FiercePharma

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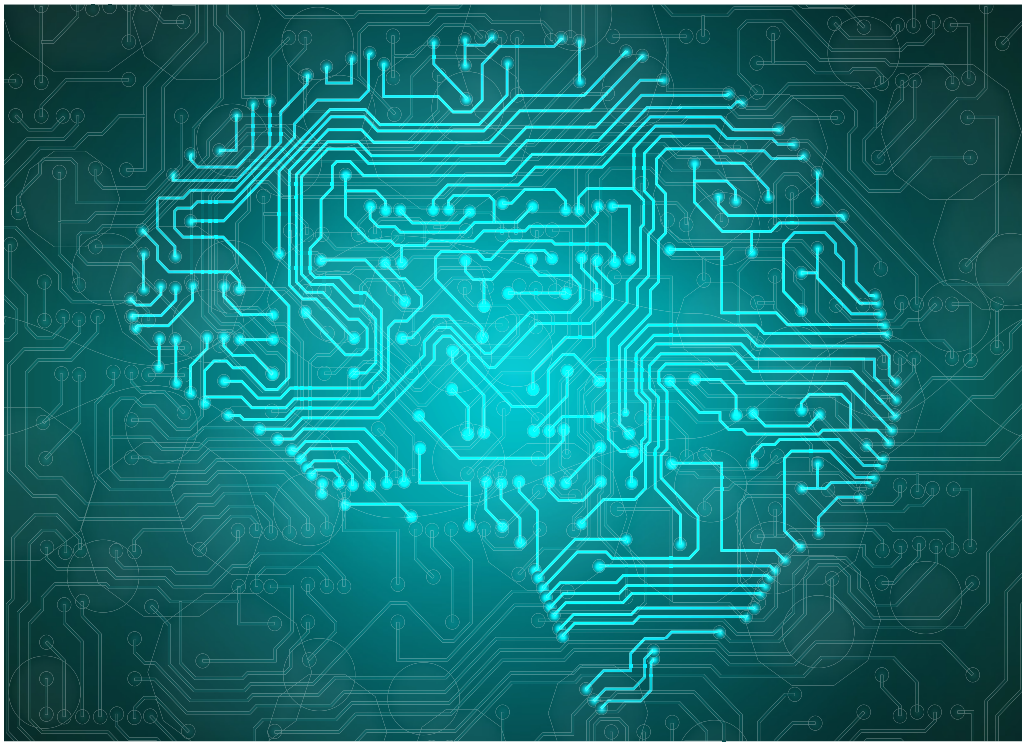
WORK SMARTER:

HOW DATA AND INFORMATICS ARE RESHAPING POST-APPROVAL FOR PHARMA



By Nick Taylor

For years, Phase III trials and the subsequent regulatory reviews stood as the last big barriers between pharma companies and the chance to recoup their hefty investments in R&D. Now, though, payers are becoming more demanding, creating an additional hurdle for drug developers: the need to show the value of a drug to healthcare systems. Data and informatics can lighten the load.

Europe's financially constrained governments have taken the lead in tightening reimbursement--with Germany and the United Kingdom both showing an unwillingness to accept sky-high prices--and now the U.S. is following them towards a more value-based model. The trend was distilled in a Nature Reviews Drug Discovery paper in 2010. "Over the past decade, the role of payers has become more prominent, and time-to-market no longer means time-to-licensing but time-to-reimbursement," the authors wrote. An increasingly common scenario is drugs get approved, but governments won't pay for them.

For pharma companies that have invested huge amounts of time and money to advance a compound through Phase III, the emergence of a further hurdle is an unwelcome development. In the past year, the U.K.'s National Institute for Health and Care Excellence (NICE) has rejected drugs from Novartis ($NVS), Pfizer ($PFE), Roche ($RHHBY) and others, often because it concludes the treatments aren't cost-effective. Germany has also delivered setbacks to drugmakers. Eisai said it was "appalled" by Germany's rejection of its antiepileptic drug Fycompa and pulled the product from the market.

The holders of each country's purse strings take different approaches, but the overall trend is to ask for more evidence that a drug delivers value to healthcare systems in the real world. Accountable care organizations (ACO) in the U.S. are part of this shift. With all of pharma's key markets rethinking reimbursement, the onus is on companies to find ways to deliver the evidence payers want. The rise of new sources of real-world data and the informatics capabilities to derive insights from the figures gives pharma a way to meet these demands. But to make the most of the information, the industry must re-think its practices.

