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The 1, 2, 3's of VBCs

VALUE-BASED CONTRACTING is an umbrella term for the many different financial arrangements made more frequently between pharma manufacturers and payers. At a DIA session, Richard Gliklich, MD, CEO of OM1, defined Value as equal to Outcomes divided by Cost, with four major types of outcomes-based contracts. These include payment based on desired outcome, larger rebates in absence of desired outcome, how well a drug performs against competitive drugs, and indication-specific pricing. As to indication-specification pricing, Gliklich noted that interest in outcomes-based contracting according to therapeutic area is rising, predominantly in hep C, oncology, MS, and rheumatoid arthritis.

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There is a growing number of pharma manufacturers engaging in outcomes or value-based contracts. Examples include: Novartis' Entresto deal with Aetna, Cigna, and Harvard Pilgrim Health Care (see *Pharmaceutical Executive* Brands of the Year article, http://bit.ly/2sribB2); Amgen providing larger rebates for missing cholesterol goals for its high cholesterol drug Repatha with Cigna and Harvard Pilgrim; Actavis' deal with Health Alliance for its osteoporosis drug Actonel, with a measured outcome of non-spinal fracture with good adherence, and the list continues to grow.

In late May, Merck and Optum, the health services business of UnitedHealth Group, launched a multi-year collaboration on a shared "Learning Laboratory" to explore these value-based and pay-for-performance models, which they call Outcomes-Based Risk Sharing Agreements (OBRSAs). In this environment, the groups will examine the potential of OBRSAs for broad adoption among health insurance companies, pharmacy benefit managers (PBMs), and pharmaceutical companies.

According to Robert P. Duffield, II, counsel for Novo Nordisk, while value-based contracts are definitely the right thing for pharmaceutical companies to do, they are unexplored territory, fraught with potential legal risk. Other hurdles include business challenges, data collection and analysis challenges, and difficulty with outcome measurement choices.

Jim Clement, executive director, cost of care and supply chain strategy for Aetna, presented the payer side at this same DIA panel titled "Value-Based Conversations with Payers: Issues, Opportunities, and Barriers." He explained that the current pricing and discount model is broken, but the value-based models will take time because the regulatory and pricing models are not in sync.

The key for pursuing different paths and contracts is having trust with the manufacturer, he said. There will never be a perfect agreement, and VBCs aren't the "be all end all," he noted, but "if there is no trust, they won't work."

Currently, VBC contracts are designed to be valid for one year. Basically, because the drugs and technologies around them evolve so quickly, the risk profiles change—new drugs are introduced, other drugs go onto generics, etc. However, some companies are starting to look into the potential for contracts to extend past the one-year timeframe, building on the trust that Clement noted, allowing for speedier contract stages in a non-perfect world.

Meanwhile, as pharma and payers discuss sharing risk and outcomes expectations for medications as a financial model, there are questions as to the role of the patient.

While we know that medications account for only 10% of the overall healthcare spend, we also know that current trends push higher co-pays down to the patient. And in a situation where a patient has to decide between paying for their medication or feeding their family, medication compliance goes to the wayside. And while the cost of a pill would be less costly on the healthcare bill later down the road, compliance itself can be hard to swallow for many. Some market access strategies address this, but they also cloud the waters of value, outcomes, and cost.

The issue of patient compliance is very difficult. Many examples in healthcare show that "patient engagement" means "make sure you do what I say" with no accounting for an individual patient. At DIA, a common theme was the key to patient engagement is to understand the patients' needs, maybe around their quality of life or life goals, and then articulate compliance that way. "If you take your medication, you will have more energy and time to spend with your grandchildren," for example.

As we step further into the waters of value-based contracting, lessons learned will need to be shared. Merck's Learning Laboratory is one step to understand in a safe environment what the stakeholders will need from these new financial models. But the patient, their needs and quality of health and life should also be factored, in a supportive and understanding way.

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2011 Neal Award Winner for "Best Commentary"

Pharma Keeps Pace with Digital Health

Michelle Maskaly, Senior Editor

The rapid development and take-up of digital technology is forever changing the way pharma engages with patients—but the industry's ultimate potential in tapping digital health to transform patient care hinges on embracing new shifts in culture and business strategy.

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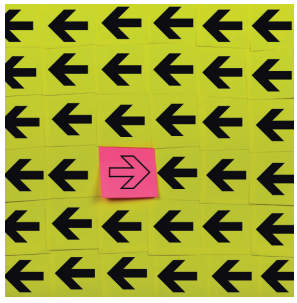

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Readers Weigh In

Twitter Talk

■ We live in the world of symptoms and transactions. How about marrying clinical and psychosocial to drive support, coping, control?

Carl Derenfeld, @CBDerenfeld 6/20/2017
"The New Age of BioDigital Pharma"
bit.ly/2s3LHwY

■ 10 out of 10 for Ireland. The world's top 10 biopharma companies have operations in Ireland.

IDA Ireland, @IDAIRELAND, 6/15/2017
"*Pharm Exec*'s Top 50 Companies 2017"
bit.ly/2sWPTSj

■ *(replying to @IDAIRELAND)* I wonder if that has anything to do with the exceptionally low Corporation Tax and if this were to change would this result be the same?

Evelyn Murphy, @Evelynn_Murphy, 6/15/2017

■ With current FDA guidance, #pharma companies aren't able to easily join the conversation to provide accurate, balanced information.

Niki, @healthdatachick, 6/2/2017
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Accelerating Approvals, Revisiting Reimbursement

Excitement over more new treatments for cancer and rare diseases is offset by cringing over prices

FDA is approving more new drugs this year, supporting predictions that the 2016 drop-off in approvals was a "blip," and that scientific advances and streamlined regulatory programs will continue to bring more new molecular entities (NMEs) to patients in the coming months. Yet the six-figure price tags on many innovative therapies raise concerns on all sides, spurring proposals to reduce exclusivity granted new drugs and biologics, to accelerate approval of more generic competitors, and to even cut drug dosing to reduce costs. Marketers are offering financial assistance to offset rising co-pays, but that draws strong opposition from insurers and pharmacy benefit managers (PBMs) and allegations of fraud from prosecutors.

More breakthroughs

FDA officials predicted that 2017 would be "a bounce-back year," with new applications easily surpassing the 22 novel drugs and biologics brought to market in 2016. Agency reviewers are realizing that goal with the approval of more than 20 NMEs by mid-year, including important treatments for rheumatoid arthritis, ALS, Parkinson's disease and multiple cancer conditions. Of note, the Vertex cystic fibrosis drug Kalydeco (ivacaftor) gained an additional indication based solely on *in vitro* data and without additional clinical trials. Another regulatory first was to authorize Merck & Co.'s cancer drug Keytruda (pembrolizumab) for the treatment of tumors associated with a specific genetic abnormality, as opposed to cancers affecting parts of the body, such as lung or breast.

No surprise that specialty therapies are prominent in the surge in applications and approvals, as biopharma companies shift resources to treatments for rare diseases and cancer that command high prices and benefit from streamlined development protocols and accelerated reviews by FDA. A fairly full R&D pipeline with many late-stage trials underway bodes well for a steady stream of breakthrough applications to the agency.

The annual meeting of the American Society of Clinical Oncology (ASCO) in June provided a visible platform for highlighting these trends. Investigators reported exciting results from studies for new checkpoint inhibitors and chimeric antigen receptor T (CAR-T) therapies, while sponsors announced plans to test numerous combinations of the new breakthroughs and older treatments in search of more effective multi-drug formulations.

Doubling costs

One problem, though, is that combination therapies can cost twice as much, or more, than monotherapy, raising questions about the value of more complex treatments. Roche met pushback at ASCO when it reported less-than-anticipated benefits from studies that combined its new drug Perjeta with established Herceptin at double the cost.

Public outrage over steady price increases for new cancer therapies and other specialty drugs continues to generate cost-cutting proposals from Congress and government agencies. FDA commissioner Scott Gottlieb recently called for extending review priority to the second and third generics entering a market, and not just the first one, to speed approvals of more low-cost generic therapies. He and others also want to prevent brands from restricting generic makers' access to comparators needed for bioequivalency testing. There evidently are some 180 brand-name drugs that lack generic competition despite patent expiration, and FDA is looking to publish this information more widely.

Drug pricing concerns also have focused attention on the role of exclusivity incentives in blocking competitive therapies from the market. A broad drug cost-cutting bill sponsored by Sen. Al Franken (D-MN) and leading Democrats includes provisions to lower the five-year exclusivity for new chemical entities in certain situations, reduce the 12-year exclusivity period for new biological products to seven years, and modify the 180-day exclusivity for the first generic to encourage additional copycat drugs. Companies convicted of fraud would lose the remaining market exclusivity periods on certain products,

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and the winner of a $2 billion prize for developing important new antibiotics would have to waive all exclusivity and patent rights, in addition to offering a "reasonable" price and sharing clinical data.

The seven-year exclusivity provided to orphan drugs also is under review, as reformers seek to prevent pharma companies from "gaming" the system by gaining additional rare disease indications for established drugs. Leading senators want the Government Accountability Office (GAO) to investigate such "evergreening" of orphan drug exclusivity through multiple orphan designations.

Another way to cut drug costs and reduce the "financial toxicity" that new cancer therapies can have on individuals may be to treat patients with smaller doses of costly new drugs. A group of cancer researchers presented data at ASCO indicating that reduced doses or shorter duration of treatment could prove effective at reduced cost, here finding that Janssen's Zytiga could be effective at lower doses when taken with food. The plan is to conduct more studies to see if such strategies apply to additional oncology therapies.

Another way to cut drug costs and reduce the "financial toxicity" that new cancer therapies can have on individuals may be to treat patients with smaller doses of costly new drugs

Attack mounts on PAPs, coupons

Insurers and pharmacy benefit managers (PBMs) blame pharma patient assistance programs (PAPs) and co-pay coupons for escalating outlays for prescription drugs, complaints that are arousing scrutiny from federal investigators and state lawmakers. Marketers have ramped up these programs in recent years to offset insurer coverage limitations and rising co-pays for drugs. But payers regard PAPs and coupons as marketing ploys designed to steer consumers to more costly therapies, and away from generics, which end up raising costs for plans and payers and leading to higher premiums.

Current rules permit pharma companies to offer PAPs and coupons to patients covered by commercial insurance, but limit the giveaways for Medicare beneficiaries. Payers and PBMs are particularly incensed about coupons to block generic competition, and Mylan's recent promotion of coupons to help patients purchase EpiPen injectors bolstered such views. California legislators recently moved to prohibit coupons for name-brand drugs when a cheaper generic is available; Massachusetts has a similar policy, and other states are considering similar moves.

To provide PAP benefits to Medicare beneficiaries without running afoul of federal antikickback laws, marketers have to link up with nonprofit disease foundations that channel funds to patients with certain medical conditions, but not necessarily to pay for specific drugs. This approach is outlined in a 2014 advisory from the HHS Inspector General, but federal prosecutors are investigating whether the charitable organizations do, in fact, promote specific drugs. More than a dozen biopharma companies have received subpoenas, according to legal experts at the CBI Pharmaceutical Compliance Congress in April. The U.S. attorney for Massachusetts has been particularly active in examining manufacturer control of PAPs, and more queries are expected.

Many of these issues were discussed at a hearing last month before the Senate Health, Education, Labor and Pensions (HELP) Committee. Avalere Health president Dan Mendelson described the need and process for shifting to value-based payments. Allan Coukell, senior director at The Pew Charitable Trusts, explained how limited competition drives up prices and urged review of exclusivity periods for biologics and orphan drugs to "ensure the appropriate balance." And Johns Hopkins professor Gerard Anderson backed policies to limit how brands block generic drug market entry and abuse orphan drug exclusivity policies. He also criticized Patient Assistance Programs (PAPs) for allowing drug companies to raise prices by keeping patients immune to cost-sharing (see sidebar). Another panel hearing this month will examine the drug development and distribution process, and a fall session will discuss a coming National Academy of Sciences study on patient access to affordable drugs. PE

EU Countries Square Up to Pharma on Prices

The recent EFPIA and EU health council conferences highlight the growing divisions—and resentments—between industry and governments in Europe

In a week last month that saw both the annual conference of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Union health council, it was inevitable that the distinct positions of drug firms and government ministers should be on display. It was equally inevitable that their customary polite acknowledgements of interdependence and mutual interest should fray a little at the edges under the closer scrutiny that these two events provoked.

Innovation argument

EFPIA got in the first strike to win the high ground, with a dynamic new agenda under dynamic new leadership, focused on "the exciting wave of pharmaceutical innovation which is transforming the lives of patients and the way we deliver healthcare." With a series of highly-mediatized pledges in which the organization's membership undertook to push for new cures, the industry depicted itself as the savior-in-waiting. The industry needed only, it suggested, an environment "to foster and support research and development in Europe."

Industry speakers lined up to boast of achievements and to dangle promises of more and better to come. Jean-Christophe Tellier, the CEO of UCB, claimed the value of the industry's products was far in excess of the investment, as demonstrated by increasing longevity. According to Tellier, to secure a healthy future, "our focus on innovation is key." Eduardo Bravo, CEO of Tigenix, banged the drum for smaller firms—he is also the current president of the European Biopharmaceutical Enterprises, EFPIA's subset of smaller health biotech companies. Most orphan medicines come from smaller organizations, he said. Nathalie Moll, the new director-general of EFPIA, described Europe as a "lighthouse of research" in the world. And the new EFPIA president, Stefan Oschmann, CEO of Merck KGaA, Darmstadt, Germany, highlighted "the transformational potential of big data" and the prospect it offers of faster development of innovative medicines.

The narrative didn't go entirely unchallenged, even on EFPIA turf. Sharing the podium with industry luminaries, the European Commission's deputy-director general for health, Martin Seychell, toyed with a needle around the industry's balloon, without directly pricking it. Yes, innovation is key to the transformation of healthcare, he agreed. But not just any old innovation—and not necessarily pharmaceutical innovation, he argued.

He challenged Tellier's claim of value for money in extended lifespans: longer life, perhaps, but not better quality. A much-needed radical shake-up of the current healthcare model should direct more investment toward prevention, primary care, or the workforce. There is still too much unmet need, and "we have a problem of access to care," from country to country and across socioeconomic groups, and even with some member states facing drug shortages, he said. At present, the timing of health intervention—and that means reliance on drugs to produce cures—is "suboptimal."

Seychell also nuanced—very heavily—the industry call for incentives for innovation. Against the background of an ongoing Commission review of EU incentive schemes for drug development, he conceded that incentives are "absolutely necessary for a sector like this." But, he went on, they have to be "the right incentives, for now and the future."

The Commission review is a direct response to anguished reflections in the EU health council just a year ago about drug companies abusing the current incentive schemes for orphan and pediatric drugs, and making exorbitant price demands. With high prices for medicines and growing strains on healthcare systems, "the landscape is changing," Seychell warned. "Healthcare expenditure is an investment—but what is the return?" Incentives must be evidence-based, he said, and "we must prove that we have the right incentives, or whether we need different or new ones."

REFLECTOR is *Pharmaceutical Executive*'s correspondent in Brussels

The access obstacle

Where Seychell was specific, the discussion in the health council two days later was more general, but a public session displayed some equally pointed ministerial skepticism about the pharma sector. An innocuously-titled debate about strengthening inter-governmental cooperation in overall healthcare provided a forum for some sharp barbs about excessive drug prices. Chris Fearne, the Maltese health minister, who chaired the meeting, opened the discussion with a candid allusion to the "obstacle" represented by the "high price tags" for medicines, and the issue of access became the leitmotif of the debate.

