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Business Model Challenges

Life-sciences companies will need to employ new business models to understand the data now available from multiple sources.

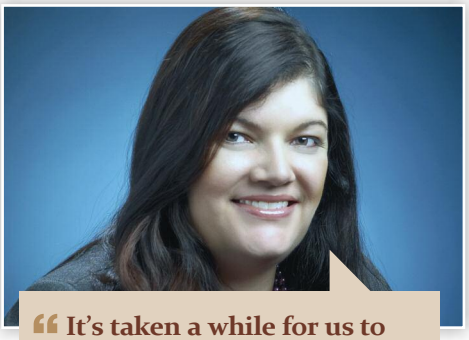
In the pharmaceutical industry, data are generated from several sources, including the R&D process itself, retailers, patients, and caregivers. Effectively using these data will help pharmaceutical companies better identify new potential drug candidates and develop them into effective, approved, and reimbursed medicines more quickly.

The McKinsey Global Institute estimates that applying big-data strategies to better inform decision making could generate up to $100 billion in value annually across the U.S. healthcare system by optimizing innovation, improving the efficiency of research and clinical trials, and building new tools for physicians, consumers, insurers, and regulators to meet the promise of more individualized approaches.

"As we move toward value-driven healthcare, every company has to rethink the value it can offer patients and how it measures that value," says Chris Clark, director, at UCB. "We are moving beyond market share as the core metric and seeking to understand the impact we have on the quality of life for the patient as a whole. The intent is to align our view of success with the view of patients and providers. This will require a fundamental shift in the way we are structured as an industry and as companies, including breaking down functional silos so that we are not looking at pieces of business but at customers at our center."

The overarching healthcare market theme is one of interoperability: connecting stakeholders and information sources in novel ways to drive efficiency, effectiveness, and equity in the system, says John Doyle, senior VP and managing director, Consulting Value and Outcomes Center of Excellence, at Quintiles.

"Health reform continues to accelerate this transformation and catalyze connectivity between the various players by encouraging health information technology investment, forging quality-based payment models, and rewarding care coordination," he says. "These structural system changes are precipitating increased data sharing on the cost and quality of care. From a life-sciences company perspective, the window of opportunity is open to companies that adopt a new mindset and help drive a new consumer-oriented paradigm in healthcare."



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>
> **OLIVIA MONTAÑO** / SynteractHCR

> "The true innovators know data must provide actionable insights, and decision support tools that will actually move their market."
>
> **BRETT HUSELTON** / United BioSource Corp.

A Year of Transition

Paul Shawah, VP, product marketing at Veeva Systems, says in this age of endless change, the best way the life-sciences industry can adapt its business strategies is by continuing the journey toward a more complete understanding of its customers.

"Pharma companies must evolve from pure drug producers and marketers to integral, active participants in the overall healthcare ecosystem, which encompasses many more participants than ever before," he says. "Today, the 'customer' includes numerous stakeholders from physicians and nurse practitioners to payers, hospital networks, administrators, and patients. Large independent delivery networks are quickly replacing one- and two-person practices. Adding to the complexity, location plays a major role, with variance in stakeholders and influence from one market to another."

Mr. Shawah says industry leaders will succeed by sticking steadfast to the journey toward discerning who the customer is, including all of its colors and, from that understanding, building a powerful customer engagement model.

"Technology has finally matured to the point that organizations will not only be able to capture critical customer data across every interaction, but also make it more actionable with real-time information," he says.

Tara Grabowsky, M.D., chief medical officer at Vencore, says over the next 10 years, data, analytics, and software will have a significant effect on the practice of medicine in many areas.

"Looking ahead to 2015, I believe we'll see significant progress in how analytics and data are leveraged to affect treatment of rare diseases," she says. "Rare diseases present a diag-

nostic challenge for doctors. There are more than 7,000 rare diseases, but because so few people have each one, most doctors have never seen a case. Using analytics developed in the defense community and applying them to the world of healthcare, researchers have begun to address the rare disease puzzle."

Matthew Howes, senior VP, head of strategic services, Palio+Ignite, an inVentiv Health company, conducted a survey of physicians in January 2014. More than 95% of HCPs who responded indicated that they are interested in digital innovations and interventions for their patients, but fewer than 8% report using them today.

"The challenge with the explosion in consumer healthcare applications is that they have not been built to any industry standard, and most importantly, they have not been integrated with EHRs, until now," Mr. Howes says. "When Apple unveiled its HealthKit cloud API for integrating data from multiple apps and monitoring devices, EHRs entered the realm of consumer health, creating the opportunity to provide physicians with the useful and usable digital patient innovations they've been waiting for."

