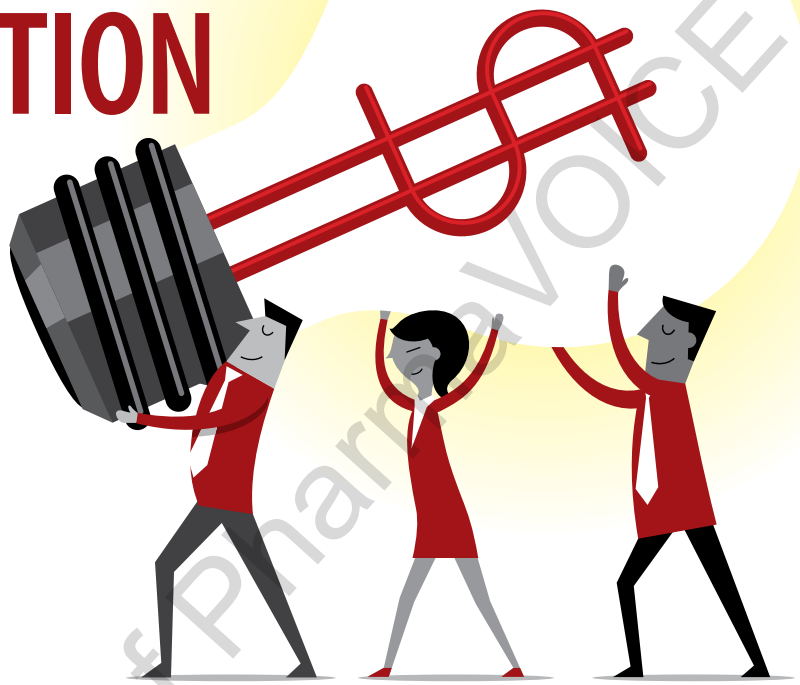
Taren Grom

A New Era of COLLABORATION



As the industry enters into a new era of collaboration that reaches across the entire ecosystem, companies are learning that traditional and nontraditional partnerships can drive efficiencies in the pursuit of innovation.

This month's special issue examines the new era of collaboration from R&D to commercialization and the role various players have in shaping the future of the life-sciences industry.

According to a recent KPMG report, the majority of the 400 U.S. chief executives surveyed say the next three years will be more critical for industries than the past 50. Analysts say as disruptive competitors, business models, and technologies threaten business as usual, CEOs have an unprecedented opportunity to reinvent their businesses and drive new growth.

Further, to navigate change and seize opportunities, KPMG analysts surmise that CEOs will foster innovation, step up customer focus, collaborate externally, and transform their businesses in numerous other ways. Despite the unknown obstacles and sharp turns on the road ahead, they are optimistic about where their journey will take them over the next three years.

PwC in its 2020 report notes that collaboration among various industry players is not new, but there are two key differences in today's ecosystem.

First, PwC says the technological and cultural pre-conditions to facilitate collaboration are now in place. In the mid-1990s, the Internet was still in its infancy and many of the tools that enable collaboration in the current ecosystem did not exist. Today, however, such tools are plentiful and the wider business culture has changed dramatically. IBM, Apple, Amazon, and similar companies have demonstrated the power of open platforms, transformed corporate attitudes toward networking, and shown that it is possible to reap much richer rewards by profiting together than by profiting alone.

Second, by 2020, PwC states collaboration will be a "do or die" requirement for pharmaceutical companies and healthcare payers alike.

PwC analysts say it will be essential for pharmaceutical companies to develop effective new medicines and address the demands of payers increasingly well equipped to measure what they are getting for their money; and it will be essential for payers to cope with rapidly escalating healthcare costs.

As various forces are changing the environment in which the pharma industry operates and the relative positions of the different players in the healthcare arena, PwC contends that these trends all point toward the need for much greater collaboration.