From the relatively mild reflection that cooperation could help in "access to health technologies arising *inter alia* from therapeutic innovation, in particular in the field of rare diseases, and the development of personalized medicine," the final conclusions moved on to more confrontational language: countries were invited "to cooperate in order to increase transparency in the pricing of pharmaceuticals, which should put the member states in a better position when negotiating with the industry."

Ireland's health minister, bruised by a recent—failed—battle with Vertex to obtain satisfactory discounts on its cystic fibrosis treatment, encouraged countries to challenge drug firms and their pricing practices, because "the prices that some companies with a monopoly are seeking to charge mean products will never reach patients." Hungary and Lithuania urged cooperation on transparency of medicines prices, to ease access across Europe. Greece wanted a cooperative framework to overcome "the injustice of medicines," and Denmark wanted equal access and the establishment of "fair pricing of pharmaceuticals."

The enthusiasm for closer cooperation to tackle drug prices was not universal. Germany stood out firmly against any form of mandatory cooperation, although it signed up to the conclusions—but the overall sentiment was strong enough and shared widely enough to make clear that the momentum in this European trend is largely one-way, and not industry's way. Even before health ministers met, Malta—in the closing days of its six-months term in charge of EU business—had put its own spin on the drug prices debate by presenting a report on similar discussions that had taken place over the previous few months.

The Maltese report, based on a series of informal meetings among EU health ministers and between ministers and European drug industry bosses, made clear the Maltese view that the shift toward greater transparency on drug pricing in Europe is irreversible. It focused particularly on a "roundtable" meeting of drug company CEOs, national health ministers and patient organizations that the presidency hosted in Valletta in May. It recorded the meeting's focus on "sustainable prices of new medicines" and "increasing transparency," and it emphasized an agreement among health ministers the day before the roundtable, to explore cooperation on information, price negotiations and joint procurement.

The conviction is growing among many national governments that the industry is operating a divide-and-rule approach to price negotiations, by insisting that the terms of each discount or managed entry agreement remain secret

"Meaningful changes are needed in the mechanisms of pharmaceutical pricing," according to the Maltese report, highlighting "improving price transparency and narrowing the gaps between retail and negotiated prices."

Pricing pile-on

Remorselessly, relentlessly, the pressures are mounting on current drug industry pricing practice. The conviction is growing among many national governments that the industry is operating a divide-and-rule approach to price negotiations, by insisting that the terms of each discount or managed entry agreement remain secret. And resentment is growing just as fast. At the EFPIA meeting, Tellier grudgingly acknowledged that the industry has not done a very good job in explaining its approach to prices, its links to value, and its contribution to outcomes. Judging from the political operating context right now, he is right. And it may be time to do more about it. PE

Front & Center

The Future of EIM, OpenText and Documentum

A conversation with Adam Howatson, CMO, OpenText

Enterprise Information Management (EIM) powerhouse OpenText invested $1.62 billion to acquire Documentum and the rest of Dell Technology's Enterprise Content Division in late 2016. Documentum users, including large and not-so-large biopharmaceutical firms, wondered what would become of their own ECM investments. Would they be forced to move to OpenText? Would OpenText continue to support and evolve Documentum?

The Short Answers: No and Yes

Pharmaceutical Executive put those questions to Adam Howatson, chief marketing officer for OpenText, in the month before the company unveiled its machine learning platform, Magellan, at its annual user conference, Enterprise World. EIM's first cognitive artificial intelligence (AI) platform carries the OpenText name, but allows Documentum users to dive deep into the disparate, unstructured data sources that account for 90% of a typical organization's knowledge and information base to generate actionable information. Documentum and OpenText users can expect ongoing investment and innovation in both platforms with a continuing focus on hybrid and cloud-based ECM solutions.

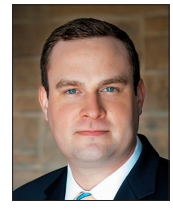
Coming Together

In 2016, Dell Technology and financial partners bought technology giant EMC for $67 billion. The deal included leading Enterprise Content Management platform Documentum, which is widely used in the biopharmaceuticals, healthcare and life sciences sectors. A week later, Dell sold its Enterprise Content Division (ECD), including Documentum, to OpenText.

Analysts saw benefits to both sides. Documentum and the other ECD software offerings seemed unlikely to help Dell (a hardware company) sell more servers and other infrastructure products. It made sense to spin off what was, to Dell, a non-core function.

OpenText had a global footprint, but it trod lightly in areas such as the Middle East, Africa, China, South Korea and Russia where Documentum had a more established presence. Documentum also brought deep experience and customer relationships in vertical markets like pharmaceutical and life sciences as well as energy, engineering and the US public sector. The acquisition played into OpenText's primary focus with expanded geographic and vertical market coverage.

Users are already seeing an active roadmap and growing investment profile in Documentum and other ECD products.



Adam Howatson

The goal is to combine Documentum's experience and product lineup with OpenText's product expertise, then roll back the integration into the combined portfolio. This integration will give biopharma firms the ability to explore the vast lakes of data that enterprises have created and acquired over recent years and decades.

Users need improved tools to help them search, find and use information that has been collected and stored across different research, clinical and regulatory programs in a host of systems and formats that weren't necessarily designed to meet the needs of different business units across multiple geographies and regulatory jurisdictions. In many organizations, this created vast information silos where valuable data is locked away, inaccessible to the rest of the organization. Some data may exist in structured databases, but most reside in unstructured collections of text, image, audio and video files. Some 80–90% of enterprise data resides in these unstructured repositories that may be invisible to conventional content management and enterprise information management systems. Being able to map, search and use that now-obscure data is the key to managing deep content and facilitating collaboration across departments and functional units to improve operations and business outcomes.

Meeting the Integration Challenge

One key ECD asset was the InfoArchive platform, which archives information from legacy applications and in many formats into a single, searchable resource. The platform lets users pull from the enterprise resource planning (ERP) system, clinical data systems, document systems and other resources while segregating and maintaining essential metadata so the original records can be traced and audited as needed.

OpenText InfoFusion and OpenText Integration Center allow users to map and search information across multiple systems and formats. Data from different files, shared drives, legacy mainframe systems, older databases and current content can all be accessed to provide a centralized view.

Biopharma is one of the most highly document-centric and most tightly regulated industries. That combination of extensive documentation and tight regulation is both a benefit and a curse.

On the positive side, every step of the product research, discovery, development and testing process is documented and cross checked. The industry has internalized and operationalized the dictum that if it wasn't documented, it effectively didn't happen.

On the negative side, documenting and tracking every aspect of operations generates enormous amounts of data that grow at accelerating rates. A single clinical trial can generate petabytes of data that must be maintained and made accessible to regulatory officials in multiple jurisdictions, most of which have different, sometimes incompatible re-

quirements for data collection, reporting and privacy. Data must be managed and governed appropriately for each jurisdiction, it must be auditable and discoverable for regulatory and litigation purposes. Meeting those needs can impose extraordinary burdens in terms of efficiency, accuracy and economy. However, for the first time, biopharma companies can fully leverage this mandated data and document collection to gain new insights into their business and customers.

While all the data must be protected against inappropriate disclosure, it must also be easy to share. The drug approval process, for example, requires effective and efficient information sharing between the clinical trial team, regulatory, operations, management and others.

The consumer cloud experience of almost-automatic sharing and prompt generation of actionable insights may not be a good fit for the highly regulated biopharma landscape, but it shapes expectations within biopharma. Some companies have shifted information systems into the cloud to foster the mobile, intuitive and engaging user experience that is so common in the consumer world.

There is strong movement toward cloud adoption. Market research leader Gartner, Inc. predicts that at least half of leading ECM vendors will move to cloud-based platforms by 2018. By 2019, more than 30% of new software investments by the 100 largest vendors will shift from cloud-first (the current standard) to cloud-only.

But the shift to cloud-based ECM is neither uniform nor steady. Not every enterprise can unplug legacy information systems tomorrow or next month and move to the cloud. Most organizations are pursuing, and will continue to pursue, a hybrid strategy. Most will continue to maintain an on-site or hosted data center capability, but far more computing power will be provided by Infrastructure as a Service (IaaS) and Platform as a Service (PaaS).

ECM, analytics, collaboration and similar information functions are relatively easy to move to the cloud. Other functions, particularly ERP and finance, are more likely to remain in-house and under the direct control of IT for perceived ease of access and security.

Collaboration Is Key

The public cloud (such as that offered by Microsoft, Google, Apple and others) offers limited options and compliance capability to meet the highly specific regulatory needs that are part of the biopharma ecosystem. Biopharma companies need more complex and customized services than are common in the public cloud.

OpenText has its own cloud infrastructure expressly designed for customized management services. Biopharma, healthcare, life sciences and other enterprises can create bespoke clouds that meet their individual needs for security, patient privacy, multiple levels of access, even data sovereignty across many locations and jurisdictions.

A global drug trial has several security, privacy and regulatory needs in different jurisdictions while facilitating easy data sharing across the entire trial. A private cloud lets firms stipulate system design and deployment to manage information and access based on geography, regulatory jurisdiction and other parameters. Data from European trial centers might be managed in a European data center while US trial centers are managed in a US-based data center, and so on. Each center meets its own regulatory requirements while the trial as a whole encourages collaboration and supports multiple regulatory approval processes.

The combined OpenText-Documentum platform serves all three levels of information integration and management regardless of the data source or format. Even sometimes-difficult issues such as the secure transmission of medical images can be integrated seamlessly.

From the user's perspective, an MRI scan is just one more image to be shared. It is irrelevant that medical images are used and exchanged in a unique format, DICOM (digital imaging and communications in medicine) or that an MRI stack may have petabytes of data and be subject to multiple requirements for secure transmission, patient privacy, retention, records management and more. All the user needs to know is how to assemble a transverse scan or other image. It is up to the system to get the image to the correct radiologist for interpretation and assessment and deal with regulatory needs in all the appropriate locations.

Collaboration is emerging as a key to long-term success in biopharma industry.

For enterprises that evolved back when information was an asset to be guarded and hoarded, collaboration can be difficult. Systems and mindsets that are focused on limiting the sharing of information must be redesigned and retained.

Moving to collaboration is a two-pronged process. Breaking down internal barriers to information sharing requires dedicated leadership from top executives who are empowered to and require restrictive processes to be changed and eager to implement change.

Collaboration also requires broad internal support. Moving ECM to the cloud and creating a consumer-like mobile experience with an intuitive, engaging user experience is what makes collaboration so compelling. Combining the resources and the experience of OpenText and Documentum is already helping biopharma firms leverage information resources to extract more meaningful and actionable insights than had been possible with either platform previously.

Documentum and OpenText users can expect ongoing innovation and investment in both platforms with a continuing focus on hybrid cloud-based ECM solutions as well as cloud-native platforms. New information management tools will make information sharing and collaboration easier and more intuitive while maintaining privacy and access safeguards as required by different regulatory regimes around the world.

easing into Change

Pharma Tries to Keep Pace with Digital Health

The rapid development and take-up of digital technology is forever changing the way pharma engages with patients—but the industry's ultimate potential in tapping digital health to transform patient care hinges on embracing new shifts in culture and business strategy

By Michelle Maskaly

If a biopharmaceutical company is not convinced it should be investing in digital health, they should perhaps consider this simple but true reality: drugs can only do so much.

"There are so many issues that selling pills by themselves can't solve because other factors are involved," says Bradley Merrill Thompson, a partner at national healthcare law firm Epstein Becker Green. "The lack of patients taking medicine is a prime example. If pharma companies just make pills, they are going to hit a wall trying to change patient behavior."

A recent review in the *Annals of Internal Medicine* backs up this assertion. The report finds that 50% of medications for chronic diseases are not taken as prescribed, and the severity of the disease doesn't matter.

Earlier this year, *The New York Times*, in an article entitled "The Cost of Not Taking Your Medicine," reported that lack of medicine adherence can cost the US healthcare system between $100 billion and $289 billion a year.

"Pharma companies want to get into the outcomes business," Thompson told *Pharm Exec*. "They want to help make people healthier."

Although a strong argument by itself, adherence is not the only reason, or way, drug manufacturers

can invest in the digital health game. In special expanded coverage in the pages ahead, *Pharm Exec* examines the explosion and increased adoption of digital health in the life sciences from several angles, including business impact, patient adherence, infrastructure, and high-tech innovations at the product level. The digital revolution may have pushed itself into the medical world slower than other industries, by there is little doubt now of its rising influence in driving the future of healthcare.

Defining digital health

Ask 10 people for their definition of digital health and you will likely get 10 different answers.

"Social media."

"Software for sales."

"Electronic health records."

Answering the not-so-simple question of what is digital health as it relates to pharma can be a bit complicated.

At first, many people automatically think of social networking sites like Twitter and Facebook, or some type of app. But, that is not always the case. Digital health strategies can extend into all aspects of a pharma company's structure—from sales and marketing, to R&D and business-to-business activities.

"Digital health means something different to everyone," says Nicole Mowad-Nassar, vice president and lead, US business operations and external partnerships, at Takeda Pharmaceuticals. "Some say wearables, some say it's apps. Digital to me means data. It's about collecting data, analyzing data, and acting on data."

Two years ago, Mowad-Nassar's company launched the Takeda Digital Accelerator, an incubator inside the organization that also works with various partners, including those outside the world of pharma.

The idea came about as a way to make it easier to learn about "digital" and try digital experiments within the company.

Such efforts also illustrate the need for pharma companies to have diversified digital portfolios. Takeda, for instance, has implemented a digital sales platform to make it easier on their sales reps. When calling on a physician, they can simply pull up data such as their referral patterns, affiliations, and publications.

While the tools helps the sales reps in the field, it also benefits the work of those back in

"Digital to me means data. It's about collecting data, analyzing data, and acting on data."

the office. "It helped us to be smarter at marketing and in customer exchanges by allowing us to know our customers more intimately," says Mowad-Nassar.

Tapping and engaging the patient community may be considered the most important digital market priority for life sciences organizations. Earlier this year, Takeda and Cognition Kit Limited, a joint venture between Cambridge Cognition Holdings PLC and Ctrl Group Limited, announced a collaboration to pilot the use of a specially designed app on the Apple Watch to monitor and assess cognitive function in patients with major depressive disorder (MDD).

The study involved 30 participants, ages 18–65, with a clinical diagnosis of mild-to-moderate depression who have been prescribed an antidepressant for MDD. The goal was to evaluate feasibility and compliance, and to understand how measures of mood and cognition on wearable technology compare to more traditional neuropsychological testing and patient reported assessments.

"This collaboration is part of our strategy to embrace new technology to better understand the patient experience and assist healthcare professionals in creating improved patient care pathways," Mowad-Nassar said in a press release.

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» Digital health start-ups raised over $6 billion in equity financing in 2016, according to CB insights, and investment in the sector is showing little signs of slowing. Investors in this space have traditionally been venture capital firms, but health insurers and pharmaceutical companies have joined in in recent years.

» McKinsey & Company reports that 70% of US consumers use an online channel to manage health and wellness, and more than 50% of US healthcare providers use three or more connected devices professionally.

» Digital health plays a key role in the new market reality for pharma, where offering patient services that go "beyond the pill" and address the entire patient experience and journey is a critical value driver.

Recognizing the differences required to be successful in the digital space is critical. Pharma leaders need to be prepared to evaluate on a different set of metrics than they are accustomed to

Regulatory worries

Whenever the topic of digital health gets brought up, a mention of the FDA is usually not far behind. Pharma companies tend to tread lightly around the idea of digital health, not just because there is a lot of uncertainty around the concept, but also because there is even more ambiguity when it comes to digital health regulations.

Companies are worried that they might overstep into uncharted territory. Experts, however, believe this is a very good time for pharma organizations to think hard about digital health in their business planning.

