The Power of Payer Partnerships *Lies in* DATA SHARING

As payers grow more influential in treatment decision making, sharing outcomes data becomes key for pharma.

Shared use of data between payers and pharma has been occurring for some time, but today — and definitely in the future — data use is being taken to a new level, such as Lilly's recent partnership with Humana (see side bar). The research collaboration is aimed at improving the health of members and patients while addressing the challenges of improving quality of care and reducing treatment costs in today's complex and changing healthcare environment. Similar corporate announcements show that Merck, AstraZeneca, and Pfizer are also working with health insurance companies, such as Medco,WellPoint and its subsidiary HealthCore, as well as Humana. While real-time access to shared data may be unlikely in the near future, pharma and payers will be elevating their collaborations around research and claims data in efforts to improve patient outcomes, and revenue.

The potential of real-time data sharing is tremendous, says Patrick Flochel, global pharmaceutical leader, at EY.

"By combining and mining multiple streams of data, payers have started gaining real-time insights into the efficacy and efficiency of different interventions allowing them to identify and pay for products and solutions that are most likely to improve outcomes in cost-efficient ways," he says.

Such approaches have the potential to offer much quicker and cheaper insights than those gained through the traditional approach of clinical trials.

"The actual implementation will depend on players' ability to address the biggest challenges and realize the potential in real-time insights from big data," Mr. Flochel says. "By collaborating and pooling data, pharma companies could gain the ability to influence such determinations, but to be successful, pharma companies must rebuild trust with payers and providers."

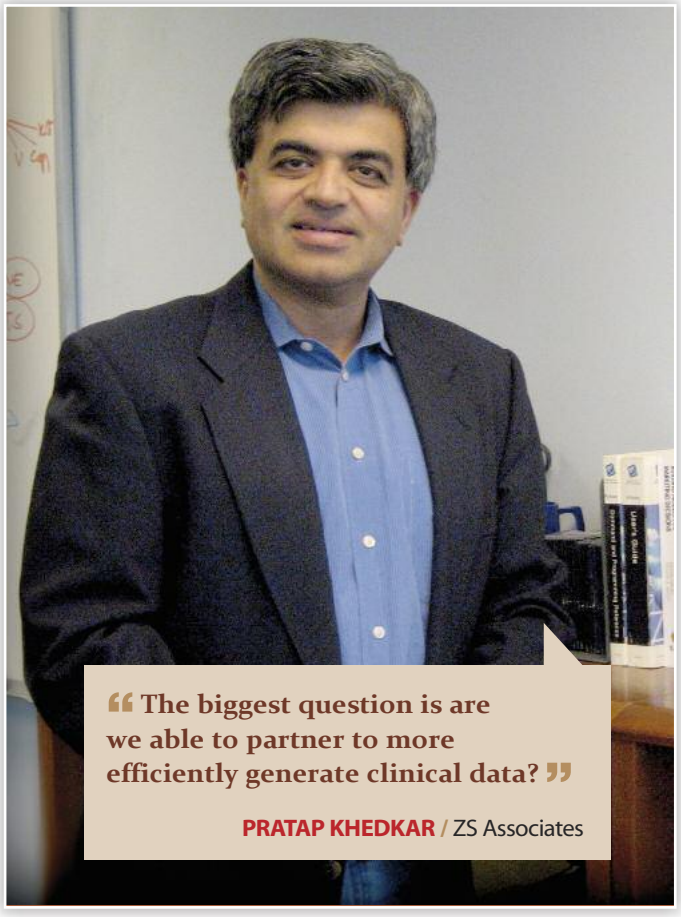
"Sharing data certainly is a valuable part of this collaboration, where the end goal is better patient outcomes; however, real-time data access is not likely," says Paul Kandle, VP and general manager, Opus Health, a division of Cegedim Relationship Management. "Collection, analysis, and evaluation of the data holds many challenges, but will be critical if the collaboration effort is to take shape and be effective."

