Why pharma needs to work differently with payers and IDNs on RWE

Learnings from recent survey and symposium

Real-World data (RWD) is patient data collected outside of a randomized controlled trial (RCT), often for non-research purposes (e.g., electronic medical records (EMRs), claims data). When analyzed using appropriate methodologies, RWD can provide insights about the way patients are diagnosed and treated in real-life settings, known as real-world evidence (RWE). With the right data and analytics, RWE should inform a common understanding that is used by healthcare stakeholders to drive decisions – still reflecting their own criteria, just not their own facts.

100% of surveyed IDNs in the US use RWD, but 55% need support to do more with it
Pharmaceutical manufacturers are clearly using RWE today, investing to varying degrees to generate scientific evidence and, usually, commercial insights. IMS Health has found that payers around the world also use RWE to inform significant decisions about drug reimbursement and use. And, as shown in the research presented in this paper, payers and IDNs in the US use varying types of RWD to inform their decision making as well.

“ Everyone is entitled to his own opinion, but not to his own facts.”
– Daniel Patrick Moynihan

However, it is clear from our ongoing interactions with clients that pharmaceutical companies still question the use of RWE by payers and providers. This report explores how RWE – with its valuable applications and high feasibility – is being applied today and what levers exist to increase its use by US payers and IDNs. These groups are potentially the most important catalysts for RWE in the US. RWE can drive reimbursement and thus impact provider actions and ultimately patient care, as illustrated with the US Patient Protection and Affordable Care Act (ACA). US payers are therefore key stakeholders to watch. The impact of IDNs on care standards and delivery also makes them an important conduit for applying RWE.

The report is based on research recently conducted by IMS Health with US payers and IDNs, after co-hosting a symposium with Johns Hopkins University on a related topic. Our own work in supplying RWE to payers and providers shows active interest in using RWE for applications such as benchmarking costs and performance. The symposium helped identify payer-related challenges to expanding the use of RWE as well as potential solutions to address them. Our next question was whether these insights were representative of payers and IDNs in general. The answer, in short, is that these groups are similar but diverge in many important ways. For pharmaceutical manufacturers to work successfully with both constituents, they need to understand the similarities and differences.

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1 For the purposes of this report, PBMs are included as ‘payers’ to represent their payer customer even if they only serve as an intermediary in those arrangements.


4 More than 2,200 hospitals paid penalties in 2013 for $280 million in total penalties. Although the financial penalties were manageable for most hospitals, the reputation risk and threat of increasing penalties appears to have encouraged hospitals to change processes to reduce admissions. Available at: http://www.advisory.com/Daily-Briefing/2013/08/09/CMS-2225-hospitals-will-pay-readmissions-penalties-next-year Accessed 9 May, 2015

5 Online survey of 70 payers and IDNs/ACOs conducted in December 2014.

6 RWE Leadership Symposium: Realizing the full potential of RWE to support pricing and reimbursement decisions. Nov 4, 2014, Baltimore. Symposium attendees included payers, executives from pharmaceutical manufacturers, faculty of JHU, and IMS Health.
What RWD do IDNs and payers use today?

The research illustrates the extensive use of RWD in analytics but also the barriers to broader application. IDNs use clinical and pharmacy data nearly universally while payers are almost exclusively focused on pharmacy and physician claims (Figure 1). This distinction is essentially a reflection of the focus and limitations of their RWE efforts.

Figure 1. Payers and IDNs use of different types of RWD. Most Frequently Used Real–World Data Sources.

How do IDNs, MCOs and PBMs use RWE?

RWE is being used by IDNs, MCOs and PBMs to help manage costs and treatment approaches. During the symposium, payers discussed the overriding priority of managing costs in a way that could lead to better outcomes, citing RWE as a valuable tool in achieving that goal. This confirms our direct experience of payers and providers using IMS Health longitudinal prescription data for benchmarking, cost and prescription use patterns, as well as RWE analyses, to answer a variety of ad hoc questions on issues such as medication adherence.
The research illustrates how IDNs, MCOs and PBMs are applying RWE in ways that reflect their business interests (Figure 2). All three groups use it heavily for formulary decision making, while IDNs and MCOs are more focused on comparing treatments. IDNs are also more likely than MCOs and PBMs to leverage RWE for patient management and guideline development. This is surprising considering the importance of medication adherence for all three groups in improving patient outcomes and reducing costs. Finally, PBMs in general seem less interested and engaged in the total healthcare experience, appearing to be more narrowly focused than are IDNs and MCOs.