"People at the FDA are excited about digital health, and don't want to overregulate it," says Thompson. "In fact, there are a number of initiatives to try and pull back some of the regulations."

For example, in the 21st Century Cures Act, passed by Congress in December 2016, the legislation excluded from FDA regulation certain clinical decision support software.

The agency is also inching closer to the creation of its own dedicated digital health unit, to be housed within its Center of Devices and Radiological Health (CDRH) division. Established as part of the next steps of the Medical Device User Fee Amendments Act, the center will be creating 13 new full-time positions focused on digital health.

According to the FDA, the unit—among other things—will develop software and digital health technical expertise to provide assistance for premarket submissions that include software as a medical device (SaMD), software inside of medical devices (SiMD), interoperable devices, or otherwise incorporate digital health technologies. The unit will leverage technical experts as appropriate, or when requested by drug manufacturers for submissions that include those three elements. Another focus will be the incorporation of appropriate metrics for digital health improvements to monitor, track, analyze, and report the results of digital health premarket review timelines.

The FDA unit will participate in international harmonization efforts related to digital health, including work on developing SaMD and other digital health convergence efforts through the International Medical Device Regulators Forum.

Digital culture shift

There is much talk and attention in the industry concerning digital health, but not always a lot of action. To that end, identifying what makes a company move away from digital pharma lip service and take action is useful. Experts attribute it to the shift in thinking by leadership at certain organizations.

"We see it succeed when it becomes C-suite imperative," says Kenneth R. Munie, managing director, Accenture Strategy. "The notion of spreading digital across P&L (profit and loss) structure around brand is not going to get big digital innovations. Instead, make it C-suite imperative, and then fund it and manage it appropriately."

Ingraining that culture and mindset into pharma management teams is no small task, however. Succeeding in the digital health arena requires a different skill set than doing so in the traditional pharma and healthcare settings.

"It's a challenge for the industry," Pete Masloski, a principal at ZS Associates, told *Pharm Exec*. "One of these [challenges] is that it's a different world than pharma. The world of Silicon Valley, high-tech apps, and consumers is a very different world. It moves at 1,000 miles an hour compared to healthcare. It's a different culture."

According to Masloski, many companies operate some type of separate organization internally that deals solely with digital health. For example, Bayer created a team to be a liaison of sorts to Silicon Valley in efforts to remain updated on the latest digital health initiatives in the tech world.

According to *MedCity News*, the Bayer group investigates ways technology can benefit the larger organization in all areas of its business—from marketing and manufacturing to research and supply chain.

Although the tech and pharma industries don't fundamentally mesh very well, experts say both need each other and could benefit strongly from closer synergies. Masloski pointed out that pharma companies possess the capital and healthcare experience that the digital health start-ups don't have.

Conversely, digital health-focused companies are nimble and have the ability to quickly create solutions in the ever-changing digital world.

But opposites do attract, and as Masloski explains, the two sectors can work together. To be successful, however, in cultivating those relationships starts with good planning.

"Have a clear investment thesis," says Masloski. "Which is basically, 'what is it our company is really trying to accomplish by getting into this digital world?' Having a clear investment thesis can help screen out investments, while simultaneously help to figure out how to invest in the right places to align the organization [for digital success]."

Recognizing the differences required to be successful in this space is also critical, Masloski notes. One of the current challenges, he explained, is that pharma leaders need to be prepared to learn about and evaluate on a different set of metrics than they are accustomed to.

Not business as usual

As millennials graduate medical school and take control of the prescription pad, the way this segment of society deals with pharma companies will also shift.

"Our job is to look beyond life sciences," says Arno Sosa, vice president of product strategy for Veeva Systems, during a media roundtable at the company's annual summit earlier this year in Philadelphia.

Looking beyond life sciences means researching how other industries have been disrupted by digital media, and learn from those experiences.

The new generation of healthcare leaders—from future CEOs and salespeople to physicians and nurses—are accustomed to being engaged on digital platforms. For pharmaceutical companies, therefore, there is going to be an expectation for a certain level of digital engagement with these communities, and with some consistency, says Stephen Davies, an analyst with Gartner.

For example, instead of signing on to multiple websites to get drug information, future healthcare providers are going to want some type of standardization. Will that mean a single healthcare portal where a doctor can sign in once and access all the drug information for every pharmaceutical company? Perhaps.

Although Davies doubts the industry will get to that point, working together to make it easier to digitally access information must be a top priority, especially given that access to physicians by pharma brand teams is becoming more restricted.

Experts note that if someone inside the industry doesn't create the solutions that customers and this new generation of physicians and customers want, someone from outside the industry, like a Google or Amazon, will have the opportunity to enter the space and truly change the way business is conducted. This can also be applied to the way pharma organizations provide other services.

Take Teva's active pharmaceutical ingredients (API) manufacturing arm, TAPI, for example. The TAPI Online customer portal is a key touchpoint for customers—it's a digital service platform, an information and communications hub for TAPI customers and representatives.

"TAPI Online is a customer-centric portal that delivers immediate access to the information and

mHealth Spurred by Value-based Medicine Push

The uptake of mobile health (mHealth) will increase in the near future as the healthcare industry continues to shift toward value-based medicine, according to business intelligence provider GBI Research.

A recent report from the company states that rapid advances in new mobile devices, the expansion of communication network coverage, and the reduction in the retail price of wireless technologies have all helped in making mHealth solutions and services a reality.

The need for more cost-effective means to deliver healthcare is considered as the most important growth driver in the mHealth market, followed by the increasing need to demonstrate the value and effectiveness of treatments and by increasing support from healthcare professionals and reimbursement entities for mHealth tools.

"These three factors are directly linked to the significant challenge governments in all key markets are facing regarding the rising cost of providing healthcare," said Rodrigo Gutierrez Gamboa, managing analyst for GBI Research, in a news release. "Insurance companies and national healthcare agencies are increasingly demanding more evidence for the cost-effectiveness of treatments. mHealth technologies can significantly lower the cost of healthcare, starting with the ability to provide medical consultations at a distance."

"The world of Silicon Valley, high-tech apps, and consumers is a very different world. It moves at 1,000 miles an hour compared to healthcare."

tools our customers need to manage day-to-day API-related work so that they can collaborate with us and their team members to keep projects on track and moving forward," says Kerri McCullough Wood, senior vice president, TAPI commercial.

TAPI Online creates a more streamlined communication exchange around specific projects, replacing the cumbersome and disjointed email communication process with a submit-and-track service request interface, adds Wood. Customers can track progress and status of their projects and orders all in one place and have immediate access to thousands of API-related documents they can "self-serve" and download instantly once logged in to the platform.

Beyond the pill

The emergence of digital services such as these is illustrative of the changing business and engagement models for pharma companies."Simply providing pills is only one piece of the picture," Masloski told *Pharm Exec*. Nowhere is that apparent more than in pharma's responsibilities and involvement in the patient experience.

Masloski's assessment that the pharma industry has a hard time actually understanding the patient, their situation, and experience with a disease or drug is not new. Investing in digital health to learn more about the people who are taking a company's therapy is a smart solution to this problem.

"It's a way to get more insight into what's going on with the patients," said Masloski.

Mowad-Nassar agrees.

"Digital allows us to get much closer [to the patient] and understand their journey," she says. "It can help us improve the dialogue and do it in a responsible way and become a trusted resource for the patient by providing more than just a pill."

Getting closer to the patient experience is something that Eric Peacock, CEO of MyHealthTeams, knows a lot about. His company builds social networks for people living with chronic conditions such as multiple sclerosis, Parkinson's disease, diabetes, HIV, and more, totaling about 24 communities and bringing together more than one million active members.

Translated into pharma speak, that's a lot of data—data that can be very valuable to drug companies who want to know what their target customer is thinking, experiencing, and doing.

Peacock works closely with pharma organizations, gathering data and patient feedback, to help those in the communities get their experiences and concerns across to the manufacturers—a win-win for both sides.

For example, Peacock cited one condition where the data showed that while the medication was treating a specific chronic condition perfectly fine, there were second, third, and fourth issues making dealing with their condition a problem.

The pharma company they worked with learned about these secondary effects and was able to help their customers address them—problems the companies previously didn't know existed if not for this community.

Social networking problems

Although a pharma company may not be actively participating in digital media channels, patients are. In fact, they are likely talking about a drug-maker somewhere, someplace at this very moment. Some of it might be good, some of it might be bad.

This is an especially sensitive subject when it comes to clinical trials. During the DIA Annual Meeting last month, Lindsay McNair, chief medical officer at WIRB-Copernicus Group, explained that patients want to discuss their experiences—and sometimes that's not necessarily a good thing.

She shared stories of patients who used social media and digital forums to talk about everything from the taste and smell of a pill to the size and color in an effort to find out if they were taking a drug or a placebo. Although innocent, sharing sensitive information like this, or side effects and other experiences, can compromise a trial.

This is where pharma companies should invest in digital health communities, in which patients can safely share their experiences in a controlled environment, and where moderators can keep an eye on the conversation and hear what people are saying.

Although it may not stop patients from divulging compromising information completely, educating them and providing them a place to share their experience and connect with others going through the same process can cut down the risk. PE

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Upgrading Adherence: Patient Insights in the Age of AI

With digital interventions in medication adherence regimes evolving to new levels of sophistication, we look at the ongoing patient-behavior and privacy issues that still present significant challenges

By Julian Upton

"One of the greatest cost drivers in healthcare is still hiding in plain sight. It's called medication nonadherence." So began an article in *Forbes* last month by Hayden Bosworth, professor of medicine, psychiatry, and nursing at Duke University Medical Center, and Prescriptions for a Healthy America's Sloane Salzburg. The authors called for the issue to be a made "a national priority," and reported on the recommendations by a group of experts representing patients, physicians, pharmacies, and pharma companies on how to fix the problem. Bosworth and Sloane identified the need for improved information sharing between the clinical and pharmacy setting, better integration of healthcare systems, the leveraging of new and better technologies, and better incentives for healthcare providers, plans and drug manufacturers to improve patient adherence in federal healthcare programs.

It is revealing that this call for action positions new and better technology as only part of the solution. In the field of digital health and patient adherence, one could be forgiven for thinking that the answers to the nonadherence problem lie in the advancing connectivity protocols and mobile solutions that incorporate medication reminders and encouragement, or enable the timing of medication access to be controlled. In the last few years, as Dr. Bill Byrom, senior director, product innovation, for the contract research organization ICON, points out, we have seen the emergence of:

- **Medication event monitoring systems** using bottle caps, refillable canisters or microcircuits incorporated into blister packaging to record medication removal events.
- **Artificial intelligence** solutions using in-app analysis of smartphone video imaging to identify medication swallowing events.
- **Ingestible electronic tags** incorporated into medication that provide a detectable signal when medication is ingested.
- Use of **smart breath analysis devices** to detect breath markers produced following medication ingestion.
- Use of **sharps-bin detectors** to identify disposal of single-use injectable medication events.

Such innovations continue apace, and their contribution to tackling nonadherence is vital. However, Bosworth reminds us that, while digital health is "definitely here, it's just part of the toolbox." He told *Pharm Exec:* "If people think of it as panacea that is going to solve everything, they will be consistently disappointed." Clare Moloney, Atlantis Healthcare's clinical strategy director, Europe, further explains: "There is still the thinking that if you put something in an app or on someone's phone, or if you put a device in someone's home, that it is going to be a magic fix. This stems from the idea that people are not adhering for just one or two specific reasons—i.e., they don't understand or they forget."

Digital platforms that remind patients to take their medication will of course play an increasing and eventually routine part in the future of healthcare provision. But forgetting to take a pill, for example, is just one problem in the nonadherence dynamic. "It's different for every person," says Jon Michaeli, executive vice president, marketing and business development at Medisafe. "It might not just be forgetfulness for many people; it might be down to complex treatment regimes. It might be about having the appropriate expectations for side effects, lack of support, lack of motivation, etc."

In other words, it's "a multifactorial problem." When patients are struggling with managing an illness as part of their day-to-day life, adds Moloney, "adherence is really a tiny part of that." If, for example, patients are experiencing low moods or have had to reduce their working hours due to the progression of multiple sclerosis (MS), or simply don't feel their

"[Digital heath is] just part of the toolbox. If people think of it as panacea, they will be consistently disappointed."
— HAYDEN BOSWORTH, DUKE UNIVERSITY MEDICAL CENTER

treatment is working, "even the whizziest app or shiniest device that awards stars for adherence is just skimming the surface in terms of motivating patients to adhere" says Moloney.

Understanding patient behavior in the real world

So what can be done? How can even the most advanced treatment-delivery or monitoring systems begin to address the emotional complexities that define fundamental human behavior? Atlantis Healthcare designs and develops in-market patient solutions from a "belief-based behavior change approach." Moloney explains that the company has a large team of health psychology specialists working in-house, who help the company "go beyond providing basic adherence interventions." She explains that the company incorporates its behavioral-science expertise into its website and app content, enabling patients to "identify their values and give them the skills to challenge some of their unhelpful thinking, become better at managing their mood or their anxieties, or helping them to accept their condition a bit more."

While no healthcare system can afford to provide a health psychologist in every hospital to talk to every patient about how to manage the psychological impact of a chronic condition, Moloney says that Atlantis "takes some of those psychological techniques and processes and makes them available to people as part of their support programs." A common feature of Atlantis's online interventions, for example, is a behavior-change technique module, "which takes patients through an exercise of how to appropriately weigh the pros and cons of making a health-related decision." On the surface, this might sound quite easy, says Moloney, but it is a matter of helping people to "weigh the value of each decision and understand their health decisions in the context of their day-to-day life."

"Value" is key here, but, for once, not in the usual health-economics context. Moloney explains: "We value health because of what it allows us to do; we don't necessarily value health for the sake of it. We value being able to work full-time or spend quality time with the kids. It is about linking those values to adherence. If you can help somebody see that taking their treatment helps them to achieve the things that they value, which is going to be very personal, then that is more likely to have a more positive impact."

Moloney says that Atlantis Healthcare, whose support programs tend to be for people with chronic conditions—MS, diabetes, cardiovascular disease, rare genetic diseases, and also oncology patients—has been able to target patients' "unhelpful" beliefs at an individual level, and "see those beliefs change and improve from unhelpful to helpful as the program continues." The result in such cases has shown a high level of adherence, says Moloney. "You can see rates of 85% or 90% persistence, which you would not see in the general population in that same group."

But can such methods work outside control groups and smaller populations? "That's the beauty of the technology," says Moloney. Once health psychology is incorporated into a patient relationship management system, she says, it can then be rolled out via the technology. "When you have set up the rules and the algorithm, you are able to deal with thousands of different profiles; in fact, this is much easier than screening patients on paper."

Michaeli, who says Medisafe is addressing the multi-factorial adherence problem "in a robust personalized way," agrees that these personalized solutions can be rolled out on an unprecedented scale. Like Atlantis, Medisafe offers a platform that aims to understand the unique barriers to adherence for each individual patient by studying their behavior and then personalizing the experience. While Medisafe is "approaching four million users globally," Michaeli admits this is only "scratching the surface" in the grand scheme of things. "But we have reached a level of critical mass to show that our platform is indeed scalable—we grow about 75,000 new users a month organically," he says.