Apple's HealthKit, a health and fitness app, was included in the June release of iOS 8. The app offers a broader range of functionality than most health and fitness trackers and is designed to aggregate health information from a range of sources including other iOS apps, wearables, and smart medical devices such as Bluetooth-equipped blood pressure cuffs and glucose monitors.

For companies to succeed in this new era, a deeper trust in data science and predictive analytics will be required, says Patrick Homer, principal industry consultant, global practice, health and life sciences, SAS.

"Data and analytics, used effectively, will raise productivity, improve decision making, and help gain a competitive advantage," he says. "But getting started is complicated. Organizations need to strategize the way forward then develop a case for these investments. Deciding which data to use, acquiring new analytic capabilities, and how to use the insights to transform operations while tackling the challenge of securing commitment and drive a business process and organizational change agenda are paramount to success."

Geno Germano, group president, global innovative pharma business, at Pfizer, says the biggest opportunities in the technology space will be for companies that can make a meaningful difference in the way that they monitor patients early on or even people before they are diagnosed.

"Being able to look back and understand everything that led up to an acute event or chronic diagnosis will help us build predictive models that can be applied to prevent other patients from following the same course," he says. "Just think of the possibilities in conditions such as Alzheimer's disease where we still have so much to learn. Companies that can do that will offer tremendous value to patients."

Unfortunately, clinical development, and healthcare for that matter, has not kept up with the fast-paced and evolving technology space, says Kent Thoelke, executive VP, scientific and medical affairs, at PRA Health Sciences.

"Equally challenging is that many of the technologies, especially in the EDC and EMR space, are not harmonized making for a patchwork of patient-level and study-level data that are challenging to link across platforms either for simple data collection or for more complicated analysis," he says. "The drug development industry needs to quickly adapt what has become an inefficient, historically paper-based model into a streamlined development process that harnesses the power of big data to speed up the time to market for new drugs, while maximizing efficiency and lowering overall costs."

Martin Marciniak, VP of U.S. health outcomes and medical policy at GlaxoSmithKline, says fully integrated EHRs have the potential to enhance quality and improve patient outcomes by making America's healthcare systems more interconnected.

"The ability to capture and display medication fill history can drive focused discussions between providers, pharmacists, and patients," he says. "As this information becomes readily available for healthcare providers, it can facilitate meaningful, comprehensive medication management that takes a holistic view of patient care by enabling review of patients' prescription and nonprescription medicines."

Mr. Marciniak says EHRs will also improve the understanding of disease management patterns and how improvements can be made.

"The inclusion of analytic and predictive capabilities could be incorporated into the EHR to enable healthcare professionals to assess a patient's medication profile, identify potential drug therapy problems, and guide tailored patient interventions," he says. "Increased access to data is helping to modernize clinical trials, as seen in the Salford Lung Study in the UK. This GSK project uses EHRs and cutting-edge research designs and analytics to better understand how a new respiratory medicine works in the real world."

This UK project is studying the safety and effectiveness of a GSK late-stage investigational respiratory medicine alongside currently available treatments. Results of the study will complement GSK's clinical trial program assessing the medicine's safety, efficacy, and quality.

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>
> **GENO GERMANO** / Pfizer

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>
> **DR. TARA GRABOWSKY** / Vencore

Crucial Business Objectives

The primary focus of the crucial business objectives in 2015 will be to deliver shareholder value given the challenges of low growth business environment, low R&D productivity, and increased business risks — scientific, legal/regulatory, political — and erosion of trust in the industry, says Chitra Lele, Ph.D., chief scientific officer at Sciformix.

"The year 2015 presents an overarching opportunity for the industry to review and revise its operating and governance standards, and redefine its image in the minds of all stakeholders," she says. "This will require a shift in the way the industry operates and in the way it communicates the value of its products and services. It will require the industry to adopt more stringent governance standards and increase information transparency. Good progress has been made in 2014 with some companies opening up their clinical development data, however, more will need to be

