliberation of pros and cons.

What is it worth?

Successful RWD strategies can shift or protect whole market opportunities in and out of a client's favor. In an extreme case, it could mean a binary judgment on the product; in others, sufficient evidence can support premium pricing, stave off a new entrant, extend an advantaged product position, or broaden/narrow a patient pool. A few examples of value at stake:

- **Gain market access versus an incumbent:** Novartis successfully expanded market access for its ophthalmology product Lucentis in the United Kingdom, into the market served by an incumbent competing product, by analyzing clinical data to identify the inflection point in the efficacy of the treatment regimen. The National Institute for Health and Clinical Excellence (NICE) agreed to expand coverage for Lucentis, despite the incumbent product's 33% lower per-treatment price, because Novartis agreed to cap the NHS's cost exposure to no more than 14 treatments.
- **Maintain formulary status:** Another pharmaco averted a public payor's switch to a competitive product going off-patent by using RWD to build an economic case for their brand, including hospitalization costs—the move protected annual sales of $50 million.
- **Maintain formulary status (II):** P&G and Sanofi-Aventis structured their contract for osteoporosis treatment Actonel with U.S. payor partner Health Alliance in 2009 to cover the cost of any non-spinal bone fractures incurred by Health Alliance members on Actonel. The move has delayed the transition from Actonel to generics, and has earned Actonel a preferred formulary position to competitor Boniva.
- **Drive product use:** A pharma client in Europe built a case for physician demand by engaging clinicians in a prospective study that looked at unidentified populations which could benefit, and the efficacy of off-label alternatives. The effort yielded incremental product uptake of 2-20% observed in European markets.

Payors and other stakeholders are pursuing their own value, as well:

- **Challenge a popular therapy combination:** In November 2008 Pharmacy Benefits Manager Medco released a study using RWD that showed an increased risk for major cardiovascular events in patients taking clopidogrel (the active ingredient in a common anti-platelet agent to inhibit blood clots) and proton pump inhibitors (PPIs, for gastric acid reduction) together—increasing the risk of a major cardiac event, such as heart attack and stroke, by 50%.[2]
- **Uncover safety concerns:** Stanford, Harvard, and Vanderbilt medical schools released a study in 2011 using electronic health records that identified a significant safety issue from a drug-to-drug interaction between Pravachol and Paxil that meaningfully increased blood sugar levels (particularly in diabetics).
- **Challenge and defend efficacy of a class of products:** Germany's Institute for Quality and Efficiency in Health Care (IQWiG) judged in March 2009 that long-acting insulin analogues like Sanofi's Lantus and Novo Nordisk's Levemir showed no proven benefit over human insulin, and excluded the class of non-human insulins from reimbursement in early 2010. Sanofi has since launched its own real-world studies, using the results to demonstrate better total cost of care performance, successfully lobbying 156 individual payors to restore access and premium pricing by the end of 2010.

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Specific value analyses for clients will vary, but the movement toward broad-scale RWD availability has begun. We believe now is the time for our pharma clients to address capabilities required to analyze RWD with partnerships, internal and external capabilities. By taking these actions now, pharma companies can shape the opportunities that RWD offers and equip themselves to establish or defend market leading positions.

2 R. E. Aubert, R. S. Epstein, J. R. Teagarden, et al, "Proton pump inhibitors effect on clopidogrel effectiveness: the Clopidogrel Medco Outcomes Study," *Circulation*, 2008;118:S_815.

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