Also like Atlantis, Medisafe has reported significantly higher levels of adherence. Michaeli points to a recent study by QuintilesIMS on Medisafe users with hyperlipidemia, hypertension, and diabetes, which provided a retrospective, six-

month analysis that looked at patient script refills and correlated them to the Medisafe adherence data. Against a matched control group of non-Medisafe users suffering the same conditions and sharing otherwise similar characteristics, Medisafe users showed after six months a higher adherence of up to 20%, measured by medication possession ratio (MPR). Many patients using Medisafe's platform have chronic conditions such as depression and anxiety, chronic pain, hypertension, diabetes, and epilepsy (although Michaeli also emphasizes that there are users who are managing more acute conditions and conditions such as cancer, HIV, and rheumatoid arthritis). As such, he says, it is "not just a case of the patient saying, 'What can you do for me in month one or month two?' but in six months, three years, or five years? It is about persistent, long-term, sustainable behavior change."

The AI promise and data concerns

Michaeli explains that Medisafe is investing heavily in artificial intelligence (AI), with which it can passively acquire information about patients to help them over the longer term. "The great thing about AI is that it enables you not to over-complicate things," he says. "You can give people the tools that are specifically relevant to them without having to clutter the interface with all the things that they, individually, are not inclined to use." He adds the caveat, however, that, "AI doesn't work in a vacuum. Other data sources (e.g., a person's physical location relative to a health facility), consumer devices (IoT, wearables), and interfaces (e.g., Amazon Alexa) are available and advancing, which 'understand' and address other aspects of people's interests, behavior, and situation. And there are other key pieces (e.g., involving caregivers), so it is also about interoperability and an integrated approach and the overall user experience, of which AI is a part."

AI has of course been generating a buzz in higher profile areas of the patient adherence debate. How it can increase the ability of platforms and devices to influence a patient's self-medication regimen and capture meaningful data for healthcare providers could see it fueling one of the greatest advances in the digital health space. inVentiv Health's Head of Digital, Alex Brock, conveys some of the excitement around the potential for connectivity with consumer platforms, such as Amazon's Echo smart speaker, Google's Home, and most recently the Apple HomePod. "Things are happening at a very fast pace in this space—it's been predicted that 40% of UK homes will have a smart speaker by 2018, and Gartner predicts that by 2020 the average person will have more conversations with virtual bots or assistants than they do with their spouse," says Brock.

"If you can help somebody see that taking their treatment helps them to achieve the things that they value, which is going to be very personal, then that is more likely to have a more positive impact."

— CLARE MOLONEY, ATLANTIS HEALTHCARE

"Much has already been said about these devices' potential application for supporting patients—setting reminders, answering questions, capturing feedback," adds Brock. "That doesn't mean that voice is going to be a killer app for patient support across the board, but there are certain audiences and conditions where voice-driven interfaces could make a world of difference. For example, conditions affecting the aging population, conditions that impact movement or vision. There are people who need home monitoring and alarm systems that don't rely on reaching and pressing a button."

According to Brock, in the UK, about 40% of the National Health Service (NHS) budget is spent on the over-65 age group. "Anything that can be done to keep people feeling secure, independent and 'normal' in their own home is going to be a big win for everyone," he says.

Brock points out that devices like the Echo are already being adopted as an assistive technology by entrepreneurial patients and carers. A voice-driven conversational interface doesn't require any manual dexterity to use it, so it's immediately suited to people with conditions such as arthritis or Parkinson's disease.

"For home monitoring, we're already seeing a raft of apps (or Skills, as Amazon calls them) that allow you to connect to an emergency contact, which has obvious utility for elderly people," Brock says. "For conditions such as Alzheimer's or demen-

"It's a matter of digital and predictive analytics being able help identify which patients need the most help and serving those patients the right tools—but oftentimes backed up by human beings."
— JON MICHAELI, MEDISAFE

tia, a tool like the Amazon Echo could act as an outsourced memory, able to take notes and reminders and replay them as often as needed. Even basic-use cases of managing a smart home, turning on the lights via a voice interface, can improve quality of life and help people to stay in their own homes for as long as possible. There's been a lot of talk about the 'healthcare internet of things,' but now that internet of things has a voice and I think it's going to become louder over the next few years."

But for all the mouth-watering promise of AI, the question of data privacy remains a sticking point in the digital health debate. The problem isn't one of technology, says Brock, it's one of integration and interoperability. "All these government health systems are not designed to integrate with these new data generating technologies. That is where there is some tension, of course."

Bosworth points to the recent cyberattack on the NHS, which left IT systems in chaos and hospitals unable to access electronic patient records. "Data privacy is certainly a legitimate issue," he says. "I think we can do it in a better way. Google right now can tell you pretty much where anybody is; the genie is out of the bottle. But if you're dealing with confidential things like HIV, we need to think it through a bit more. There are companies and places that have figured it out, but it isn't clear. If there was one thing that could make things a bit easier, it would be some consistency in the regulations and their interpretation."

Michaeli says, "There are people out there who are going to try and expose private information, so I wouldn't say we are at a place where people don't need to worry at all." People need to understand how their data is being handled and the security procedures being followed, he adds. "But, ultimately, the benefit of using services like ours to a patient's health and well-being is far greater than the risk."

Patient-led patient adherence

Whether the moves to ease data privacy tensions will be effective in the coming years, digital interventions in patient treatment and adherence will continue to evolve at a rapid pace. ICON's VP of Innovation, Dr. Willie Muehlhausen, says we will see more unobtrusive ways to monitor and understand patients' behavior, but for this to be effective, pharma "will need to understand that patients will be more knowledgeable about treatments and will have higher expectations regarding their drug and their dosing." It will not be good enough to have an effective drug in the market, he explains—it will also need to be easy to apply or to ingest.

"Patients will need to be seen as consumers, and consumers will have an opinion on how the 'product' should be designed and how it should behave," says Muehlhausen.

As with the shift toward patient-centricity across the rest of the industry, patient involvement in improving patient adherence at a technological, cultural, and strategic level will be paramount. "We need to listen to the patients' feedback," says Moloney. "Some things they need we may not be able to provide, but we can focus the research and innovation to be a bit more 'bottom up.'"

Bosworth adds: "if we really want patient-centered care, patients should choose the mode of how they want messages."

So, for digital adherence interventions to truly work, the technology needs to be tempered by human insight. "It comes back to balance," says Moloney. "If everything becomes online and virtual, patients begin to miss the element of social support. It's important that we don't just do everything digitally; that might be cost-effective and scalable, but there is the risk that it becomes too impersonal for people who need other types of support. Digital screening is never going to be as able to asses someone's needs in the 'here and now' in the same way a human being can."

Michaeli agrees: "I don't want to be so simplistic as to say that everything is digital, everything is mobile. It's a matter of digital and predictive analytics being able help identify which patients need the most help and serving those patients the right content tools, resources and interventions—but oftentimes backed up by human beings." PE

Improving Patients' Lives and Boosting Mature Product Portfolios

By Julian Upton

Easypod—an automated drug delivery device manufactured by Merck KGaA, Darmstadt, Germany for its recombinant human growth hormone, Saizen—is the only electronic, fully automated injection device for growth hormone therapy. Its features include automated dose delivery and prescription tracking, which records injection history and any missed injections, and allows patients to know when to change their cartridge by displaying how much medicine is left in the device.

Speaking to *Pharm Exec*, Merck KGaA's Chief Operating Officer of Biopharma, Simon Sturge, outlines the device's development and highlights its position in the context of a changing treatment-adherence landscape that could bring benefits both to patients and mature product portfolios.

Simon Sturge, Chief Operating Officer, Biopharma, Merck KGaA, Darmstadt, Germany

PE: *Are digital interventions in patient adherence becoming more of a focus at your company?*

STURGE: Absolutely. We are a major player in the area of diabetes, for example, and as we all know, lifestyle has a huge impact on the outcome of diabetes. How much we as a company should be able to offer a whole package that helps to support the lifestyle changes needed is a very important element of us preventing or delaying the onset of diabetes. In other areas, many people who are sick have a degree of depression. There are excellent apps that are reimbursed in some countries to help treat depression, and those sorts of things should be offered as part of a solution. We believe it is an essential part of our business to look holistically at the patient and bring to that patient as many practical things as possible to help them overcome their disease.

However, innovative drugs are also at the core of what we do. A few years ago, we established a clear strategy of driving innovation in the area of spe-

"We believe it is an essential part of our business to look holistically at the patient and bring to that patient as many practical things as possible."

cialty products. This has taken quite some time from an R&D perspective, but it is now coming to fruition, with a focus on the areas of oncology, immuno-oncology, and immunology. We have a number of exciting innovative products coming to market, and what we're also seeing is substantial growth on the portfolio of our established products, one of which is our growth hormone, Saizen.

PE: *How much did you incorporate patients' adherence behaviors in developing easypod?*

STURGE: Quite a few of our products are biotech products that need to be given via injection. Understanding the patient need around that product, how they inject, what the issues are, particularly for children, has helped drive our e-health and digital platform. We have a number of different applications around our growth hormone product, but the most sophisticated is easypod. The device sends administration data such as time and dose to the cloud via a mobile device or home network, and then shares that data with the treating physician or carer, to be able to understand the usage of that product.

There are digital ways that you can track people and their activities, of course, but what we've found is that you can't beat having somebody almost living with a patient. In some circumstances we do that. We use an external group, and they send an observer to stay with a family for several days to really understand the practical issues that surround the use of the product. It's those kinds of insights that really help to provide solutions that are practical and that address genuine issues that the patient wants to overcome.

Adherence in using an injectable product in a chronic environment can be very low, as low as 25%, but we've seen in controlled studies that with easypod that we can take that up to close to 90%.

[Ramy Sourial, growth hormone franchise director at Merck KGaA, Darmstadt, Germany, adds: We worked with patient organizations and healthcare providers at different stages of planning the device, and we used focus groups and market researchers to identify the needs. During development, we conduct regular tests to check that we are on the right track. And when the product is on the market, we continue to improve the device, even small things like designing covers and designing smaller needles.]

PE: *Can this higher adherence be sustained in a real-world setting?*

STURGE: We're moving to very elegant devices, more universal devices; physicians and caregivers are becoming a lot more comfortable using the data that is generated. Where the big transition needs to take place is still with the payers. The NHS (National Health Service) is one of the most sophisticated providers in terms of understanding usage of products on a more holistic basis and has a willingness to work with the pharma industry on pricing and payment mechanisms that ultimately link efficacy with payment. As governments, payers, and the industry work more closely together, this will be of benefit to all parties and especially patients.

Our responsibility as a pharma company is broader than just supplying the drug. We have worked with the NHS on schemes where they only pay if the drug is used. If adherence levels are low, they don't pay. In some of the pilot schemes with the NHS in a real-world setting, we were getting those adherence rates of close to 90%; we think that is quite achievable in everyday use. But there's always things you can add, adding digital gains into these things to encourage children to use these devices on a daily basis; it's a dynamic process and our aim is to try and maintain these increased adherence rates.

PE: *What would you say are the remaining challenges in patient adherence?*

STURGE: One of the biggest challenges we face is data privacy, the different data privacy laws country by country. If you end up having to develop software that has to be different in every country, it becomes less meaningful. Respecting and understanding data privacy but having a broader global alignment on data privacy laws in our industry will help everybody.

It will remain a sticking point for quite some time; it's a highly complex and politically emotive subject, for very good reasons. But our concern isn't around data privacy, *per se*—it's consistency of the regulations thereof. PE

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The Core Four Elements of a Solid Digital Health Infrastructure

Digital health devices, and the data and insights that they provide, are changing the way the pharma industry engages with patients and providers. Here's how—and what—companies can do to lay the groundwork for success

By Hensley Evans, Anshul Agarwal, and Connie Bazos

Digital devices and applications deliver on patients' desire to take control of their health by being more informed and empowered, enabling a more personalized and supportive healthcare experience. On the healthcare provider's end, real-time health data tracking and monitoring allow providers to keep up with patients outside of regular doctor visits, alerting them to problems that require immediate attention—a more efficient way of providing care.

The opportunities that digital health data offer pharmaceutical companies are just as significant. Data from digital health devices can help teams understand which patients will get the most value out of specific programs, allowing for more easily personalized services. For example, based on segmented patient data, companies can design a patient services program to provide unique support to patients with comorbid diseases, or can adjust their program to suit the needs of patients receiving private, in-home care. Digital health data also can lead to vast improvements in clinical trials—long before a patient begins his or her healthcare journey.

While there are many more ways that pharma organizations are starting to use the data that comes from innovative digital health solutions, these types of advances don't happen overnight. In order to fully leverage and integrate digital health data, pharma companies need a solid digital health infrastructure.

Building a digital health Infrastructure

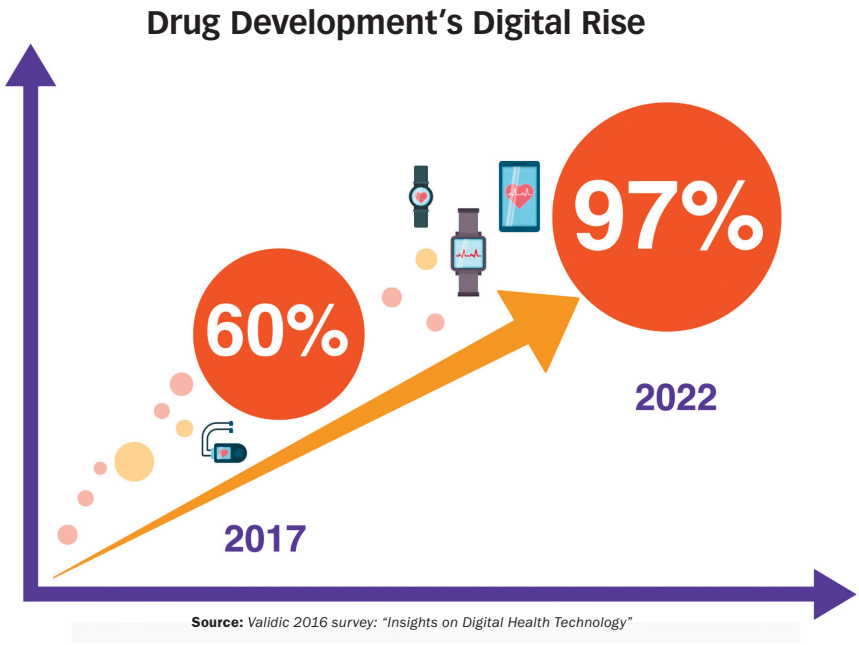
Drug manufacturers looking to leverage digital health data need to first develop the proper foundation to ensure that they're able to deliver on the promise of these technologies. The required infrastructure consists of four key elements:

1. A patient data ecosystem: Healthcare organizations today are inundated with data coming in from various sources, so a data ecosystem that integrates several sources of data—digital health data, claims data, electronic medical record (EMR) data, third-party data, etc.—at the patient level is critical. An established ecosystem will help companies standardize those different sources and combine the data to offer a holistic, more complete view of the patient. From there, companies can derive better insights into what kind of an impact digital health is having on patients, and whether it's worth continued investment. While building a patient data ecosystem seems like a daunting undertaking, many companies can leverage learnings from their current view of healthcare providers. Most pharma companies already have a view into their provider networks, and many of the same nuances, combining of data points and processes for adding new information, can be leveraged to create a patient data ecosystem.

2. A "secure enclave" for protected health information: While HIPAA regulations limit access to secure data, data scientists can work within a secure platform to integrate and enrich sensitive patient information, and patient services teams can leverage the integrated, de-identified data to improve their programs and support services.

Secure enclaves are especially important for leveraging digital health data. Pharma companies can receive only de-identified patient data from wearable devices, which limits the analytics and insights that they can generate. But if that digital health data is integrated with other secondary data sources and the patient-identified information within the secure enclave, companies can generate more comprehensive patient insights while ensuring that all confidential patient information remains confidential.

3. The capability to make predictions based on small data sets: Digital health data sources are typically thin, and they get thinner as you integrate with other patient-level data sources. To get the most out of the data, companies need to be comfortable drawing insights from a small patient population



The adoption of digital tools in clinical trials over the next five years.