Chris Wright, managing director at ZS Associates, counters that real opportunities do exist in areas where there are synergies in objectives between industry and payers, providers, and physicians, but this will not be the case for every drug and every customer.

"Understanding how a value proposition fits with customer needs will help identify opportunities for partnerships, but this will not happen quickly," he says.

Mr. Wright says that because of the significant IT-related undertaking that must occur industrywide, the likelihood of real-time data sharing appears low in the near term, but in pockets of fully integrated systems, it may become a reality faster.

"Compliance with FDA guidelines is a major consideration here," he says. "Integrated use of real-time lab data, patient-reported outcomes, actual outcomes, physician notes, and



> "The biggest question is are we able to partner to more efficiently generate clinical data?"
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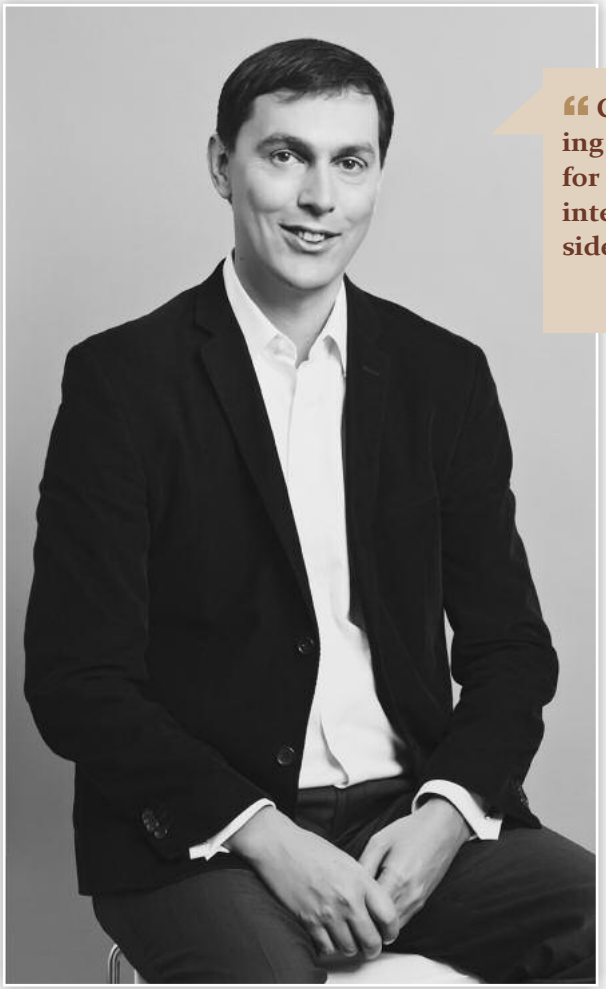
> **PRATAP KHEDKAR** / ZS Associates



> "Companies that are succeeding in data sharing are investing for the long term and have an interdisciplinary team on both sides of the relationship."
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> **TED SWEENEY** / Icon

clinical trial data could really help payers and providers deliver better value to patients. However, if the use of the drug or discussion of it deviates from what was explicitly evaluated in clinical trials, pharma will have trouble participating unless OIG/government guidelines change to reflect the new reality."

Real-time data may not be necessary in all situations, since information on clinical benefits is derived in two ways from claims data: conclusions based on population health and those based on data from an individual patient.

"The former may not need real-time data sharing, although it will require open data sharing and can provide several benefits in terms of real-world evidence to this payer/pharma collaboration," Mr. Wright says.

There are several instances of this already happening. For example, HealthCore is working with pharma companies mining its real-world data of 40 million lives to prove outcome facts for drugs, he says.

"The patient-level use does require quasi-real-time data access — hours/days if not seconds, but certainly not months — but privacy concerns, regulations, and IT costs are likely to make it a lower priority for pharma participation," Mr. Wright says.