Value Creation

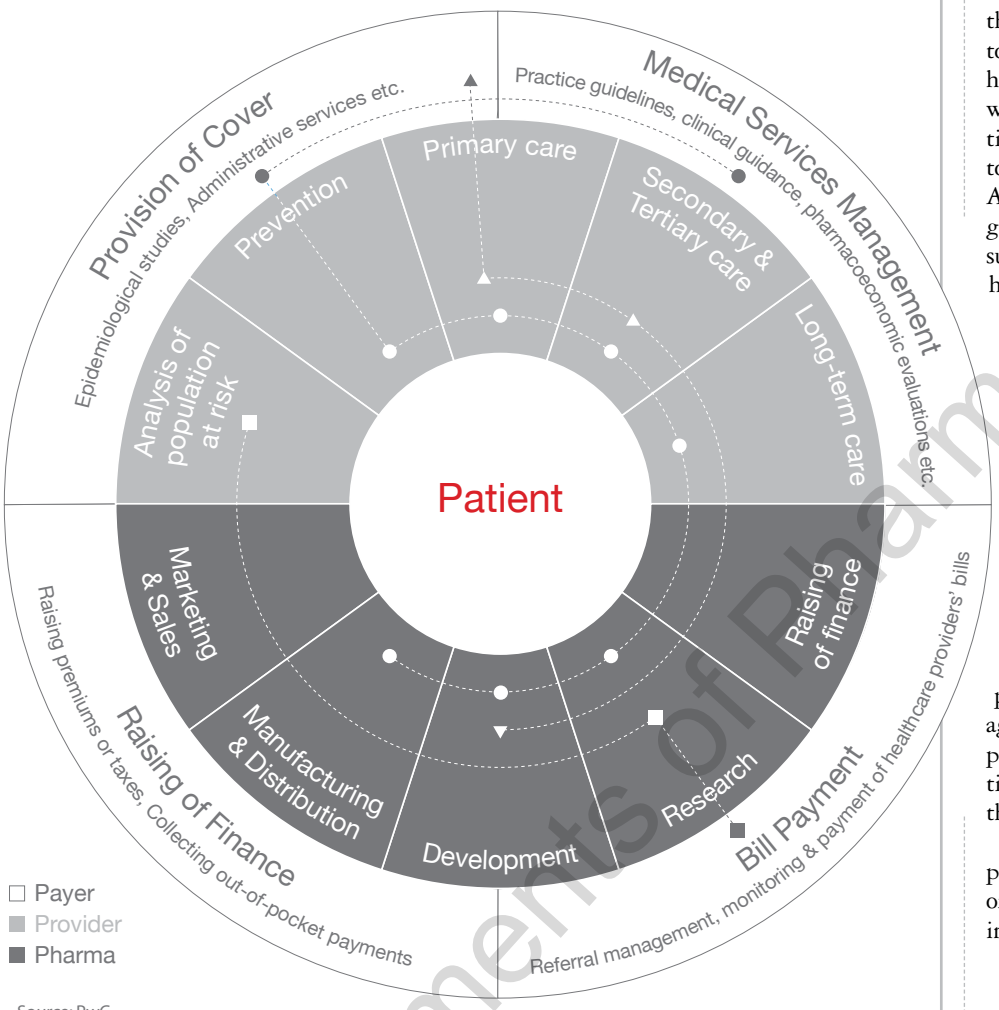
Value and outcomes continue to dominate the conversations around all things pharma — and rightfully so. Experts predict that these two factors will be heavily influenced by a confluence of different sectors intersecting toward increased efficiency and greater innovation.

PwC states pharma currently creates value by developing new medicines (and a relatively limited number of diagnostics). Collaborating much more closely with the key stakeholders in the healthcare sector will enable the industry both to expand its remit and to align its value chain more closely with those of healthcare payers and providers. As PwC analysts indicated in an earlier report, the value chains of the three parties are heavily interdependent. The value payers generate depends on the policies and practices of the providers they use. The value providers generate depends on the revenue payers raise and the medicines pharma companies make. And the value pharma generates depends on getting access to the patients whom providers serve and income from the payers who fund those providers. Yet the relationship between the different players is often quite antagonistic and, while they continue to clash, they are struggling to retain their respective goals.