We're no longer in the exploratory phase. Many companies risk lagging behind because they aren't adopting these new technologies or are ill-equipped to maximize their value

and applying their findings to a larger patient population.

For example, let's say that a company wants to assess medication adherence among patients with specific comorbidities who also use wearable devices. After assessing the data from that small group of patients, their findings show that adherence within this population is low. From there, the company uses advanced analytics to determine if this small sample of patients is a good representation of the larger group of patients with the same comorbidities who don't use wearable devices. If it's an accurate representation, the marketing team could develop patient services programs to help improve adherence among the larger comorbidities patient population, not just those with wearable devices.

4. Collaboration: The integration of patient data is only one piece of the puzzle. Multiple groups and stakeholders need to break down silos and collaborate from the outset. To roll out a successful digital health program, the brand team needs to define the objective of the program, the patient marketing team needs to determine the appropriate patient services that will help achieve those objectives, the IT team will have to work with external vendors to implement the digital program, and the data science team will have to analyze the resulting data to generate insights into the program's effectiveness.

For example, if the marketing team knows that medication adherence among patients with wearable devices is especially important for brand success, they can design a digital health program that rewards patients for adhering to their medication. Then marketing will collaborate with IT and the internal compliance team to define the details of the program, and to choose a vendor to implement it. After launching the program, the data science team will process the resulting data and integrate it with other data sources to determine if the program was effective. All of these collaborations in the design phase will improve efficiency and, ultimately, provide opportunities for success.

Data in action

While many pharma companies are still grappling with the opportunities that digital health devices—and the resulting data—can provide, many companies that have already established the proper infrastructure have taken the leap, partnering with technology companies to develop solutions. Novartis, for example, collaborated with Propeller Health to develop a custom add-on sensor for the Breezhaler inhaler, a device in the company's portfolio of treatments for chronic obstructive pulmonary disease (COPD).

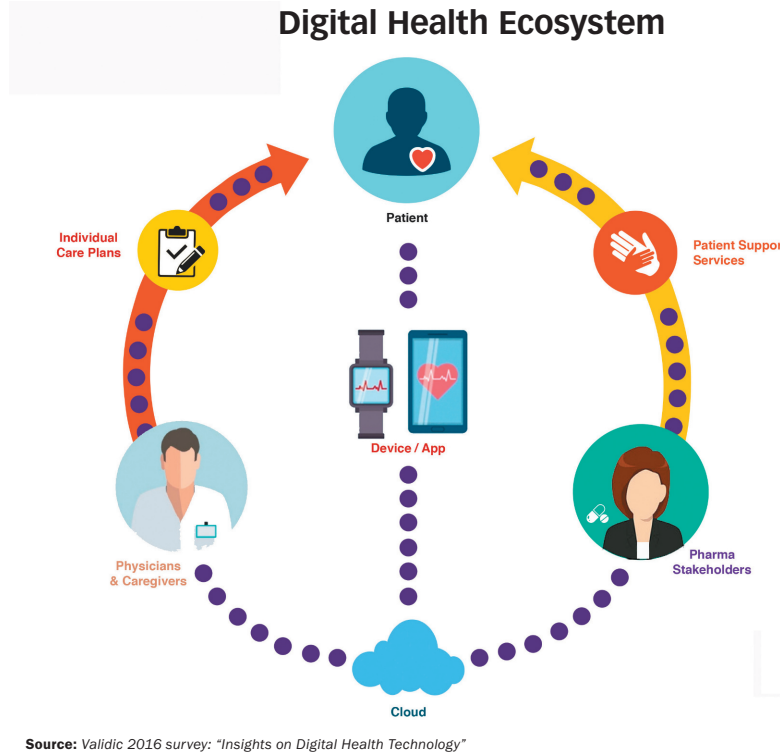
The sensor monitors when and where a patient with asthma or COPD uses his or her medications, and connects to Propeller's digital health platform that's designed to help patients and physicians understand what may be causing symptoms. GPS and

Bluetooth technology in the inhalers identify environmental triggers that cause asthma sufferers to use their device. Then the device and app convert data into learnings to create an experience that's highly targeted and personalized, delivering insights on the patient's condition through alerts, messages, or educational content. These learnings help patients reduce the hassle of managing asthma or COPD and keep the patients connected with their caregivers.

Technology companies also can help manufacturers integrate digital devices into the clinical trial timeline. In fact, according to a recent Validic survey, 97% of pharma companies say that they plan to use digital tools increasingly in clinical trials over the next five years, up from 60% today. The resulting data can lead to reduced trial costs by demonstrating real-world efficacy and improving disease management and outcomes.

Case in point: specialty drugmaker Cynapsus Therapeutics works with the Michael J. Fox Foundation and chipmaker Intel to incorporate wearable technology into a clinical trial for APL-130277, a film that administers a fast-acting, sublingual dose of apomorphine to treat motor fluctuations—known as "off" episodes—in patients with Parkinson's disease. Through the wearable device and a related app, patients will share data on movement and the medication's effect, which will help researchers gain new insight into the disease and the "off" episodes, along with the efficacy of APL-130277.

Patients and physicians also have access to a plethora of digital health devices that aren't currently pharma-sponsored, and many of these devices could represent future opportunities for partnership. One example is the VitalConnect real-time heart monitoring device. This wearable patch collects data on patients' vital signs, which physicians can stream to their smartphones or tablets. As a result, physicians can boost the efficacy of post-discharge care and reduce the readmission rate of patients with heart failure.

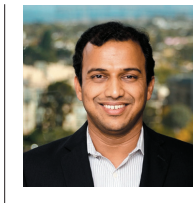


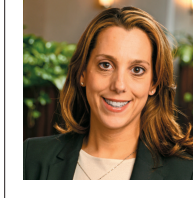
Source: *Validic 2016 survey: "Insights on Digital Health Technology"*

Looking ahead

The pharma industry has the opportunity, motivation, and technology to create great impact in healthcare by incorporating digital health technology into the patient journey. To do so, companies need to cultivate a culture of exploration and innovation. Key focus areas will include creating engaging experiences to help patients understand and manage their diseases, the delivery of personalized and actionable information, and the real-time health data tracking and monitoring for healthcare providers to care for patients outside of regular doctor visits.

As technology keeps evolving and healthcare organizations increasingly focus on patient centricity, digital solutions are not only rapidly improving, but also becoming more mainstream. We're no longer in the exploratory phase. However, many companies risk lagging behind because they aren't adopting these new technologies or are ill-equipped to maximize their value. But by taking the right steps to build the necessary infrastructure, pharma companies will be on their way to efficiently and effectively delivering solutions that will impact a patient's quality of life, improve outcomes, and set the companies apart from the competition. PE





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There's a Digital Health App for That!

Highlighting a sampling of new digital health devices that span the wide focus terrain in health technology

By Christen Harm

What comes to mind when you hear the phrase "digital health?" I immediately jump to wearables, devices, and mobile apps. The running joke that there's an app for that isn't lost on the healthcare arena. But what can we really consider as the digital health "healthcare arena?" With fitness trackers in demand, the plethora of applications considered "health" related are endless; digital devices can benefit patient efficacy, treatment, and drug adherence. A survey by Transcend Insights found that 64% of patients admit to using digital devices and mobile apps to manage their health and 71% think it would be beneficial for their doctor to have access to this information as part of their medical history.

The following is a sampling of current digital health devices that can offer relief, assistance, and understanding to patients spanning various diseases and conditions and better communication with doctors. We break our list down into focus areas that all contribute to the digital health sphere—patient engagement, product enhancement, platform solutions, and combination therapy.

Patient engagement

The myriad of new digital health solutions, platforms, tech start-ups, and more are the future for digital health and are important for pharmaceutical development. Patients are already engaging with digital devices for a range of uses, but pharma is also embracing this evolution and creating its own space in the digital sphere.

Qardiocore, Qardio Inc.

QardioCore is a wireless electrocardiogram (ECG) monitor that wraps around the chest. Available for a variety of uses—the tool was created for people with increased health risk caused by family predisposition, history of heart attacks or strokes, high blood pressure, high cholesterol, diabetes, and excess weight. The monitor tracks complete heart health onto smartphones, providing medically accurate electrocardiograph trace for deeper heart health insights, which users can automatically share with doctors. This allows doctors better monitoring and preventative care for heart conditions. QardioCore records over 20 million data points each day, enabling users to better manage heart conditions. It also monitors heart rate and heart rate variability, skin temperature, respiratory rate, and activity tracking. The device is currently available for pre-order and is expected to be available in August.

Bodytrak, Inova Design Solutions Ltd

Bodytrak is an in-ear device that records body temperature, heart rate, VO2 and motion. Its benefits to healthcare range from pediatrics to geriatrics and from in-patient hospital care to out-patient healthcare—including telecare and telehealth. The ability to accurately monitor multiple vital signs continuously can help reduce injury, detect illness or relapses, and improve recovery time.

In case of a fall or collapse, Bodytrak immediately signals for help. All data is sent wirelessly from the device, in real-time, to a cloud-based analytics platform by way of a smartphone, tablet, smartwatch, or internet hub—allowing for physiological changes to be identified quickly for earlier intervention and closer management of individual performance. Currently, Bodytrak is unavailable to purchase, but is going through development, field trials, and testing.

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Product enhancement

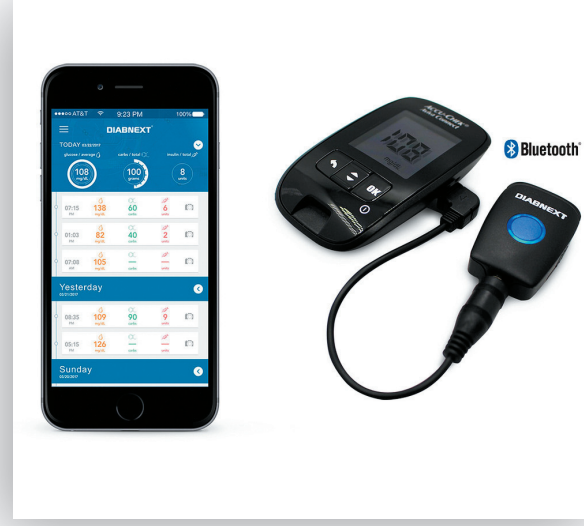
Digital health solutions that are considered product enhancement are already on the market (e.g., inhalers, monitors) but now have additional components included that make it easier and more efficient for patient care by connecting to mobile devices.

Intelligent Control Inhaler, 3M

3M looked at studies showing 94% of inhaler users making mistakes using their devices and 60% who lack medication adherence with an urgency for understanding and change. The company's launch of the Intelligent Control Inhaler provides patients a simple, intuitive, breath-actuated inhaler that delivers flow rate, and removes breath-profile variability and user-operation variability without the need for technique training. The inhaler links to digital devices to deliver patients additional information regarding usage, allows them to set reminders, and transmit adherence data. The adherence data will help healthcare providers (HCPs) and payers receive a better understanding of patient progress and direct patient care.

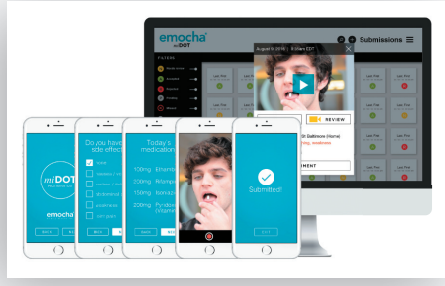
Clipsulin, Diabnext

Diabnext's Clipsulin is a smart insulin injection recorder that clips onto any insulin pen, including reusable pens. The device records the dose, date, and time of each injection. The collected data is then transferred via Bluetooth and stored onto its compatible mobile app logbook. Logbooks can be shared with doctors, nurses, or other HCPs, to receive better care and advice. The app also provides tables and graphs of data to help patients manage their diabetes metrics. The ability to check their last injection and how many units used in each dose helps avoid mistakes that can cause hypoglycemia or hyperglycemia. The recorder is currently available for pre-order.



Platform solutions

Platform solutions are broader applications that create a space allowing for multi-faceted solutions and opportunities. Platforms connect with various wearables for healthcare, medical, pharma, and fitness. Platform solutions address more than one thing, rather than just one end-goal solution, and can be used across the board instead of just one particular application.



emocha, emocha Mobile Health

emocha is a mobile technology platform solution that focuses on improving patient adherence, with the use of video-based directly observed therapy (VDOT). Patients first record themselves taking their medication on their mobile device; then, providers verify each dose on a HIPAA-compliant platform, assessing adherence analytics, and support patients through treatment. Patients achieve 90%-plus average adherence, according to information provided emocha Mobile Health. The platform also allows patients to report symptoms. It has been used by patients with tuberculosis and multi-drug-resistant tuberculosis (MDR-TB), HIV, hepatitis C, hemophilia, cancer, diabetes, and more.

Propeller, Propeller Health

Propeller is a platform for people managing asthma and chronic obstructive pulmonary disease (COPD). Patients can sign up online, using a smartphone or computer, and receive the Propeller sensor in the mail. The sensor attaches to most inhalers and doesn't affect how medications are inhaled. It sends insights about inhale techniques and symptom triggers to mobile devices, helping patients understand what causes their specific symptoms. Currently, the tool is available by going through one of Propeller's 50 commercial partners.

Combination therapy

Combination therapy digital devices compliment the treatment of drugs that are already on the market or coming to market. This category includes devices and apps that aid drug delivery and adherence in tandem with the drug for efficiency.

MiniMed 670G, Medtronic MiniMed, Inc.

An estimated 1.25 million Americans live with type 1 diabetes, pushing companies to create "artificial pancreases." An artificial pancreas is a technology currently in development to aid diabetics in controlling blood glucose levels automatically, providing the substitute endocrine functionality of a healthy pancreas. Those in healthcare prefer the term "hybrid closed-loop artificial pancreas systems," because the system doesn't act solely as a pancreas; it requires intermittent intervention from patients during mealtimes, exercise, and for occasional calibration.

Every five minutes, the MiniMed 670G closed-looped system—available for type 1 diabetes sufferers 14 years of age and older —constantly adjusts the amount of basal insulin that is delivered to patients. The device adjusts insulin based on the patient's specific needs and level of activity. The automated basal insulin delivery decreases the level of patient interaction needed, enhancing quality of life and easing the burden patients experience with the constant management of blood sugar levels, both during the day and at night. The tool is especially helpful for the lows that cannot be detected while sleeping. PE

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Beyond KOL Marketing

Tapping Digital Opinion Influencers

With healthcare professionals and patients now collecting much of their information online, there is new opportunity for "digital opinion influencers" to amplify traditional KOL messaging—or create their own

By Gregg Fisher and Kevin Michels-Kim

FAST FOCUS

» According to a study conducted for a pharma company that analyzed a healthcare provider's DOI community, active posters regularly reached an aggregate audience of about 2.8 million people, many of whom were key prescribers, patient prospects and payer influencers.