Respondents indicate that in the future, they expect to use RWE more broadly; in some cases, usage is expected to increase dramatically (Figure 3). For example, 60% of IDNs feel RWE could be used to simulate RCT results. The challenge will be in addressing barriers to generating and translating RWD into useful RWE.

Figure 2. Payer and IDN use of RWE today.
The research reveals the application of RWE across every major therapy area (TA) although most respondents report using it only for three to seven TAs at this time (Figures 4 and 5). One hypothesis for the IDN focus on patient management in a few therapy areas is their implementation of the service-line model, reflecting their efforts to examine and improve care delivery for a disease area holistically across treatment settings.
Commonalities in RWE interest among payers and IDNs are greatest in oncology and to some extent cardiovascular and metabolic diseases. In general, IDNs have focused on diseases affecting the most patients, often with a meaningful inpatient component which they are able to analyze with their hospital data. This emphasis on hospital activity may also stem from their greater ability to influence what happens in a hospital rather than outpatient settings. Their lack of activity in a few areas can be observed but more notable is the divergent efforts. Almost every IDN surveyed uses RWE in the anti-infecive area. Conversely, this TA is of minimal interest to payers, who are much more focused on specialty products and treatments for respiratory disorders.

Figure 4. IDNs and MCOs usually reported using RWE for about 3–7 TAs. Number of TAs where a payer applies RWE.

Source: 2014 IMS Health Payer RWE survey, n=70 US Payers and IDNs

y = Percent of responders
x = Number of TAs
When asked about their future interests, payers envisage increasing their efforts in other TAs but the change is relatively small from today’s use (Figure 6). IDNs, on the other hand, plan to dramatically shift their RWE focus. Whether this suggests they have sufficient information on their current focus areas or that they simply want to bring their understanding of all TAs up to the same baseline is an open question.
Figure 6. Payer and IDN TA interests are expected to change.

What would accelerate payer and IDN generation and use of RWE?

RWE is difficult to generate. As shown in Figure 7, almost every respondent agreed that it poses some level of difficulty; almost half find it very-to-extremely difficult to acquire the RWE they need for decision making and monitoring.
Figure 7. Payers and IDNs find RWE difficult to generate. Difficulty in getting desired RWE.

ISPOR task forces and other forums\(^7\) have identified many specific barriers to generating RWE, principally around the availability and usability of RWD, technology, analytic methodologies and policy. These barriers were confirmed by participants during the symposium, with comments that included: “I have never seen a pharma study that found the drug to be not cost-effective” and “For every one positive study pharma brings us, there are 13 more we never see.”

Our survey further shows that these barriers reflect the fact that payers and IDNs have not yet built up all the required internal capabilities to generate RWE, but are too distrustful of pharma-provided RWE to rely on it as a primary source. An additional barrier, alluded to during the symposium and confirmed in the survey (Figure 8), is that even when they can obtain the RWE they need, payers and IDNs often find the insights too costly to apply. Issues may include contracting terms that limit formulary management changes as well as lack of control over the full spectrum of patient care. Or they may not see adequate benefit for all the effort involved.

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\(^7\) Examples include ISPOR Real-World Data Task Force Report (2007); Roundtable to incorporate observational data into formulary-decision making (2007); Roundtable to assess observational studies for decision making in healthcare (2008); ISPOR-AMCP-NPC Good Practice Task Force (2014).
Against this background, payers and IDNs have been sourcing RWE in three ways: (1) generated internally, (2) received from pharma, and (3) purchased from a third party. Most of these third-party providers specialize in delivering statistical analysis of observational data, meta-analysis of existing literature, and economic models.