Big Data Prescription for Pharmaceutical R&D

- **Integrate all data.** Effective end-to-end data integration establishes an authoritative source for all pieces of information and accurately links disparate data regardless of the source — be it internal or external, proprietary or publicly available.
- **Collaborate internally and externally.** By breaking the silos that separate internal functions and enhancing collaboration with external partners, pharmaceutical companies can extend their knowledge and data networks.
- **Employ IT-enabled portfolio-decision support.** To ensure the appropriate allocation of scarce R&D funds, it is critical to enable expedited decision making for portfolio and pipeline progression. Pharmaceutical companies often find it challenging to make appropriate decisions about which assets to pursue or, sometimes more important, which assets to kill.
- **Leverage new discovery technologies.** Pharmaceutical R&D must continue to use cutting-edge tools. These include sophisticated modeling techniques such as systems biology and high-throughput data-production technologies, that is, technologies that produce a lot of data quickly.
- **Deploy sensors and devices.** Pharmaceutical companies can deploy smart devices to gather large quantities of real-world data not previously available to scientists. Remote monitoring of patients through sensors and devices represents an immense opportunity.
- **Raise clinical-trial efficiency.** A combination of new, smarter devices and fluid data exchange will enable improvements in clinical-trial design and outcomes as well as greater efficiency. Clinical trials will become increasingly adaptable to react to drug-safety signals seen only in small but identifiable subpopulations of patients.
- **Improve safety and risk management.** Safety monitoring is moving beyond traditional approaches to sophisticated methods that identify possible safety signals arising from rare adverse events. Furthermore, signals could be detected from a range of sources, for example, patient inquiries on websites and search engines.
- **Sharpen focus on real-world evidence.** Real-world outcomes are becoming more important to pharmaceutical companies as payers increasingly impose value-based pricing.

Source: McKinsey

done in 2015. Companies that embrace open communication and timely disclosure of risks will be more likely to succeed in the long run."

Mr. Shawah says in 2015, more pharma companies will be focused on transitioning, or accelerating their transition, from pure drug manufacturers to healthcare providers.

"In fact, the entire healthcare landscape is looking to our industry for support in this area, as overburdened physicians struggle to provide the level of service to patients that they would like," he says. "Seven out of 10 physicians say pharma companies should provide more patient resources and services alongside drugs to stay relevant in the emerging healthcare system, according to a new Manhattan Research survey. Lundbeck Pharma is one customer of ours that has made patient services a large part of its commercial approach."

Olivia Montaño, senior director, clinical data management at SynteractHCR, says professionals in the biopharma industry need to be open-minded.

"We need to think outside of the box and be open to new ideas," she says. "It's taken a while for us to get to the point of accepting and embracing centralized medical records and other areas of technology such as electronic data capture. It's unfortunate that innovation is often met with resistance."

Ms. Montaño says in the clinical research field, there is sometimes a lack of education on the sponsors' end, which can lead them to make decisions that cost them more money.

"Producing quality services doesn't necessarily mean you need to work harder, but you need to dedicate yourself to education and have some trustworthy subject matter experts on your side."

Information management has been a core focus for companies over the past 24 months, and this will continue, says Brett Huselton, VP, commercial strategy and opportunity development, United BioSource Corp.

"While companies have been hearing the construct around big data for some time, the true innovators know data must provide actionable insights and decision support tools

> "The window of opportunity is open to help shape the market for those companies willing to adopt a new mindset."
>
> **DR. JOHN DOYLE** / Quintiles

that will actually move their market," he says. "The complex part of big data centers around a fundamental understanding of key relational aspects between the data elements that power a brand. Unlocking these data relationships and communicating how they tie to a product, service, buyer, organizational dynamics or competitive position, provide a powerful basis for making informed decisions that outpace the competition."

Technologies now exist to greatly amplify the ability to listen to the voices of patients, along with those of their caregivers and healthcare providers, says Stuart Sowder, Pharm.D., VP external medical communications, at Pfizer.

"We must have both the will and the flexibility to harness these technologies and capitalize on a much more connected world," he says. "2015 can be an important year for our industry in integrating patient, caregiver, and provider voices into all the goals we set and strategies we pursue. We have to 'build in' the patient's voice throughout the entire sequence, from discovery to distribution, just as best-in-class manufacturers build in quality rather than just fix defective products when they come off the assembly line. Doing so will require a level of collaboration that is not typically seen in our industry."

Mr. Germano says Pfizer's main objectives include using big data to better inform drug development decisions and to ensure the safe and effective use of our medicines.