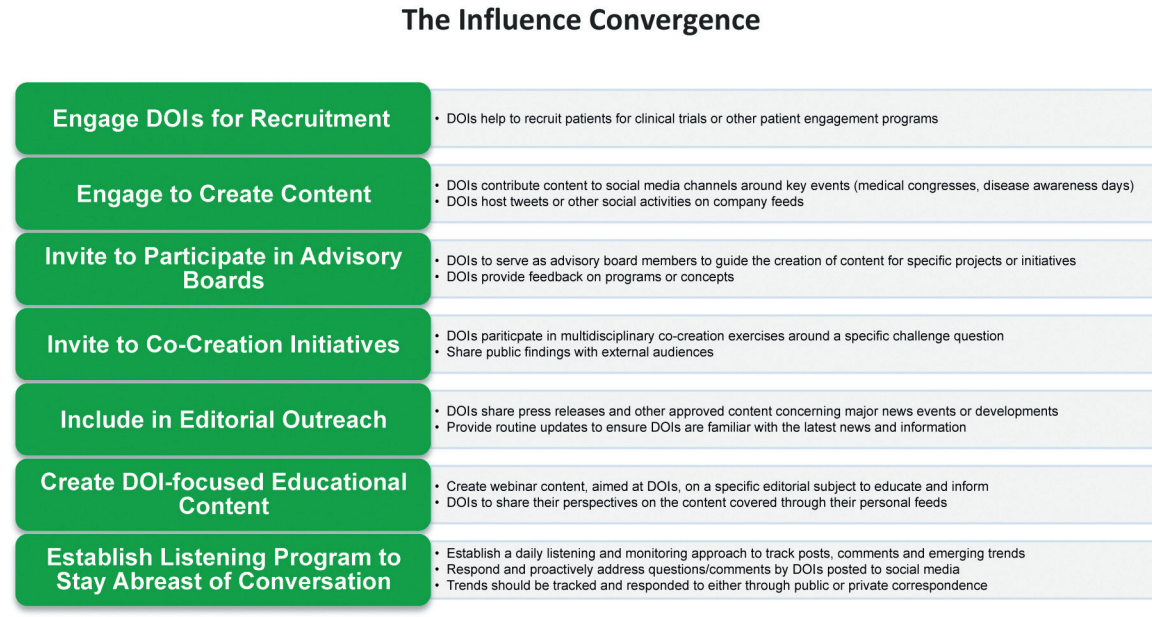
» DOIs and KOLs tend to exist in largely different universes, with little overlap. Typically, less than 20% of KOLs will also have a social media presence.

» It is important that outreach efforts for DOIs by pharmaceutical companies are integrated into the relationship building functions and processes within the organization. For example, integrating DOI activity into customer profiles to provide actionable data to front-line sales.

Pharmaceutical companies have long recognized the power of key opinion leaders (KOLs) in driving influence through traditional channels: journals, speaking events and word of mouth. The problem, however, is that healthcare providers (HCPs) and patients are acquiring information about disease and treatment in the online world—and many KOLs are not "digital opinion influencers," or DOIs. This creates an opportunity—strategic DOI identification, outreach and management—for brand, communications and medical teams that is often overlooked or poorly addressed.

Sizing the opportunity

This opportunity is largest for pharmaceutical companies providing drugs to address chronic conditions to active patient communities, in which



An overview of common digital opinion influencer (DOI) engagement techniques.

there are high levels of treatment innovation. For example, The Stem recently conducted a study for a pharma client to analyze the healthcare provider DOI community across seven markets for a chronic condition. The results were notable. Of 4,000 HCPs in the community, we identified 1,400 active posters who posted at least three times in the past year. And of these, we identified 131 influencers driving the lion's share of influence. Interestingly, more than a quarter of these were not traditional KOLs already on the client's radar. Further, we discovered active posters regularly reached an aggregate audience of approximately 2.8 million followers and fans, many of whom were strategically important prescribers, patient prospects and payer influencers.

This example illustrates the potential power of managing relationships with a small number of DOIs, who act as a force multiplier for life sciences peer-influence programs. A traditional KOL may have influence in terms of the articles written or the conferences at which they speak, but a DOI has an outsized reach made possible through social media.

Who are DOIs?

Digital opinion influencers are influential members of a health community turned to for advice, opinions and information. Their influence flows from reach (followers), their resonance (content sharing) and relevance (topics discussed). Their distinguishing characteristic (versus traditional KOLs) is their use of social media to either create or amplify messages. DOIs are both medical professionals and non-professionals.

In the medical world, DOIs are typically drawn to social media as a platform for building their reputations. These DOIs share opinions on therapies, discuss presentations from medical congresses and share advice on disease and patient management. Another segment—researchers and academics—frequently communicate models of disease understanding based on the latest studies. These professional DOIs have converged around Twitter as the preferred channel, particularly around major medical conferences, while simultaneously turning to closed HCP platforms for peer-to-peer discussions.

In the patient world, DOIs include patients and caregivers who typically emerge from personal experience—the quest for advice, information or connection—which transforms into a mission. Health bloggers and so-called e-patients (who take an active online role in their health) have amassed large followings, sometimes leveraging their influence to form non-profits, online media companies or patient associations. Traditional patient groups have also joined the fray, seeing new ways to reach audiences. Patient

DOIs use a variety of channels (Facebook, Instagram and blogs, to name a few) and are not concentrated in a single medium, such as HCPs with their use of Twitter).

Based on our analyses for a range of pharma customers, we have found that DOIs and KOLs often exist in largely different universes, with little overlap. Typically, fewer than 20% of KOLs will also have a social media presence and just a handful will rank alongside DOIs in terms of online reach. In the patient world, this is to be expected, as many DOIs are individuals as opposed to patient advocacy groups that would already be on a pharmaceutical company's radar.

Identifying, profiling, and engaging DOIs

The first step in establishing a DOI program is to understand the disease area community of interest.

- How large is the community?
- What is the split between different segments?
- How many are active posters versus passive listeners?
- How many followers do the active posters have?
- What are the different topics being discussed?
- Which channels are used most heavily?

This step provides a robust understanding of the online community and can be used to select topical segments (or "social personae") of greatest interest.

The second step is to dig deeper into the community to identify those posters who have the most significant and relevant follower reach, and the greatest resonance and relevance of posts. This allows teams to:

- Create rich DOI profiles covering channels, topics, followers, geography, among others.
- Develop network maps to highlight connections between DOIs and followers, which often highlight opportunities to build connections between otherwise separate nodes of a network.

From here, a final list of prioritized DOIs can be selected.

The next step is to formulate an engagement strategy. Unlike promotional marketing, DOI engagement plans must be designed to deliver mutual value. Programs that focus narrowly on brand goals, versus a program that considers both brand and stakeholder goals, will fail. Fortunately, there are many opportunities to advance a pharmaceutical company's corporate, franchise or brand objectives while addressing community needs.

There are several notable examples of successful DOI outreach. Boehringer Ingelheim, a leading pharmaceutical player in social media, leveraged a DOI relationship by having the expert host a live Twitter chat during a respiratory event congress. BI now regularly participates to encourage DOI commentary, adding value to the discussion. In the patient realm, Medtronic, a medical device company, engages patient DOIs in multiple regions for ongoing campaigns and feedback. Influencers are leveraged for guest editorial, product trials, feedback and education campaigns.

Organizing for success

Engaging DOIs is fundamentally a relationship-building task. Many DOI engagement efforts fail because they are seen as a one-off tactic (such as a blogger summit), versus a sustained relationship-building process.

As such, DOI outreach must be integrated into the relationship-building functions and processes within the organization. The Stem's most successful clients have integrated HCP DOI management within the global and affiliate medical function and patient DOI management within the patient advocacy or communications function, with strong support from a social media or digital competence center. These companies have taken steps to integrate DOI activity into customer profiles to provide valuable actionable data to front-line sales, medical science liaisons and patient advocacy staff. Furthermore, they have developed new processes for engaging with DOIs in real time and working them in an educational, support, research and advisory capacity.

Enhance the message

Pharmaceutical companies have long ago recognized the power of peer influence in supporting their strategic objectives. A well-planned and supported DOI program offers the potential to amplify those efforts by propagating key messages through social media. It's not a replacement for traditional KOL marketing, but rather a supplement to it. DOI marketing offers the possibility to build authentic, mutually beneficial relationships with key stakeholders in online communities. This can deliver important advantages to life sciences organization's in terms of customer insight, brand image and authenticity, and content relevance and engagement. PE

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Can AI Improve Sales Productivity in Pharma?

With the physician-access climate as daunting as ever for sales reps, four best practices in implementing artificial intelligence-based technology to help achieve engagement wins are explored

By David Keane

For years, pharmaceutical sales representatives have been dealing with access challenges and shrinking availability of prescribers, stemming from a more restrictive regulatory environment, changing economic conditions and new healthcare business models. These factors, in turn, have pressured physicians to see more patients, leaving less time to learn about even potentially life-saving drugs. Whether it's with key opinion leaders (KOLs), high prescribers, administrators or any other decision--makers, yesterday's sales strategies and tactics are not only less effective, they're also highly restricted and regulated.

Regulatory requirements are creating hurdles for salespeople. Federal and state regulations, and guidelines from industry associations such as the Pharmaceutical Research and Manufacturers of America (PhRMA), set boundaries for how pharmaceutical sales reps can interact with customers. The "lunch 'n learn" meeting between reps and physicians, once a key part of the sales playbook, has been significantly curtailed, reducing both the frequency and average time per rep/physician interaction. In addition, the Open Payments program, created by the Physician Payments Sunshine Act (part of the Affordable Care Act), requires drug and medical-device manufacturers to report to the Centers for Medicare & Medicaid Services (CMS) every "transfer of value" of $10 or more to physicians and teaching hospitals. Only 44% of physicians routinely meet with sales reps and there is even less access to many specialists. For example,

By having a means to better measure and learn from the successes and failures of other sales people across the team and identify the habits of its best reps, organizations can improve outcomes

according to a 2016 ZS Associates report on physician access, just 17% of oncologists are available to sales reps.

Today, the most successful reps are always prepared to present the right content and employ best practices at every opportunity, making a greater impact in less time. Most reps simply aren't able to achieve this on their own. According to Kapost, 65% of sales reps report that they cannot find the most impactful content to send to, let alone find it on the spot when a physician suddenly gives them two minutes to either present impactful content or become a "no-see" physician to them.

Reps need help from sales leadership, marketing, training and their peers to know and implement best practices in each sales scenario. There is generally even less time to meet with the busiest and most vital customers, KOLs and high prescribers. On average, reps aren't earning more time, as physicians have only a 38% recall of sales rep activity, the ZS report notes. In the new age of the "30-second detail," reps must be armed with guided selling so that they can give a more targeted, impactful message. When the message and content is more timely and relevant, detail time increases. When detail time increases, sales increase.

The tech imperative

Due to the current pharmaceutical sales environment, sales teams must find new and different ways to engage with their customers and close more deals. In today's competitive business climate where growing top-line revenue is a constant struggle yet sales reps are expected to do more with less, the implementation of technology solutions has become increasingly critical.

More recently, machine learning and artificial intelligence (AI) technologies have emerged to aid in this effort. These technologies have the potential to make a real difference for pharmaceutical companies when it comes to helping their sales teams improve productivity, win rates and customer satisfaction. An AI-based selling solution, for instance, can help pharmaceutical sales reps do more in the restricted time that they have by serving as a virtual sales assistant. It can provide relevant content recommendations that guide the salesperson and the customer down the most effective path to a sale.

Here are just a few of the ways AI can help drug manufacturers looking to achieve and sustain a more productive sales team:

1. Prioritizes pre-call planning. AI technology can provide the required training and certification materials needed to make sure that the pharmaceutical sales rep is ready for the meeting in advance. AI can also make recommendations on what information and content is going to have the most impact in the meeting, including sharing and recommending best practices and specific sales collateral to reps. This, in turn, minimizes the time consumed by the rep looking for and gathering these materials. By implementing more effective pre-call preparation, sales reps can maximize their effectiveness in every customer meeting.

For instance, sales reps can ascertain in advance that a particular doctor is more interested in making time for reps who have more treatments to discuss. Recognizing this ahead of time empowers the rep to come armed with details on all the drugs that would be relevant for this particular physician. AI can also recommend the most important reprints, detail aids, abstracts, and leave-behinds for each call with a prescriber as determined by the sales teams' best practices, marketing,

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» Sixty-five percent of sales reps reportedly are unable to find the most influential content to send to their healthcare provider customer to elicit an engagement opportunity. This results in less time to meet with the busiest and most vital customers, key opinion leaders, and high prescribers.

» The argument for sales reps applying machine learning and AI technology approaches include the easing of restrictive time constraints by serving as a virtual sales assistant. More specifically, AI can recommend the highest priority reprints, detail aids, abstracts, and leave-behinds for each call with a prescriber as determined by the sales teams' best practices.

» Implementing AI-powered technology that automates manual tasks, such as call logging, can free up reps to focus on perhaps their most important task: cultivating relationships. Physicians reportedly have only a 38% recall of sales rep activity.

and sales leadership. By optimizing pre-call planning, more time can be spent meeting with physicians, physician assistants (PAs), and nurse practitioners.

2. Reduces administrative tasks. Reducing time spent on administrative tasks will help maximize the time reps can spend in the field. One way to do this is by using technology that automates manual tasks, freeing up reps to cultivate relationships. For instance, technology can help by automatically logging calls with physicians, nurses, pharmacists and other key customers into customer relationship management (CRM) systems like SalesForce or Veeva. In addition, taking advantage of smart forms, which enable digital data entry and connect to back-end systems, allows reps to complete them while in the field from their mobile devices. This eliminates time-consuming paper-based forms—enabling reps to place orders on-site and in real time versus later when they're back in the office—and increases overall productivity. This content, in turn, can be fed into an AI-powered tool to help inform the self-learning algorithms. The result: automatic content recommendations provided to sales people based on factors such as where they are in the sales cycle, their role or what their peers are using—and a significant reduction in time spent hunting for the right content.

Now, pharmaceutical sales reps are able to stay in the field longer and call on more customers since the admin-heavy tasks that have traditionally forced them to spend more time at their desks, like inputing sales calls into their CRM systems and emailing a reprint to a physician, are now automated.

3. Identifies and shares best practices. By measuring every user action and learning from this process, an AI-powered solution can identify what works and what doesn't for engaging prospects and closing deals. From this, AI solutions can make real-time content recommendations for a sales rep, tailored to where they are in the sales cycle, and greatly improve their chances for a successful outcome.

For instance, if the top 10% of sales people use a particular presentation during their initial meetings, the system would push that content to other sales people as they were headed toward their own introductory session with a prospect. By having a means to better measure and learn from the successes and failures of other sales people across the team and identify the habits of its best reps, organizations can improve outcomes by elevating the performance of the entire sales teams. In other words, AI can become a sales trainer and mentor that is always by the sales rep's side.

With pharmaceutical sales reps typically only meeting to share thoughts and advice with their peers at quarterly plan of-actions (POAs) or national sales meetings, which occur one to two times per year, AI technology enables the reps to share and implement these best practices in real time and potentially translate to immediate improvements.

4. Enables real-world, step-by-step guided selling. By taking input data, AI-powered sales enablement technology helps guide the sales person through the entire sales cycle, suggesting the best next steps, activities, and assets based on that information. Acting as a virtual mentor, this technology guides a sales person and recommends the right content to be successful, while also allowing them to benefit from the marketing's expertise. In fact, according to SiriusDecisions, aligning sales and marketing is proven to deliver 19% more growth.

In addition, this technology allows sales teams to take advantage of the best reps' experience and wisdom, while also alerting them to missing information or other issues that could put a deal in jeopardy. Often called guided selling, this approach offers a real-world way to help sales people be successful, especially when they have limited time with the physician. This could include providing a customized prescriber profile and call history to better prepare sales reps before engaging with physicians, PAs, and nurse practitioners to sharing the best practices of the top sales reps in the organization to maximize the time in front of the physician.