It is interesting to note (Figure 9) that pharma is a common source of RWE. Writing recently in the journal *Health Affairs*, James Robinson confirms the increasing use of RWE for formulary decisions by the pharmacy and therapeutics (P&T) committees of major insurers. However, despite requiring manufacturers to provide studies and observational data for formulary placement of new therapeutics, P&T committees do not always trust that manufacturers are providing all the analysis they have conducted. As a suggested approach to increasing transparency, the creation of an RWE version of “clinicaltrials.gov” was explored during the symposium. This concept received great support although participants were aware that some RWE (e.g., phase IV trials) is already listed on this site. Our survey research garnered a similar response: 47% of respondents find the idea very-to-extremely interesting, further suggesting its potential as an avenue for increasing trust in manufacturer-generated evidence (Figure 10).

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**Figure 8. Overcoming RWE Hurdles Barriers to using RWE more.**

Source: 2014 IMS Health Payer RWE survey, n=70 US Payers and IDNs

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When presented with options for increasing the use of RWE, payers and IDNs are open to proposals that both help their RWE efforts and make it easier to assess the quality of the RWE received. These options were based on ideas supported by pharma, academic and payer participants in the symposium.

Figure 9. Third-party RWE providers are the most common partner for IDNs; MCOs work with both third-party providers and pharma Partners for RWE Efforts.
Is pharma stopping itself from doing more?

In discussions during the symposium, pharmaceutical manufacturers cited legal constraints as a reason for not sharing more of the RWE they produce with payers and others. As previously noted, payers have shown skepticism in accepting manufacturer-provided data. But is pharma impeding its own ability by being too risk adverse to share RWE with payers and IDNs?

Below are some parameters for sharing RWE that may help pharma move beyond risk aversion–induced paralysis. This framework is provided for consideration of approaches and is not a legal opinion.

- **Make versus buy.** Payers express unease about receiving information without understanding the intended approach to the analysis, which data sources would be used and how the final insight would be applied. Instead, they seemed keen to be involved in developing a shared hypothesis and even including third parties to address trust issues. Their willingness to help 'make' the RWE increases their likelihood of using it. To reduce the risk of the unknown, pharmaceutical manufacturers have found that running various hypotheses on broader or alternative datasets can help them to better characterize the risks involved.
• **Past vs. present.** Concerns were raised around the application of RWE to risk shares and other future-oriented outcomes. One client mitigated this by modeling-out a risk share agreement on retrospective data and then ‘testing’ it on the previous year’s data (held out from the first phase) in order to gain confidence in the approach. Payers and IDNs can take a similar approach to gain equal confidence in the equity of contracting, an area where they express interest in using RWE.

• **Engaging vs. avoiding.** Pharmaceutical manufacturers are understandably conservative about the way they leverage insights around markets, patients and treatment outcomes. At the most cautious end of the spectrum, some are creating a distinct barrier between commercial and scientific colleagues to prevent internal conversations about this data. Other companies, meanwhile, have created RWE platforms that support cross-functional collaborations, external publications and even partnerships with payers/providers on improving patient care. The challenge is that the lines are not clearly defined. Companies should ensure that the barriers they impose for using RWE internally and externally are reasoned and appropriate. Preventing commercial colleagues from using this information to understand competitive dynamics, for example, comes at the cost of either reduced insight and/or more costly primary market research expenses. Siloed views of the environment can also make internal collaborations on topics such as evidence plans more difficult to achieve.

### What are the implications for pharma?

As with any relationship where partners have opposing interests, progress requires each stakeholder to recognize the role of the other, as well as transparency and a series of incremental steps designed to build trust between the parties. Thus, while payers and IDNs acknowledge that pharmaceutical manufacturers are able to generate more RWE than they can, perceptions of its trustworthiness would be accelerated by the full disclosure of the data, methods and findings (both positive and negative) to an independent third party. And yet their distrust of pharma-generated RWE is their biggest barrier to actually applying it to decisions, underscoring the trust issues discussed earlier.

The challenges and opportunities for pharmaceutical manufacturers reside in five key facts.