Collaboration between the organizations can lead to identifying better health economic outcomes for targeted disease states, especially if stakeholders can assuage security and privacy fears of patients and policy makers. Solving the privacy concerns would speed the uptake of this degree of sharing, says Nagaraja Srivatsan, senior VP and venture partner, at Cognizant.

"In selected partnerships and consortiums, we already see this level of sharing of information between payers, providers, and pharma to address the challenges in the healthcare ecosystem," he says. "One concern that must be addressed for the industry to move toward free-flow of information is that patients and policymakers must be convinced of the security and privacy of healthcare data."

One of the most challenging steps will be building information-sharing avenues that rely on transparency as a vehicle for innovation, says John Doyle, Dr. P.H., senior VP and managing director, global market access, Quintiles. At the core of this model is end-to-end thinking that incorporates data streams from both scientific, policy, and market resources. Data become the connective tissue that bind a successful course of action.

"When we link data across stakeholders in the system and embed them into end-to-end development processes from planning and design through late-phase research, we can more accurately design products and solutions that meet the needs of multiple players in the healthcare system," Dr. Doyle says. "Once we are able to demonstrate the value of an integrated information-sharing model through better patient outcomes and greater ROI, the industry will be more open to this holistic approach."

Lessons Learned from Payer/Pharma Partnerships

The progressive pharma-payer partnerships that are forging the path for others have culminated in some important learnings and best practices, including the importance of building trust, creating value-based conversations rather than product-based, preparing for the long haul, and being ready to meet the various challenges that arise from this new relationship.

> "To be able to move toward a free-flow of information, the industry must first address the privacy concerns of patients and policymakers."
>
> **NAGARAJA SRIVATSAN** / Cognizant

As in most relationships, trust is paramount to a successful partnership between payers and pharma, and this is a big shift from previous adversarial perceptions of the past. Both sides suffer from a trust deficit, according to Mr. Flochel.

"Payers perceive pharma companies as having conflicts of interest, such as preferring their own products over those of competitors, or preferring treatment over prevention and not being transparent with their data," he says. "Pharma companies worry that outcomes measures used to evaluate their products will not be sufficiently transparent or objective."

As long as such attitudes exist, it will be

Payer Influence On The Rise

The story that manufacturers need to convey is no longer just one of efficacy and safety or of a reasonably priced therapy; manufacturers must now convey value in terms of impact on patients' health and quality of life and impact on direct and indirect costs. Indicative of the change in target audience are the results of a survey that asked 236 pharma experts about current and historic healthcare marketplace stakeholders: over the last decade, payers' influence has risen dramatically, coinciding with a loss of influence for general practitioners.

Source: Manhattan Research

> "Sharing data is a valuable part of pharma-payer collaboration, where the end goal is better patient outcomes."
>
> **PAUL KANDLE** / Opus Health

> "As an industry, one of our biggest challenges is how to adequately acknowledge payer preferences and needs."
>
> **CHRIS WRIGHT** / ZS Associates

difficult for pharma companies to be taken seriously as potential partners around data collaboration.

"Pharma companies, therefore, need to move quickly and visibly with concrete and consistent efforts to be more open with their data," Mr. Flochel advises.

Mr. Srivatsan says pharma definitely needs to move away from its product focus and instead concentrate on providing value to payer partners.

"Life-sciences companies need to understand the perspective of the payers and start articulating their value more in terms of the outcomes that payers are driving," he says.

Pratap Khedkar, managing principal and leader of ZS Associates' pharmaceuticals practice, agrees that it's time for pharma to go beyond pills and partner with payers in a valuable way. For example, if a pharma manufacturer has a promising asset to be examined in particular patient types, millions could be saved if payers played a role in trial targeting and enrollment and perhaps also help shape the trials to prove more real-world value, he says.

"In the United States, we are not surrounded by success stories that involve partnerships that go significantly beyond an economic exchange, which is most always some type of rebate," Mr. Khedkar says. "The biggest question is: are we able to partner to more efficiently generate clinical data?"