Future 'rep' in balance

Leveraging technology where a machine is taking on manual work typically done by a human offers significant opportunity to boost efficiencies, improve sales team preparedness, increase time reps can spend with physicians, KOLs, and other key decision-makers, and enhance cross-team collaboration. In turn, sales teams can better prepare for meetings, successfully present to those time-strapped physicians, more effectively follow-up after meetings, and share best practices with their colleagues. Ultimately, AI has the potential to help pharmaceutical sales reps increase their productivity, close deals faster and help drive revenue. PE

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Industry Forecasts Update: Mix of Sun and Uncertainty

Through the first quarter of 2017, pharma and biotech valuations were still feeling the effects of negative pricing publicity, uncertain healthcare legislation and tax reform pictures, and the sustained lull of M&A activity. The strong R&D and innovation trajectory in both sectors, however, continues to hold out hopes for business resurgence ahead

By Peter Young

For most of the last 10 years, there has been a lot to be happy about in the pharmaceutical and biotechnology industries. The number of new drugs approved and under development escalated for pharma and biotech companies alike. A host of new treatment methods, such as immunotherapy, CRISPR, personalized medicine, stem cells, and biologics have opened up a surge in productive innovation. We are beginning to see drugs that cure difficult diseases rather than just extend life—an extraordinary development. There have even been recent US regulatory and funding changes that are intended to increase government funding and ease the drug approval process, although time will tell if the actual results match the intent.

The access to equity capital and the valuations of pharma and biotech organizations in the public and M&A markets soared until the end of 2014, in part because of these positive developments.

Since then, the innovation successes have continued, but there have been times when heavy clouds have appeared in terms of the stock market, access to capital, pricing controversies, and uncertainties around the ongoing structural changes in a number of the major markets such as the US and China. There also was a slowdown

in FDA drug approvals in 2016 in the US, with only 22 approved, although the pace has picked up considerably so far in 2017; as of late June, 23 new medicines have been greenlighted by the FDA this year.

Share prices and public valuations have been volatile since late 2014, with industry uncertainties and the drug-pricing controversies to blame. Public biotech shares were hit particularly severely and, as a result, the IPO market started to cool off in the second half of 2015 and plunged in 2016. Secondary offerings were strong in 2015, but then fell precipitously in 2016. This is creating a difficult equity financing environment for biotech companies, which, in turn, has limited the choices available to biotech firms to continue to fund their companies. This has contributed to a surge in M&A activity in 2015 and 2016, as many biotechs have had to sell their companies earlier than they would have liked, often just after they achieved certain clinical trial milestones.

This article will provide the data behind these historical observations through the end of last year and the first quarter of 2017. We will also explore the implications of these trends for decisions being made by senior executives and investors in the pharma and biotech industries.

Pharma equity market performance

During 2016, the equity markets plunged in January and February and then recovered in March. Global markets saw a drastic dip again in late June 2016 in the wake of the Brexit decision, but quickly recovered. After the US presidential election, the markets rallied strongly.

> There have been recent US regulatory and funding changes that are intended to increase government funding and ease the drug approval process, although time will tell if the actual results match the intent

As a result, 2016 saw the S&P 500 increase 11.2% from the beginning of the year and the FTSE 100 increased by 17.2%.

In contrast, the Young & Partners (Y&P) pharmaceutical indices did not do well as a group. The Y&P US Pharma index increased, but only by 6%.

The rest fell. The Y&P European Pharma decreased by 14.6%, the Y&P Specialty Pharma index by 20.5%, and the Y&P Generic Pharma index by 28.3%. As a result, there was a decline in the public valuations of ethical pharma, generic pharma, and specialty pharma organizations in the West.

Clouds of uncertainty around the pharma industry were a heavy contributor, such as the US presidential election and the very visible and damaging pricing controversy.

The industry fared better in the first quarter of 2017. The global equity markets performed modestly well with the S&P 500 increasing by 4.6% and the FTSE 100 growing by 2%. However, three of the four Y&P pharma indices performed better than the market. The Y&P US Pharma and European indices did well, increasing by 5.1% and 7.1%, respectively, and the Y&P Specialty Pharma index rose by 6.5%.

Only the Y&P Generic Pharma index did poorly, decreasing by 6.7%.

Pharma equity financing and M&A

Equity issuance during 2016 was $16.4 billion of equity issued—versus $32.7 billion for all of 2015—a drop by about half. Part of the reason was the reduced M&A volume that dampened the need for equity. However, it was also partly due to the volatility of the equity markets and the negative sentiment about the biopharma industry.

There were only eight pharmaceutical IPOs in 2016.

In 2016, 44 M&A deals were completed worth $120.5 billion, versus 58 deals completed worth $201.5 billion the year before. These were healthy numbers, but were major decreases from the activity in the previous year in terms of dollars and numbers of deals.

With only two large deals completed, the $31 billion acquisition of Baxalta by Shire and the $40.4 billion purchase of Allergan's generics business by Teva, there were very few mega deals compared to previous years.

The rationale for dealmaking remained the same, as pharma companies sought to strengthen their product portfolios, replace pending revenue losses from patent expirations, and restructure their business portfolios.

Biotech M&A activity has almost always been modest historically, with small spurts of activity from time to time

However, the loss of tax inversions as an alternative for US drug companies, the negative publicity around treatment pricing, and the political uncertainties associated with the US presidential election all contributed to a dampening of M&A activity.

As of December 31, 2016, the value of the deals announced, but not closed, was $4.4 billion (15 deals), a very modest number in terms of dollars, but a solid number of deals. In contrast, the pipeline of deals announced, but not closed, at the end of 2015 was $240.4 billion (16 deals)—but many did not close and the biggest failed deal was the massive would-be merger of Pfizer and Allergan.

How was the M&A climate through the first quarter of this year? During that time period, six deals were completed worth $7.1 billion versus 44 deals completed worth $120.5 billion in 2016. On an annualized basis, this represents a dramatic decrease in both numbers of transaction and the dollar volume.

This illustrates a continuation of a subdued M&A market that, in spite of the need for pharma companies to buy pharma businesses for strategic reasons and to shed non-core assets, is being held down by the same factors that caused the slowdown in the latter part of last year. Additionally, there are some added factors such as the move to replace Obamacare and revise the tax laws. Both developments could help and hurt M&A activity if corporate tax rates are lowered in the US, and the penalty to repatriate overseas cash by US drug manufacturers is reduced.

As of March 31, the pipeline of the deals announced, but not closed, had increased from year-end to $34.7 billion (16 deals), but most of the dollar volume was attributed to Johnson & Johnson's then-proposed acquisition of Actelion Ltd. Last month, the deal was completed for a total purchase price of about $30 billion in cash.

Biotech equity market performance

As indicated earlier, 2016 saw the S&P 500 rise 11.2% from the beginning of the year. The FTSE 100 increased by 17.2%. Most of our biotech indices did poorly. In 2016, the Y&P Large Cap Biotech index decreased by 14.6%, the Y&P Mid Cap Biotech index fell by 5.2%, and the Y&P Small Cap Biotech index increased by 10.4%. Much of the blame was due to the negative publicity around drug pricing.

During the first quarter of 2017, when the S&P 500 increased by 4.6% and the FTSE 100 rose by 2%, the Y&P Large, Mid, and Small Cap Biotech indices performed well, increasing by 5.1%, 15.5%, and 21.6%, respectively. This was a welcomed improvement during a period when equity financing was still a challenge.

Biotech equity financing and M&A

Equity issuance in 2016 fell significantly, with 126 equity offerings worth $8.7 billion completed—compared to 206 offerings worth $20.1 billion in 2015. In 2016, only 26 IPOs were completed for a total of $1.9 billion in new equity, well below 2015, when 61 IPOs were completed, totaling $5.3 billion. The equity and IPO markets have continued to be tepid for biotech.

Biotech M&A activity has almost always been modest historically, with small spurts of activity from time to time.

In 2016, there were 42 biotech M&A deals completed worth $19 billion, compared to 31 deals worth $19 billion in 2015, and 28 deals worth $13 billion in 2014. The number of deals and the dollar volume has increased significantly since 2014. This increase has been fueled by pharma companies and their need to fill product pipelines and by the financial squeeze facing biotech organizations due to the slowdown in IPOs and public secondary offerings.

Sealed off from high valuation equity offerings, biotech companies have been less fortunate than they were in 2013, 2014, and most of 2015, when

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Pharma M&A activity for the rest of 2017 is expected to be moderate.

they were able to raise money at high valuations. In many cases, biotech companies have not been able to go public at all. As a result, those biotech organizations in the midst of Phase II and Phase III clinical trials, where the cash consumption is high, have been forced to either sell or to partner in order to deal with their shortage of cash.

However, the pipeline of deals slowed significantly toward the end of last year. Global M&A slowed with increased geopolitical uncertainties around the world and the controversial US presidential election, but there was added uncertainty surrounding the biotech sector with the US Republican Party's promises to repeal and replace Obamacare, uncertainty around changes in tax laws and rates in the US, and the pricing controversies surrounding many companies such as Mylan, Mallinckrodt, and the industry as a whole. This slowdown continued in the first quarter of 2017, with only eight biotech M&A deals completed worth $1.4 billion. This was a significant slowdown on an annualized basis, compared to 2016.

The pipeline of deals announced but not closed as of March 31 was also weak at only $600 million (three deals).

Outlook: Pharma

The business outlook for pharma companies will continue to be positive in regard to drug development, with promising medicines in the pipeline. The industry's trajectory in drug development innovation and productivity, directly and indirectly through the biotech industry, is strong and will continue to be strong.

There was some uncertainty about the 2016 drop in FDA approvals, but activity has picked up and there is a push to ease the approval process in the US.

Generic pharma companies will continue to consolidate, cut costs, and push selectively into higher value and more protected product areas.

Ethical and specialty pharma organizations will continue to partner, license, and acquire to maintain the strength of their overall business portfolios and scale, but some companies are under attack due to the drug pricing issue.

The stock market prices and valuations of the ethical pharma industry have suffered with the recent volatility in the overall markets and the controversy over drug pricing that has become a very public issue.

Specialty and generic pharma companies have suffered even more with regard to their public company valuations.

It is unclear how long the overall equity markets will be disrupted, but it is our expecta-

tion that the negative news will continue to counterbalance the positive for the biopharma industry. Equity issuance will continue at a modest pace. However, companies will continue to rebalance their balance sheets to post larger M&A transactions.

Y&P expects M&A activity for the rest of 2017 to be moderate, a continuation of the relative weakness experienced in 2016. The general uncertainties affecting the industry will be a factor. In any case, the shutdown of the large inversion deals will continue to block what was previously a flurry of mega deals.

However, number of deals will still be significant, driven by restructuring and strategic needs of pharma companies and the residual impact of what was a feeding frenzy.

Drug manufacturers will continue to acquire to enhance their product pipelines and strategic thrusts, while selling off non-core businesses.

The need to fill the shrinking drug pipeline will also fuel in-licensing arrangements, partnerships, and joint ventures with biotech companies and other pharma firms.

Outlook: Biotech

The development capabilities of biotech companies have been and will continue to be positive overall. Although there will be successes and failures by individual organizations, biotech companies have demonstrated their ability to develop new drugs at a faster pace than the larger pharma firms.

The stock market favored biotech companies for a number of years. This changed in the second half of 2015 for a number of reasons, including the negative stories around drug pricing.

It is hard to predict whether and when the current depressed biotech equity market will recover to more attractive levels.

However, we do not see a near-term recovery in the equity issuance market, particularly for IPOs, as long as the uncertainties about the industry and the negative public view of the industry continues.

Biotech companies will have to turn more to partnering, licensing, and M&A for funding and shareholder liquidity.

The primary biotech M&A theme has been pharma and big biotech acquisitions of biotech companies for pipeline enhancement.

The most promising biotechs over the previous three years were able to go public first and attract significant interest and high prices later. However, the recent slowdown in IPOs has driven many companies to either sell themselves or raise funds via partnering deals and/or discounted private placements, and we believe this will continue for some time.

Therefore, M&A volume and partnering deals will be active in 2017 and beyond, but well below the level of the pharma industry, as has been the case for many years.

Generic pharma companies will continue to face a number of challenges. This will result in a continuation of the current industry consolidation and selective strategies around diversification

Implications for senior management

For ethical pharma companies, there will continue to be a wide variety of tools to acquire revenues and pipeline drugs, but the valuations are challenging, particularly for promising drugs in late-stage clinical trials and for companies with strong products.

The challenge will be to pick the right overall mix of M&A, licensing, and partnering to accomplish corporate strategic goals and defend and deliver shareholder value.

The generic pharma companies will continue to face a number of industry challenges. This will result in a continuation of the current industry consolidation and selective strategies around diversification.

For biotech companies—public and private—the future is exciting from the drug development side, but troubling on the private funding, IPO, secondary equity financing, and M&A fronts.

Time will tell whether the very public attack on drug pricing and the likely changes in the US healthcare insurance and tax regulations will force changes in the industry. PE

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Reinventing the Role of Medical Affairs

As digital technologies transform drug development and marketing, a retooled medical affairs function can be a competitive differentiator

The most competitive pharma companies in the coming decade will be masters of data and digital technologies. They will generate and analyze vast volumes of real-world data and excel at communicating scientific evidence. Above all, they will help physicians navigate in a far more complex healthcare universe.

That profound shift is already under way. But information channels are changing, and many companies have difficulty communicating science effectively with the growing array of stakeholders that influence purchasing decisions. That shortfall is one reason many new drug launches underperform: 50% of all launches now fail to meet company expectations, research has shown.

Leading companies are upgrading medical affairs to overcome that deficit. Equipped with deep product knowledge and disease understanding, medical affairs teams can become a strategic ace in an era of big data. They are well positioned to generate and present high-quality scientific knowledge to the market and educate stakeholders about next-generation products.

As the demand for real-world evidence grows, those two roles will become increasingly critical to pharma companies' performance. Physicians already are reducing their reliance on sales representatives and turning to more scientific sources of information. That shift is even more pronounced among younger physicians. In parallel, the total number of sales representatives has fallen. In North America, pharma salesforce levels have dropped by about 7% between 2005 and 2011 and have leveled off since then. In Europe, they have fallen by 10% between 2006 and 2010.

An experienced medical affairs team can link scientific and clinical results to patient outcomes, adding value at every stage of a drug's development. When discussing a potential new compound with physicians, payers and key opinion leaders (KOLs), for example, medical affairs teams gather vital feedback on its market potential and patient needs at the earliest stages of the drug development process. The insights they glean over time can improve return on investment and create a strong competitive advantage by helping companies design more effective clinical programs and launches.

From medical affairs to medical value

Why have so few pharma companies started down this path? Most remain focused on products instead of outcomes, and they regard medical affairs staff as technical product advisers. That traditional approach could become a handicap as rivals retrain medical affairs teams to develop scientific evidence and demonstrate to physicians, payers, patient groups and KOLs how new products improve patient outcomes.

The winners in an era of big data will transform medical affairs teams into medical value teams with three strategic roles: communicating scientific evidence, providing market-based strategic input to drug development and portfolio management, and overseeing the effort to produce big data and real-world evidence.

Engaging stakeholders, communicating science

Bain research shows that 88% of US physicians and 83% of European Union physicians consider real-world evidence a top criterion in prescribing drugs. But sorting through the vast increase in evidence has become an overwhelming task—physicians, payers and healthcare providers are struggling with data overload. At the same time, diagnostic tools are becoming more sophisticated and drugs increasingly complex. Those developments have increased the need for more transparent data on drug performance.

Leading companies have understood that medical value teams can step into the breach and help physicians, payers, providers and KOLs make sense of a deluge of data and identify the best use for new products. That approach creates a virtuous circle for pharma companies.

As medical value teams build long-term relationships with a variety of stakeholders, they benefit from continual market feedback and a better, more nuanced understanding of the

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market and patient needs. At the same time, increased engagement with stakeholders helps pharma companies focus on outcomes.