The limits of pharma's in-house knowledge

Over the past few years, Big Pharma companies have recognized their limitations in multiple areas. The model of fully integrated companies has fallen in popularity, with even the biggest businesses working with numerous third parties to discover, develop and commercialize drugs. "More data exists outside the walls of the company than inside," says Dr. Sachin Jain, Merck's ($MRK) chief medical information and innovation officer.

Merck responded to this realization--and its management's belief that health IT will be huge--by setting up M2i2, a group focused on medical information and innovation. Jain was hired to lead the group and decided on three areas of focus: real-world data, clinician-facing technologies, and patient-facing technologies. In each area, M2i2 has formed multiple collaborations, some of which are well outside Merck's traditional business but aligned with its therapeutic areas of focus. For example, Merck is collaborating with the Indianapolis-based nonprofit research organization Regenstrief Institute to tap records from 13 million patients and gain insights about osteoporosis, diabetes, cancer and human papillomavirus (HPV). The five-year partnership has spawned multiple projects across biostatistics, data analytics and natural language processing. Jain said the long-term nature of the collaboration has allowed the allies to commit to data aggregation projects that enable researchers to better mine the records.

Merck has formed a similar partnership with Maccabi Healthcare, an Israeli health maintenance organization (HMO) that made an early commitment to electronic medical records (EMRs). The tendency for Israelis to stick with an HMO for life means the organization is sitting on a treasure trove of patient data. By mining this resource, the partners hope to better understand unmet needs, drugs' real-world outcomes and how to improve adherence. Garnering such insights should improve patient care, but also has implications for commercial success in a world in which payers focus on the value of a drug.

AstraZeneca ($AZN) has equipped itself for this new reimbursement environment by partnering with IMS Health and WellPoint subsidiary HealthCore. The HealthCore alliance dates back to 2011, putting it among the first wave of pharma-payer collaborations. Consequently, there is a growing body of research detailing projects run by the partners, such as a paper

GETTING THE HEALTH CARE PROVIDER DATA RIGHT REQUIRES THE RIGHT INFORMATION SOLUTION

How important is good data to your company's bottom line? Most would agree that it's fairly important for a lot of businesses. But for life sciences organizations that depend on good data for sales and marketing, compliance issues and customer management, it is that much more critical. On average, about 40 percent of the provider records within the typical customer master file contain errors or are missing data. Incorrect or outdated provider data is a serious problem. Consider this: life sciences organizations spend upwards of $1 to $2 billion annually seeking new data and information about health care providers.

Problem data leads to big problems

It's estimated that at least 25 to 30 percent of the demographic/contact information for health care providers changes annually. Address errors alone are the reason for up to 15 percent of all correspondence and payments to providers being returned. It's not unusual for health care providers to move, change their telephone numbers, professional status or affiliation. Nor is it surprising that physician records become inaccurate because of these many changes. A recent analysis revealed other common data problems: 28 percent of records are duplicates; 22 percent of providers have inaccurate or missing identifier numbers and 15 percent of phone numbers are wrong or missing. The challenge to keep this information up-to-date becomes a daunting and nearly impossible task for companies to manage themselves.

The scope in which provider data is used in the life sciences arena is enormous – this information is needed to create account plans, assign sales territories, create accurate marketing and sales campaigns and track aggregate spend activity. Unfortunately significant data quality problems exist in the majority of customer master files utilized by life sciences organizations. In today's difficult and complex health care environment, the need for these organizations to have correct, complete and comprehensive health care provider data cannot be overemphasized.

Finding the right solution, getting the best information

Better use of reliable, accurate information is critical to compliance reporting and sales and account management, in addition to gaining a competitive edge and giving sales teams the information they need to be effective and efficient. Because keeping track of constantly changing provider information requires a continuous concerted effort and focus as well as an in-depth understanding of industry-specific data sources and practices, many organizations over the last few years have turned to specialized expertise in health care provider information solutions after internal data management efforts failed.

But what goes into choosing the right vendor? The main objective when selecting an information solution provider is to ensure that the provider has the ability to deliver results for your business and meet your specific requirements. There are four other factors that should be considered when evaluating solution providers, including:

- **Impact** – the quality and volume of the solution provider's data and matching abilities
- **Accuracy** – the ability to confirm the data is correct or accurately replace it or augment the data with additional information
- **Usability** – support of internal processes such as technical help, reports and workflow capabilities that assist decision-making, retention of historical attribute values
- **Measurement of information quality and associated return on investment** – the need to monitor progress and do meaningful comparisons

If a life sciences organization is experiencing inaccurate compliance reporting and problems with confirming provider specialty or is struggling to effectively deploy sales and marketing resources, it's most likely the result of bad data. Recognizing the need for improvement, understanding the economic value that the improvement can foster and selecting the right information solution provider to serve as a business partner in this important process are crucial decisions – and are critical to an organization's success in the life sciences health care market.