The industry must shift its approach to one that will better serve patients and make treatment and prescribing easier for physicians.

Currently, many partnerships have focused on risk-sharing approaches that are a thinly veiled approach to achieving price discounts in exchange for access and market share, Mr. Sweeney says.

"These are often product-oriented, as opposed to being focused on the disease, patient, and society," he says. "Learning from experience and building from there is crucial — pharma is notorious for trying something, failing, and stopping. Companies that are succeeding in this area are investing in it for the long term and have interdisciplinary team representation on both sides of the relationship, which is complex and, therefore, difficult to achieve."

Successful partnerships have already proven that every stakeholder can gain value while striving toward the common goal of patient outcomes. Dr. Doyle cites a 2011 partnership between Pfizer and Humana that demonstrated that value creation is modulated by many different players in the healthcare system, each demanding favorable cost-benefit input along the patient's journey. Through the collaboration, they brought together researchers and healthcare experts from both organizations to study key issues and deliver interventions to reduce inefficiencies.

"Macro-economic pressures and pricing scrutiny will only sharpen this already intense focus on value," Dr. Doyle says. "By integrating clinical and commercial functions to ensure biopharma assets are value-priced and supported with the appropriate customer service, biopharma can improve their return on innovation."

Risks and Challenges of Collaboration

While the potential value of data collaboration is tremendous, there are also significant risks and challenges that need to be addressed.

"The various players will need to change traditional mindsets and be willing to be more open," Mr. Flochel says. "They will need to ad-

Humana and Lilly Form Collaboration to Improve Healthcare Outcomes

In August, Humana and Lilly embarked on a joint-research collaboration aimed at improving the healthcare of their members and patients. Under the partnership, the companies combined their expertise and resources to identify and analyze data and information with a focus on improving healthcare quality and outcomes. Under the terms of the multi-year agreement, the companies will conduct a range of studies related to various disease states. The initial project is aimed at investigating patient characteristics associated with increased healthcare costs in people with type 2 diabetes.

This retrospective analysis uses de-identified medical, pharmacy, and laboratory claims data, in addition to research algorithms focused on exploring patient attitudes and behaviors. Future studies may use this information to identify modifiable characteristics that can be targeted with behavioral and other therapeutic interventions. This information will be used to provide patients with insights and guidance for tailoring their care to best match their individual needs.

Source: Lilly.
For more information, visit newsroom.lilly.com.

dress challenges around interoperability of data. Privacy and security protections will need to be a key area of focus, and these will have to be communicated transparently to patients to address their misgivings."

Lastly, he says, participants will need to develop new business models to extract and share the value gained from pooled data.

The likelihood of the industry adopting open standards and access to real-world data, such as EMRs, claims, and costs, is inevitable, if not imminent, Mr. Srivatsan adds.

While open access to data sounds beneficial, it comes with a host of challenges with implementation, Mr. Sweeney warns.

"We see similar issues with risk-sharing schemes around the world," he says. "Addressing these problems is time-consuming and expensive. The heterogeneity of electronic medical records systems is one problem; the use of a variety of data collection methodologies is another. Right now there is an assumption that parties will subsidize data cleaning and preparation out of goodwill alone. Under these conditions, it's important that a strong business rationale be established to make any partnership attractive to all parties involved."

Other challenges cited by Mr. Sweeney include concerns regarding individual privacy, and risks of revealing proprietary strategic objectives and tactics. The tremendous cost of cleaning data to the point they can be shared creates a financial burden and there are problems stemming from allowing data on specific products to be freely analyzed and published by persons who may not accurately reflect the unique qualities of the dataset.

"Another factor is the duration of data being measured; many outcomes require tracking over many years, as opposed to being an outcome that can be detected within weeks or months, although HCV is a notable exception to this," Mr. Sweeney says. "For these efforts to be meaningful, the individuals being tracked must stay within the system."