"We believe the biggest opportunities exist in helping to better understand disease progression," he says. "In the near-term, this will help with better and earlier diagnosis and treatment. Mid-term, this will help companies to better and more quickly identify medicines that will be safe and effective, thereby offering patients more personalized options. And in the long run, as diagnosis and treatment move earlier and earlier, we will see a shift toward more

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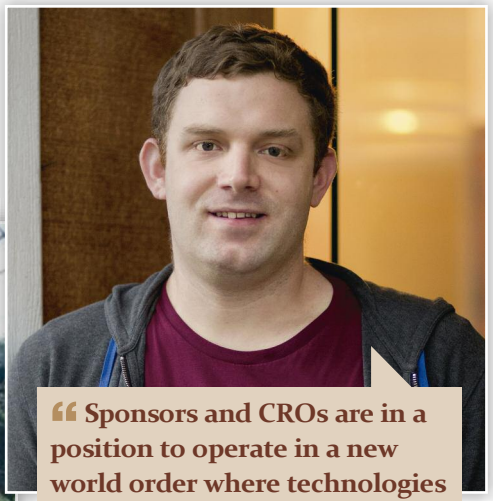
> "Innovative companies are taking the integration of big data one step further by shifting their focus away from competition on information toward data sharing for the purpose of driving efficiencies for researchers."
>
> **ELISA CASCADE** / DrugDev



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>
> **RICK MORRISON** / Comprehend

preventive and continuous care versus today's paradigm of acute and episodic care."

Key Strategies for Pharma

Paula Brown Stafford, president, clinical development at Quintiles, says advances in science, analytics, and therapeutic knowledge offer the promise of better treatments, and the healthcare industry has tremendous opportunity to conquer the global burden of disease.

Dr. Lele says companies will focus on products that will meet the needs of emerging a markets from where the majority of the revenue growth is expected.

"It will be important to find ways of delivering new medicines at much lower prices," she says. "This will have to drive a change in the way clinical development is done — increase efficiency of clinical development programs through an integrated data driven approach, open data models and information sharing, smarter designs, and more outsourcing to the right service providers."

She says companies have to invest in marketing and sales infrastructure for the future, focusing on integration with social media and mobility, especially because the penetration of social media is extremely high in the emerging markets.

"They will also need to find ways to optimize the application and integration of recent advances in technology, such as cloud computing," she says.

IMS Institute for Healthcare Informatics finds the shift toward cloud-based storage, including embedded analytics, is gathering momentum and provides options for individual participants in the healthcare sector that are able to outsource with confidence to third parties. In fact, efforts by Google, Apple, and Samsung to bring mobile technologies to healthcare are a harbinger of change.

Advancing the R&D Paradigm

Mr. Thoelke says the ability to leverage multiple technologies across disparate data platforms in ways that makes data useful for clinical drug development is crucial.

"Drug development costs continue to escalate as a result of the challenges to get patients into clinical trials," he says. "As an industry, we must focus on leveraging the wealth of new technologies, taking advantage of the best-in-class solutions regardless of which industry domain they currently exist and apply these to clinical development. We must take a holistic approach to understanding data and how best to leverage data to not only identify patients for clinical trials but how to best translate those patients into clinical trial subjects and to most efficiently collect and analyze that data."

Ms. Stafford says to manage the influx of data in today's clinical research landscape, as well as increase the quality and speed of clinical research, biopharmaceutical companies must consider implementing standards around data transparency and master data management.

"For instance, data standards proposed by CDISC offer numerous operational benefits, including speeding clinical trial processes from start-up to submission, informing decisions that increase patient safety, and enable emerging technologies like electronic medical records," she says. "By improving the quality of data collection and accessibility of data through data standards, companies can also accelerate patient recruitment by finding the right sites with access to the right patients. This is crucial given the increasingly complex inclusion/exclusion criteria of more targeted therapies."

The technology overlay currently under way across the industry will continue to expand rapidly to encompass all the vital data points that drive measurable clinical trial outcomes, says M. Clareece West, chief operating officer, at MedNet Solutions.

"This expanding automation, made possible by growing eClinical platform capabilities, allows greater data visibility and real-time insights across each trial, allowing companies to measure results sooner, resulting in significant cost savings," she says. "The industry's continued adoption of technology allows trial sponsors to quickly access all vital information needed to make informed decisions, proactively gauge potential resource requirements in advance, and easily monitor study progress either at a micro or macro level."

Elisa Cascade, president, hosted data solutions, DrugDev, says pharmaceutical companies and CROs have access to a variety of data sources in support of clinical trial operations, but these data are often spread across multiple internal and external systems.