For example, when a new entrant launched a product challenging a big specialty pharma company, the strong relationship and trust the pharma organization had built with prescribers over many years allowed it to engage in a frank dialogue with them about the competition. By using scientific data, the pharma company's medical affairs team was able to cut through the marketing noise and profile its product fairly versus the new entrant.

Strategic input for R&D, portfolio management

By leveraging deep relationships with prescribers and KOLs and continually collecting feedback and signals from the market, medical value teams can provide critical input to drug development and life cycle management from early identification of promising compounds through post-launch market strategies.

When leading companies initiate a new drug program, their medical value teams provide market-based input on unmet medical needs and clinical requirements, informing the development strategy and evaluation of the clinical and economic potential of a program. During clinical development, they contribute early stakeholder feedback, providing first-hand input on product positioning and the scientific platform.

As companies prepare to launch a new drug, medical value teams develop a strategy for market education. Finally, once the product is on the market, they design and implement data-generation strategies, integrating classical Phase IV studies with real-world evidence and big data analytics.

To do all those things effectively, medical value teams need to be an integral part of cross-functional product development and product management teams. By working with all pharma functions along the value chain, they help to increase a company's understanding of unmet medical needs, attractiveness of treatment pathways, value of clinical trial protocol options, speed of regulatory approvals and launch success rates.

> Equipped with deep product knowledge and disease understanding, medical affairs teams can become a strategic ace in an era of big data

Advancing big data and real-world evidence

A third important role for medical value teams is creating scientific evidence to support drug development, including real-world evidence, in-house data and scientific analysis. A medical value team can help companies cope not only with the sharp increase in demand for independent data but also the steady rise in drug protocols and guidelines and greater transparency requirements. Leading companies deploy medical value teams to integrate new types of evidence and steer collaborations with data providers and big analytics companies.

Digital technologies, in particular, offer pharma companies innovative new ways to engage with customers and collect real-world data at lower cost. For instance, GlaxoSmithKline partnered with Apple in June 2016, using Apple's ResearchKit app framework to monitor patient progress in a large rheumatoid arthritis trial. The app gathers data on joint pain and fatigue using a mix of surveys and sensor-enabled tests. It's an early milestone in the medical data revolution, but underscores the capabilities that medical value teams will need in the future.

Shire is also leveraging digital medicine and data to improve patient outcomes. Its myPKFiT software uses data analytics to reduce the number of blood samples needed in calculating prophylactic medication dosages for hemophilia patients. The tool uses existing clinical data to predict patients' pharmacokinetics (PK) curves based on two blood samples instead of 11.

Biotech companies such as Celgene have led the way by infusing science and medical knowledge in their go-to-market models and creating a pivotal role for medical value teams. By performing multiple trials and giving physicians early access to drugs still under development, these companies spread knowledge about new compounds while gaining valuable expert input. Pharma companies can build on that experience by developing scientific evidence and reaching out to the entire spectrum of stakeholders to demonstrate the value of new compounds. That, in turn, will help shift their focus from products to outcomes. PE

Removing Uncertainty from the Drug Insurance Conversation

To gain better alignment of coverage and risk, evidence-based arguments are critical during the underwriting process

In the 1950s, a drug called thalidomide came to market in West Germany. It was promoted as a sedative that alleviated insomnia, anxiety and tension, and was later used to combat morning sickness in pregnant women. But the drug had devastating side effects on newborns. Over the next several years, more than 10,000 infants were born with disfigured limbs, spinal cord defects and other disabilities, and many died shortly after birth. The drug, which was available in more than 46 countries under various brand names, was banned worldwide in 1961.

The pharmaceutical industry knows this story well. It was a hallmark case for the FDA, which resisted approving thalidomide in the US due to insufficient evidence of its safety. The department was hailed for its level of scrutiny, and a new era of stringent, but necessary, approvals was upon us.

But the story of thalidomide isn't over. In the 1990s, researchers began evaluating thalidomide as a treatment for patients with cancer. It has since been approved by the FDA for treatment of multiple myeloma and skin complications caused by leprosy. Ongoing research continues to explore the drug's effectiveness in treating inflammatory skin diseases and other cancers. Thalidomide is perhaps the best example of a comeback drug, once rejected by the global medical community but later re-introduced as an effective treatment.

Successfully bringing a product back to market or exploring new applications for drugs once considered harmful can be challenging and costly, with skepticism from regulators, physicians and patients at every stage of the process. And as pharmaceutical companies make their cases to various parties along the supply and approval chain, many fail to consider the important and often costly implications on their insurance policies.

The price of a comeback drug

There are many products and ingredients that insurers either commonly exclude from policies or price high—sometimes at a crippling rate. This primarily applies to drugs that are easily abused, or like in the case of thalidomide, have proven problematic in the past.

One timely example is the narcotic fentanyl, which is widely considered high risk for addiction and overdose. The growing issue of opioid addiction has motivated many pharmaceutical companies to explore alternative delivery systems for fentanyl, with the goal of finding an effective but non-addictive treatment approach. Yet most insurance policies include outright coverage exclusions for the use of fentanyl—or, if companies require coverage, insurers can charge them a fortune in product liability insurance.

This becomes a critical issue when pharmaceutical companies don't factor increased insurance costs into the budget to bring a new product like this to market. By the time the price increases are accounted for, the new product's pricing may be materially, and unexpectedly, different from the rest of their portfolio. Firms need to ensure their due diligence process includes conversations with their insurance broker, to determine if and how they can secure coverage without compromising profitability of their product.

The most effective approach is to eliminate uncertainty from the underwriting process. Insurance companies will either exclude or price for uncertainty, often relying on a traditional understanding of a product and its associated risks. In the case of historically harmful products or ingredients, pharmaceutical companies need to take steps to reduce or eliminate the uncertainty of what the insurance company believes is a loss waiting to happen.

Building a compelling case

For insurance companies to accurately price the risk for a particular product or ingredient, they must fully understand how it is being used and delivered. It's up to the pharmaceutical com-

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pany to demonstrate this, and to curtail the concern for patient injury by qualifying the safety of the product.

This is done most effectively by gathering all key stakeholders during the underwriting process. Most often, a meeting is facilitated by the pharmaceutical organization's insurance broker. The drug company's scientists, risk managers, chief medical officer, head of regulatory and chief financial officer, among others, will come together with the insurance company to spell out exactly what will be insured, how it works, and how it's different from what the insurers think they know about the medical product.

In this meeting, the pharmaceutical company's scientists and researchers will walk through the chemical structure of the product and review clinical trial data, if available. The chief medical officer will field questions on its efficacy and safety. The risk manager will evaluate vulnerabilities and the evolution of this particular drug in the marketplace.

For drug companies with a deep bench of experts, this is the time to make evidence-based arguments to affirm the safety of the product and its feasibility in the market.

The insurance company's underwriting team will then review the drug manufacturer's evidence and potentially bring in a medical advisor or outside consultant to further evaluate it. If an update to the firm's policy is warranted, underwriters will determine pricing and work with the broker to modify the policy accordingly. Most often, these changes will appear in a pharmaceutical company's product liability policy under bodily injury and property damage. Importantly, these updates should also be made to the advertising injury and personal injury sections of a company's general liability policy. Too often, pharmaceutical companies don't realize that exclusions are mirrored across policies, and fail to ensure they have coverage in all of these areas.

Insurance companies will either exclude or price for uncertainty, often relying on a traditional understanding of a product and its associated risks. In the case of historically harmful products or ingredients, pharma needs to take steps to reduce or eliminate the uncertainty of what the insurance company believes is a loss waiting to happen

The evidence or else

When adding a previously—or potentially—harmful drug or ingredient to their portfolio, pharmaceutical companies need to do everything in their power to prove the safety and efficacy to their insurers. By removing uncertainty from the conversation, companies can secure coverage and pricing that accurately match the risk of the product they're bringing to market. PE

Surfacing Clues for the Undiagnosed Patient

How life sciences companies can seize on the untapped potential of the undiagnosed patient market

Imagine you were given the choice of fishing in two ponds. The first pond is filled with other anglers, all competing to try to land the same fish. The other pond, which potentially has even more fish than the first, has no one on it. Which do you think would give you the best chance of coming home with enough fish for a banquet?

This is the opportunity today in front of a broad group of life sciences and pharma commercial personnel, including marketing directors, brand managers, market research directors, sales directors, and managed market strategists. There is a tremendous, untapped market of undiagnosed patients for a variety of conditions. These are individuals who either have the condition but have not had it detected (often patients who are overdue for a physical exam or laboratory work), or those who do not have the condition yet but are trending toward it.

Informing physicians and healthcare providers regarding these undiagnosed patients may fortify their practices, both in enhanced patient care and financial growth. Yet, how do you identify them when they are essentially hidden from view through conventional means?

JOHN PAGLIUCA is Vice President, Life Sciences, at SCIO Health Analytics

Behavioral analytics discover the potential

This is where next-generation behavioral analytics can be a real difference-maker. Like a fish finder providing a picture of what's below the surface to fishermen, behavioral analytics—along with socioeconomic and attitudinal data—help uncover a multitude of opportunities for life sciences organizations that don't show up in clinical or claims data alone.

Your commercial teams are now able to make these discoveries by looking at a much broader expanse of data, including socioeconomic and demographic indicators, such as income, education, spending patterns, ethnicity, home values in a given area, age, gender, health services utilization (primary care versus more expensive emergency department visits), coupled with medical and pharmacy claims data.

Leveraging predictive and prescriptive analytics methodologies, these data are then crunched and used to develop "patient personas" that represent new and unique patient segments and their propensity toward certain conditions. Armed with this information, sales and marketing teams can approach their targeted physicians or, at an integrated delivery network (IDN) level, share these persona types along with their total cost of care and inform them on what types of patients may need to be educated or provided therapeutic care.

Behavioral analytics can benefit life sciences and pharma organizations, physicians, and patients. For example, the analytics can show that patients in a particular neighborhood tend to be older, have lower income, work on an hourly rather than salaried basis, and possess a 10th-grade-or-less education. There are a lot of fast food restaurants in that area and very few grocery stores selling fresh food, so the patients' diets tend to be high in sugars and saturated fats.

Patients of this type tend to use the emergency department as their primary healthcare facility, either because they don't have an established relationship with a primary care doctor or can't afford to take time away from work to see a physician for preventive care.

With that persona in hand, pharma company representatives can compare it to demographic information about patients in the area a physician or hospital serves, to demonstrate which conditions are likely to be prevalent among its population. (In the example above, there is a high risk of diabetes and heart disease.) The provider can then use this information to stratify the population and begin targeting patients to be checked for those conditions.

In the meantime, pharma company sales and marketing teams have the opportunity to demonstrate why their organization's treatment will deliver

the best results for that population based on evidence in the real world—without having to worry about competing directly with other companies' commercial teams for the business. Additionally, the team will be building a higher-value relationship with providers by identifying opportunities no one else is bringing to them.

Getting out ahead

These same behavioral analytics can be applied to identify patients who may not be classified as having a condition such as diabetes or heart disease yet, but are trending (or likely to trend) in that direction. Once again, by comparing the personas to patient information, pharma companies' commercial teams can identify a sub-segment of the population that is at higher risk of acquiring these conditions once certain triggers are met.

Age is one trigger. The data may show that once a patient who meets certain other criteria crosses over from the 18-35 to the 36-50 age range, the risk of developing certain conditions increases by "x" percent. An increase in emergency department utilization could be another, as the issues being treated may be indicators of a deeper underlying problem that is developing.

Identifying these issues early give physicians the opportunity to address them before they become more serious (and costly), both with patient education and pharmaceuticals. It also creates a new market opportunity for life sciences companies to sell products that help prevent those conditions from developing, such as a weight control drug to reverse a trend toward obesity, hypertension, diabetes, or other conditions.

Leveraging predictive and prescriptive analytics methodologies, data is used to develop "patient personas" that represent new and unique patient segments and their propensity toward certain conditions

Cast a wider net

As massive as the life sciences industry is already, there is still tremendous untapped potential in the form of all the undiagnosed patients who also need solutions. Rather than fighting for space on an already crowded pond, the better decision is to find a new pond where you can cast a net rather than a pole and expand your market exponentially, with little competition—or margin pressure. All while building better relationships with your provider customers by helping them deliver better care. PE

Reflections from DIA

Three messages that resonated from this year's annual meeting of the Drug Information Association

Every June, the Drug Information Association (DIA) brings together global thought leaders and innovators from industry, academia, regulatory and government agencies, health, patient, and philanthropic organizations to discuss the compelling healthcare and R&D issues of the day. Ahead, members of *Pharm Exec*'s editorial team who were on hand for last month's 53rd annual gathering in Chicago, share their biggest takeaway messages from the event.

Reality show

Lisa Henderson, Editor-in-Chief

Real-world evidence. That's my three-word takeaway from the DIA conference. Whether it was in the learning sessions or in the exhibit hall, gaining the insights needed for making decisions after a drug is developed or informing a new entity in clinical trials, was top of mind. Real-world evidence spans the use of long-term observational registries, analytics, and insights into current claims or EHR data, as well as the basis for current and future value-based contracts between health plans and manufacturers.

Sessions spanned standardizing outcomes for patient registries to breaking down the wall for global regulators to leverage real-world data to value-based conversations with payers. Innovators in real-world evidence from the exhibit floor included IBM Watson Health, Evidera, and QuintilesIMS. Poster sessions included Developing Research Networks with Health Networks for Real-World Evidence Generation, presented by Nancy A. Dreyer, PhD, global chief of scientific affairs, head, Center for Advanced Evidence Generation, QuintilesIMS Real World Insights. Dreyer was also named to the DIA Fellows Class of 2017 for her long history in shaping real-world evidence in the pharmaceutical industry.

Judgement call

Mike Christel, Managing Editor

One message that hit home with me was debunking, in a way, the notion that the FDA is never flexible in its evaluation of new drugs—and from a rare disease context, and the controversial approval late last year of Duchenne muscular dystrophy (DMD) drug Exondys 51, the damned if you do, damned if you don't sentiment that FDA must feel at times. Learning more about the background of the Exondys 51 approval made me rethink the popular narrative. Yes, the drug can potentially help only 13% of DMD patients (those with a gene mutation amenable to exon 51 skipping), but, as we found out, during testing, it slowed the progression of the disease noticeably for some of the young men afflicted, giving them at least a chance at a few more years of quality of life. Putting aside pricing issues that have arisen since, what's really wrong with that? As one speaker noted, it's okay for the FDA to be flexible as long as the science is good. And "flexibility equals clinical judgement."

Not speaking to Exondys 51 directly, Sudip Parikh, senior vice president and managing director of DIA Americas, told me of the FDA: "They don't want to be a bottleneck, they want to be a well-oiled machine that does the right regulatory work, protects the patient, but is not selling it down anymore than necessary."

Action, please

Michelle Maskaly, Senior Editor

The future is now. The days of talking about patient centricity, advanced technologies, cutting-edge drugs, artificial intelligence, and other initiatives in terms of just ideas, are over. These buzzwords have now become a reality. "Yesterday's conversation is today's science," Debra Lappin, head, health bioscience practice at FaegreBD Consulting, said at the meeting. During a *Pharm Exec* video interview with Barbara Lopez Kunz, global chief executive of DIA, she agreed with the sentiment, while touting all of the advances going on in the industry and the commitment to bring technology not just into the labs, but everywhere—including to the patient.

Conversations centered around the various ways companies were including patients in everything from clinical trials to postmarketing opportunities, including independent social networking sites dedicated to creating a community for those with chronic diseases.

Another common theme of the conference was the four-way intersection of healthcare, pricing, politics, and policy—and the uncertainty around it all. While advanced science and technology is leading the way for all these new therapies to become available, it is also bringing up a lot of questions about how they will be priced, what will be covered, and who will be paying for them. PE

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