Another challenge that exists within the industry is the ability to put itself into payer's shoes.

"As an industry, one of our biggest challenges has been the failure to acknowledge payer preferences and needs," Mr. Wright says. "For example, when outcomes-based contracting was pursued, it was more from an 'interest in data' perspective rather than truly based on what payers can get value from. It did not take payers long to realize that they would rather have a discount."

Another big risk is the misuse of the data.

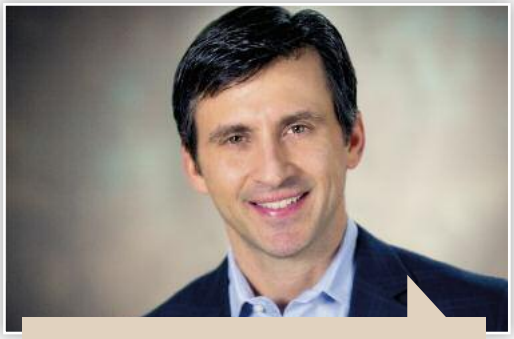
"Let us not forget that medical insurance almost did not come to pass in the United States due to the citizenry's concern for privacy," Mr. Wright says. "The temptation for manufacturers or payers to use data for marketing, claim denials, and unwelcome interventions may be too high. Even some minor breaches of ethics could destroy the public trust, and recent governmental access of communication data considered private has already shown that legal restrictions are not always sufficient."

In addition to these, the regulatory restrictions on pharma promotion may make it difficult for pharma to participate in the results of the data collaboration between payer and provider, unless data-supported use of a product is put on an equally legitimate footing with the trial-supported evidence.

One huge obstacle to embracing this new paradigm includes limits to interoperability between health system components.

These must be bridged in order to facilitate data sharing. Increasing the level of information-sharing, transparency, and cross-industry collaboration adds uncertainty and risk to the development process. Figuring out who is responsible for outcomes, who benefits from success and who must be held accountable for failures are all issues for the industry to consider as biopharma moves into the world of big data. Validity, reliability, and relevance of outcome measures also will be pivotal in an outcomes-based system.

The industry will need to address all these challenges in order to gain access to the new, more fractionated market. According to Manhattan Research, manufacturers must consider the impact that their drugs could have on all stakeholders in the marketplace, understand how marketplace changes could influence use of their drugs, and develop and nurture an awareness of the value that their drugs can bring to the marketplace — for all stakeholders. PV



"Pharma-payer partnerships demonstrate that value creation is modulated by many players in the healthcare system."

DR. JOHN DOYLE / Quintiles

"As long as trust issues exist, it will be difficult for pharma to be taken seriously by payers as potential partners around data collaboration."

PATRICK FLOCHEL / EY

Payer Issues and Trends Impacting the Commercialization Landscape

- **Global market access teams** need to be strengthened in an effort to integrate with and impact the thinking of global product teams earlier in the product development cycle. This thinking should begin as early as Phase II and include tactics and strategies for health economics, pricing, and even advocacy. The result will be enhanced product value propositions and product profiles, and go/no go decisions early in the product lifecycle.
- **Cross-functional teams** with well-defined charters need to continually assess the impact of healthcare reform for U.S. affiliates, including what other pharma companies are doing in this space. Many believe there's a first-mover disadvantage for companies that devote too many resources now to actually executing initiatives addressing the ever-changing healthcare landscape.
- **Contract strategy personnel** need to examine the possibility of creating outcomes-based/risk-based contracting. There has been tremendous chatter in the past several years about these initiatives, but companies have recently begun to execute them, often as pilots, within appropriate therapeutic areas. Data accuracy and integrity are the primary roadblocks to success in this space, but creation of appropriate strategies can be a win-win for pharma, payer, and patient.

Source: Brian Deppen, TGaS Advisors/Managed Markets Practice. For more information, visit tgas.com.