Note: Statistics based on internal analysis of Enclarity, a LexisNexis Company data.

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published in Clinical Therapeutics late last year. The initiative mined HealthCore's claims data to assess the use and associated costs of the extended and immediate release versions of AstraZeneca's Seroquel.

The researchers found patients taking the extended release formulation, Seroquel XR, were less likely to be hospitalized for mental health-related reasons and incurred lower mental health-related costs. No differences in overall healthcare costs were seen. The data has real implications for the business: With U.S. sales of Seroquel XR suffering in the wake of the introduction of immediate release generics in March 2012, the evidence could help AstraZeneca claw back market share. The generics rivals may be cheaper upfront, but value-focused payers can be swayed by metrics like a drop in hospitalizations.

The diversity of projects at AstraZeneca and Merck alone demonstrates the variety of electronic data sources now available to drugmakers. While the HealthCore collaboration made use of claims data--a long-standing source of real-world information--pharma can also tap into EMRs, disease registries and prescription databases.

Pharma firms have looked outside their walls to access data, but some have also built their own resources. Genentech supported the creation of a National Registry of Myocardial Infarction that collates data from 1,600 hospitals, while Genzyme has set up rare disease registries.

FDA's Big Data Ambitions

The health insurance industry now possesses an unprecedented depth and breadth of patient care data, the value of which is magnified by integrating different sources of information. This poses technical and political challenges, though. Writing in the journal Cancer in 2012, U.S. researchers bemoaned the reluctance of private payers and registries to link their data.

Public bodies have been more open to combining their data, and in doing so have shown the potential of such linkages. SEER-Medicare--a combination of a National Cancer Institute registry and claims data--has allowed researchers to calculate the risk of hospitalization after prostate biopsy, the cost of breast cancer recurrence and other healthcare metrics. Such studies have implications for the commercial success of drugs, but exist beyond the control of pharma companies. By working with the holders of real-world data, drug developers can at least ensure they know how their products fit into treatment pathways.

This can ensure companies are prepared in the event a third party presents data questioning the safety or efficacy of a drug. FDA now has access to a wealth of safety data, with the Mini-Sentinel database containing records on 160 million individuals, 3.5 billion medication dispensings and 3.8 billion unique medical encounters as of July 2012. The data is currently helping FDA assess rates of bleeding among patients taking Boehringer-Ingelheim's Pradaxa. By slicing the data, FDA might be able to spot groups of high-risk patients.

FDA set up the database in the wake of the safety scandal involving Merck's arthritis drug Vioxx. With such a database, nobody should ever again be able to ask a question like this one posed by Harvard Medical School's Dr. Jerry Avorn at a 2011 symposium: "How did we have a drug on the market for five years that was taken by tens of millions of people, cost over $2 billion per year in U.S. sales alone, had no more analgesic efficacy than OTC NSAIDs, yet doubled the risk of heart attack and stroke, without our knowing that?!" FDA is also making raw downloads and application programming interfaces (APIs) of adverse events data available publicly.

Drugmakers are tightening their own adverse event monitoring activities in parallel with FDA. Pfizer's ($PFE) partnership with insurance company Humana

provides it with real-world data on side effects and other unintended consequences of prescribing a drug. In 2013 the partners published a series of papers assessing the market for pain drugs, with a particular focus on the prevalence and cost drivers of prescription opioid abuse. Late last year, Pfizer committed to supporting further clinical trials of Pain Therapeutics' abuse-resistant painkiller, Remoxy. FDA wants data on Remoxy's abuse potential.

The timing of Pfizer's decision--which came towards the end of its series of papers with Humana--shows how pharma companies are aligning their real-world data collaborations to their core businesses. FDA has already rejected Remoxy twice, and in May 2013 Pfizer was unsure whether it would support further trials. By using real-world data to understand diseases and treatment pathways, pharma companies can make more informed go/no-go decisions about clinical candidates and be better prepared for subsequent talks with regulators and payers.

Such work is pushing companies away from soley being providers of pills and towards becoming

improvers of health. Payers--which are ultimately pharma's customers--have set this path and are tapping data and informatics to help them make the transition. ●

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