If the pharma industry broadens its value proposition, it can begin to close the gap. Creating feedback loops to capture outcomes data will help it to establish a more dynamic relationship with healthcare payers and providers. So, too, will building the networks required to deliver healthcare packages that encompass a wide range of products and services from numerous different suppliers. This will ulti-

Intertwined Value Chains

BY 2020, THE PHARMACEUTICAL, PAYER AND PROVIDER VALUE CHAINS WILL BE MUCH MORE CLOSELY INTERTWINED



mately result in the convergence of the separate, linear value chains that exist today and the emergence of a single, circular value chain.

Industry-Driven Collaborations

As collaborations and partnerships between traditional and nontraditional players continue to move the needle, several nonprofit groups, including tranSMART, TransCelerate, and CoMMpass have been formed to provide open collaboration among various sectors.

The tranSMART Foundation, a nonprofit organization, provides a global, open-source, open-data knowledge management platform for scientists to share pre-competitive translational research data. In February 2017, the foundation released its tranSMART platform, version 16.2. This version includes significant contributions from numerous members of the tranSMART community and provides users with more advanced functionality to enhance their translational research studies.

The newly developed features in version 16.2 include the SmartR plugin (ITTM/University of Luxembourg/eTRIKS), genomics-based cohort selection (Janssen), GWAS enhancements (Pfizer), GWAS PLINK integration (Clarivate Analytics), XNAT image database integration (Imperial College London and Erasmus Medical Center), and ETL enhancements (Imperial College London/eTRIKS).

"As an open-source platform, tranSMART wouldn't be possible without the contributions of our community," says Keith Elliston, Ph.D., CEO of The tranSMART Foundation.

The expanding capabilities of the tranSMART platform provide the translational research community with an improved set of tools. For example, SmartR plugin offers the ability to tap into the richness of research to provide workflows for Boxplot, correlation, heat map line graph, and volcano plots. Others will be added in upcoming releases. In addition, there is a workflow that provides a link to the Qiagen Ingenuity Pathway Analysis. Another example is the Janssen contributed genomics cohort selection, HiDome, which supports the use of gene expression and other high dimensional data in the comparison and summary statistics tabs to build cohorts.

Each of these contributions has followed tranSMART's contributor process and guidelines, producing a product that has been subjected to automated testing all along the process. The 16.2 release exemplifies the Foundation's ability to bring new innovations to the platform from a variety of community contributors, while maintaining the quality and reliability of the platform through its release process.

The tranSMART Foundation enables scientists at universities, disease foundations, pharmaceutical companies, and government agencies around the world to share pre-competitive data in a way that saves money and time in translating research findings into new therapies and diagnostic tools.

For TransCelerate biopharma, 2016 was a pivotal year, say its officials, as the nonprofit organization demonstrated a clear evolution in the way the biopharma industry aims to streamline efficiencies through the sharing of data, and harmonizing on critical challenges.

According to TransCelerate, its core initiatives reflect long-felt procedural pain points, and over the last year it has seen measurable progress in its mission to help drive the efficient, effective, and high-quality delivery of new medicines for patients.

In addition, TransCelerate committed substantial effort in 2016 building true foundations for its patient-facing initiatives, invigorating the organization's focus on the patient experience during clinical trials.

"In just four years, TransCelerate has demonstrated what we're capable of, if we work together," says TransCelerate CEO Dalvir Gill, Ph.D. "We serve as a platform for multi-stakeholder collaboration, while bringing together some of the best minds in biopharmaceutical research and development. We continue to pioneer pragmatic and transformational improvements to the drug development process."

The Key Trends Now Emerging and Their Implications for Pharma

TRENDS

MARKET TRENDS

- Patients are becoming better informed
- Patients are picking up a bigger share of the bill
- Demand for personalized medicine is increasing
- Patients want cures, not treatments
- The emerging markets are becoming more important

HEALTH AND HEALTHCARE TRENDS

- The burden of – and bill for – chronic disease is soaring
- Healthcare payers are establishing treatment protocols
- Pay-for-performance is on the rise
- The boundaries between different forms of care are blurring
- Financial constraints on payers are increasing

SCIENTIFIC AND TECHNOLOGICAL TRENDS

- R&D is becoming more virtualized
- The research base is shifting to Asia
- Remote monitoring is improving rapidly