"Because the time and complexity required to integrate across these data sources is significant, companies often make sub-optimal decisions related to study planning, feasibility, and site selection," she says. "A best practice is to visualize multiple sources of investigator, site, and protocol data through one single global technology platform. Innovative companies are taking this integration of big data one step further by shifting their focus away from competition on information toward data sharing for the purpose of driving efficiencies for re-

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>
> **PAUL SHAWAH** / Veeva Systems

> "The excitement of integrating evolving eClinical technology solutions has created a flood of new companies working to be one of the first to help the industry further increase efficiencies."
>
> **M. CLAREECE WEST** / MedNet Solutions

searchers as well as decreasing burden for investigators."

Glen de Vries, president, Medidata Solutions, says with organizations such as TransCelerate and Project Data Share paving the way, life-sciences companies are focused on making their data assets even more valuable by looking at them across multiple studies.

"The need to improve patient care and management of clinical trial sites has resulted in recent introductions of better, more efficient ways to share data among R&D teams, CRO partners, and vendors," he says. "However, having access to more data doesn't necessarily make the data more useful. To ensure success, life-sciences companies need an overall predictive analytics strategy."

Ms. West says a big challenge is bringing together all the data captured and stored in independent systems into a single view.

"But these challenges will continue to be addressed and resolved due to the tremendous savings in time and money that a consolidated data view can provide, as well as the huge benefits that result from measuring study results along the way vs. at the end of the trial," she says.

Mr. Clark says interoperability has been a challenge for the industry for a long time.

"Big data and its potential to transform healthcare has been overwhelmed by its own hype and now as an industry we are moving beyond that hype to the hard work of figuring out exactly which data are valuable and how to translate it into meaningful information for clinicians and patients," he says.

Information is an asset, Mr. Huselton says.

"Transacting on these new assets requires organizational-wide alignment and commitment," he says. "If we do not dedicate and align resources to enhance, refine, and embed these information assets into sales, operations, and other key functional areas, the body of decision support tools will fall hopelessly behind other competitors."

The sheer volume of information makes the case for greater collaboration, Dr. Sowder says.

"No single actor in the healthcare ecosystem can hope to master the terabytes of information flowing in from numerous sources, including the real world," he says. "Recognizing this, we at Pfizer have several collaborations with healthcare organizations such as Humana to gain insights from many streams of real-world information and comparative effectiveness studies, with the stated needs of patients in mind."

Pfizer's five-year research partnership with Humana, which began in 2011, brings together researchers and healthcare experts to study key issues and deliver interventions to reduce inefficiencies in the management of chronic conditions such as pain, cardiovascular disease, and Alzheimer's disease.

Comprehend CEO Rick Morrison says technology is going to continue to make measurable improvements in clinical development — from speeding study start-up, to streamlining transmission of clinical trial data, and to overhauling how studies are monitored.

"Sponsors and CROs are heading into a new world order where technologies will challenge the status quo, but also change drug and device development for the better," Mr. Morrison says. "The pressure is mounting and a full technological transformation will occur in the next five to 10 years. The changing technology landscape is in full effect, and the industry must be ready for change. In 2015, sponsors and CROs need to consider new eClinical strategies to remain competitive, with the understanding that what has always worked will not necessarily work in the future."

Niklas Morton, VP, global biostatistics, programming and medical writing, at PPD, says the opportunities ahead for using data science and software to do more for medicine are exciting, especially for improvements to engage patients with clinical development by making trial participation more convenient.

"For example, social media and data mining techniques that identify and engage patient populations with appropriate trials; mobile technologies that allow direct communication with patients on eligibility screening; virtual visits supported by direct audio/visual links; and an extensive and rapidly growing array of medical devices or wearable technologies that can collect data directly from patients in real time and pass this information to cloud-based data stores," he says.

Mr. Morton says statistical and scientific developments in clinical trial design are equally important.

"With adaptive designs that ensure trials are modified to what the accumulating data are telling us about the populations, endpoints, treatments or doses of interest, we are now in position to look forward to more easily engaging patients into clinical development and doing so with more appropriately targeted trials and therapies," he says.

Innovative adaptive trial design is changing the way drug developers design their protocols, says Phil Birch, D.Phil., VP, innovation strategy, alliance partnerships, ICON.

"The use of adaptive design is increasing significantly in exploratory development where dose selection, identification of appropriate patient subpopulations who respond to therapy, and use of appropriate endpoints all need to be rigorously tested and optimized before commitments are made to expensive confirmatory pivotal trials," he says.