1. **Pharma can benefit from the alignment RWE can drive.** Providing more substantial proof, based on real-life use, can elevate brand propositioning by placing its cost into a broader evaluation to better show its benefits and value. Looking at patient outcomes, for example, QoL, broader impact and total overall cost can change the value proposition and actual value of innovative and differentiated brands. RWE creates a common understanding and basis for decision making that should help companies move payers and IDNs away from “if” a product has value to “where” it has value and the price that value deserves.
2. **IDNs and payers differentiate “pharma” as an industry from individual companies creating room to build direct relationships.** This is similar to the political phenomena where voters will dislike congress as a whole but like and consistently vote for their congressperson. As shown in Figures 11 and 12, each group sees each pharmaceutical manufacturer’s credibility distinctly. Indeed, it appears that there are attributes that create differentiation and opportunities for some players in a crowded competitive landscape. It may also reflect the fact that different people see them based on the pharma sales approach. Some IDNs restrict access to pharma representatives so, for them, perceptions of pharma may be based on those sales teams rather than the Managed Care, HEOR and other pharma teams that spend more time with payers.

3. **Payers and IDNs need help.** Both groups identify barriers in generating and applying RWE while having a desire to use more of it. They lack many of the internal analytic and technological skills needed to generate more complex RWE, especially as they leverage data external to their systems. Building a partnership between manufacturers and payers and IDNs to produce information that is needed will obviously enhance the credibility and usefulness of RWE. That said, there are definitely innovative RWE payers, including Express Scripts⁹, so the bar for what is seen as “help” varies.

4. **IDNs and payers are open to solutions that involve pharma.** It was repeatedly stressed in both the symposium and research that solutions involving pharmaceutical manufacturers are both interesting and easy to imagine implementing. The current use of pharma–generated RWE today suggests an opportunity for companies to be involved in its increased generation and application. The involvement of third parties (e.g., to validate data and methodologies, create transparency) may be a helpful enabler of these solutions.

5. **The window for action for pharma may not last long.** IDN openness to collaboration likely reflects their position on the learning curve. Given that pharmaceutical manufacturers have been conducting outcomes research for decades and are building RWE capabilities today, they have valuable skills and experience to bring to the table. Investment will help, but pharma would be marginalizing itself by only supporting funding. All parties involved should share insights to inform patient care as well as future development. And with so many of the IDN respondents working with third–party RWE vendors, the value proposition for a manufacturer needs to be clear and compelling.

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Figure 11. MCO and IDN views of pharma companies. Perception that Pharma Company is credible provider of RWE.

Source: 2014 IMS Health Payer RWE survey, n=70 US Payers and IDNs

Figure 12. MCO and IDN views of pharma companies. Perception that Pharma Company is NOT a credible provider of RWE.

Source: 2014 IMS Health Payer RWE survey, n=70 US Payers and IDNs
A deeper look at the path forward with IDNs

While there is significant variation in a pharmaceutical manufacturer’s reputation for providing credible information to IDNs, MCOs and PBMs, now appears to be a uniquely good time to focus on collaborating with IDNs on RWE. Relative to other risk-bearing entities without care delivery capabilities and objectives (e.g., MCOs), IDNs are uniquely interested in developing a holistic patient view across settings of care. This increases their appeal as potential collaborators on efforts to improve patient outcomes. The process should begin by understanding how RWE could fit into IDN plans for quality and care management.

The rationale of integrating a delivery network should in no small part involve gaining fundamental value out of the integration. Recent research conducted by IMS Consulting Group with IDNs found they believe the creation of a common patient data platform – or at least linkable data – would be a key enabler of this integration. The goal would be allowing them to implement guidelines, programs and pathways across their systems to achieve optimal outcomes and manage healthcare costs, but the first step would be in just understanding their system’s current performance.

This first step can be defined as **Level 1 – Understand current performance** (Figure 13) and requires IDNs to develop a common platform for electronic information to achieve a more complete picture of their system’s performance. Many are still struggling at this level, sitting on highly fragmented data, especially if they have gone through the acquisition of local hospitals and practices. Even IDNs that analyze EMRs or electronic health records (EHRs) may not be analyzing all of them if they are in incompatible systems.

Some IDNs have moved past Level 1 and are approaching **Level 2 – Identify areas for improvement**. At this point, they are focusing on improvement efforts for specific disease states. Since these improvements involve clinical care decisions rather than formulary design or other more administrative actions, they typically concentrate on a few disease areas only. IDN priorities here reasonably reflect the cost of the disease and their patient demographics but also their system’s ability to make changes in that disease. This effort can identify best practice in their own system or insights from other systems.