IMPLICATIONS

PHARMA WILL NEED TO GO "BEYOND THE MEDICINE"

- Pharma will be paid for outcomes, not products
- Outcomes data will drive healthcare policy
- Prevention will gain a higher healthcare profile
- Pharma will need to offer "medicineplus" packages of care
- Pharma will have to adopt more flexible pricing strategies

R&D WILL NEED TO GO BEYOND THE LAB

- Pharma will need access to outcomes data
- Pharma will have to work with technology vendors to virtualize R&D
- Pharma will need a wider, more multi-disciplinary skills base
- Pharma will need to expand its presence in Asia
- Pharma will need to demonstrate "real" value-for-money

THE PHARMA AND HEALTHCARE VALUE CHAINS WILL BECOME MUCH MORE INTERTWINED

- Pharma will have to work more closely with the regulators
- Pharma will have to collaborate with payers and providers to perform continuous trials
- Pharma will have to collaborate with numerous service providers to deliver

Source: PwC

On two core initiatives, TransCelerate uncovered results that communicate significant progress in the journey to improve patient safety and efficiency in clinical trials.

First, the Comparator Network executed end-to-end operations on updated technology, enabling access to top global comparator products, and eliminating the chance for counterfeit drugs to enter the investigational supply chain.

The network has exceeded transaction volume of $120 million and saves members approximately 10% to 12% per transaction. By providing detailed stability data, the network has avoided wasting substantial quantities of investigational product.

Most importantly, avoiding drug loss due to potential temperature excursions has prevented delays in getting lifesaving products to patients who participate in clinical trials.

Second, TransCelerate has made significant progress in the Placebo & Standard of Care Data Sharing Initiative. Thus far, preliminary results indicate that use of such well-defined historical data can reduce study time significantly, and reduce the number of patients in the placebo/standard of care arm.

TransCelerate also made progress on the goal to empower and engage patients, launching a new initiative dedicated to understanding patient burden, and use of technology in clinical trials — Patient Experience & Technology, and solidifying the Initiative centered on supporting better informed patients — Clinical Research Awareness & Access.

The eConsent Initiative released its draft Implementation Guidance, aimed at evolving the informed consent practice toward increased efficiency, compliance and patient understanding, supported by electronic consent tools. An updated guidance paper will be made available in 2017.

And the eLabels Initiative continued to work toward laying the foundation for digitally enabled, patient-centric labels on clinical trial medicines, propelling the needle forward on patient and site utility.

Through a collaboration with the Center for Information and Study on Clinical Research Participation (CISCRP), TransCelerate is working with international Patient Advisory Boards to gather patient feedback on key patient engagement initiatives that will help inform recommendations for new approaches and best practices.

According to TransCelerate with the support, passion, and knowledge of hundreds of industry experts from 18 biopharmaceutical companies, and collaborative efforts with more than 40 global health authorities and industry organizations, the organization is transforming the industry's approach to clinical trial monitoring through the Risk Based Monitoring Initiative, reducing duplication in investigator site training through the Site Qualification Training Initiative, and creating value where there were serious redundancies in clinical operations related forms, templates, and processes.

In 2016, The Multiple Myeloma Research Foundation (MMRF) held its CoMMpass Study Data Jamboree. Held in Cambridge, Mass., the MMRF invited more than 40 attendees from various nonprofit, academic, and pharmaceutical organizations to discuss new findings and next steps related to the landmark CoMMpass Study, an open-source initiative that is changing how researchers think about using data to drive actionable insights in the clinic.

CoMMpass, the cornerstone of the MMRF's Precision Medicine Initiative, is a prospective, longitudinal, observational study capturing the largest genomic data set in multiple myeloma. This study follows 1,000 patients throughout the course of their disease. By mapping each patient's genomic profiles to clinical outcomes, CoMMpass is enabling precision medicine in multiple myeloma patients — delivering the right treatment at the right time.

Moving forward, the MMRF and CoMMpass stakeholders are committed to continued collaboration, data sharing and the use of broad, cutting-edge technology in order to advance precision medicine — with the ultimate goal of improving the lives of patients with multiple myeloma. PV

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