All IDNs seem to understand that **Level 3 – Implement changes to realize value** – would be critical for capturing the benefit of integrating healthcare data. However, few have been successful here even in one or two diseases. The challenge is understandable given the difficulty in shifting physician and patient behaviors, but it is more addressable when informed by relevant, quality RWE.
Figure 13. Three levels of IDN data aspiration.

Within this context, there are clear areas where pharmaceutical manufacturers could pursue RWE with IDNs. Supporting IDN efforts to integrate their data platforms through pilots or programs (likely through a third party) would not be recommended, being a low value activity for pharma where the main asset they provide is financing. However, below are three examples of how pharmaceutical manufacturers with RWE capabilities (RWE Leaders) could partner with IDNs in innovative, valuable ways.

1. **Provide additional data.** As noted, IDNs often sit on highly fragmented data. They may not be analyzing all of this, let alone complementary datasets. RWE Leaders potentially could play a role by helping to bring in other data sources or working to integrate data for analysis in specific priority areas. This could involve an extraction of EMR data by a trusted party to analyze with other data such as payer claims or even social media, to develop a true picture of the current situation.

2. **Provide quality benchmarks and analytics using broader information sets.** IDNs that have moved beyond Level 1 and understand their current performance may not be fully prepared to compare it to best clinical practice and/or implications for their financial performance. RWE Leaders can provide insights to support this activity. IMS Health, for example, helped a company improve relationships with providers facing Pay-for-Performance (P4P) in high-risk patients. Using Healthcare Effectiveness Data and Information Set (HEDIS) measures for quality benchmarks and EMR, it was able to help the provider create patient segments based on factors such as BMI and look for ways of contracting to optimize the P4P situation.
3. Develop pilot programs for improving outcomes. Pilot programs can serve to apply learnings and continue to use data to improve outcomes, such as compliance. Pharma’s knowledge of diseases, treatments and methodologies such as predictive analytics could be especially valuable in helping identify at-risk patients, find rare disease patients, create more tailored treatment models and even change payment approaches to better reflect value. These types of programs can be built on external data that pharma uses to create and validate the algorithms and interfaces and then pulls from the IDN to simplify implementation.

Recommendations

The first step is to identify the right IDN to work with based on aligned disease areas of interest. Given the effort these partnerships will require, the diseases should be those that are priorities for both the IDN and RWE Leader. The partners should also align around objectives. To succeed, companies have had to overcome their focus on products and appeal to IDNs’ disease-centric interest. Some have reasonable concerns about taking this approach and must build internal agreement before reaching out to IDNs, who have expressed concern about manufacturers “starting and stopping” pilots without making a long-term commitment. Issues for RWE Leaders to consider include the uncertainty of real-world results beyond a product’s influence, “free rider” concerns for competitors potentially benefitting, and the ambiguity of calculating a clear ROI.

RWE Leaders should also bring real solutions to the table. The goal is not to “sell” a totally formed RWE offering to payers or IDNs but instead to provide a clearer vision of how they can use RWE more effectively. Pharma brings expertise and resources that can create unique offerings beyond those that a payer or provider could develop themselves. These solutions need to reflect IDN and payer needs, requiring a frank dialogue with these groups. The ideas cited above could provide a starting point for consideration.

Pharma needs to look at RWE for the long-term. This is a learning process for all involved, where proof of concept can be a catalyst for more RWE adoption. The principles of effective partnerships and pilots apply here, including being clear about each side’s objectives and incentives, transparency in assessing progress against goals, and processes to resolve issues quickly. The need for an iterative relationship where consistent engagement at many levels and times takes place cannot be overstated.

Conclusion

RWE is a critical mechanism for major improvements in healthcare. It creates an opportunity to better understand the current situation and evaluate alternative treatment approaches. IDNs, MCOs and PBMs are fundamental stakeholders in applying RWE; working with them to help generate and apply this evidence is thus an important goal for all parties who are committed to improving outcomes for patients and the US healthcare system. Pharma can play a key role in proactively increasing engagement with RWE whilst also benefitting from the additional insights it provides.
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