BEYOND 2020:

Collaboration for Value Creation

The competitive landscape for life science companies around the world is changing rapidly. In today's New Health Economy, drug pricing pressures, scientific breakthroughs, expanding global demand for healthcare access, and emerging digital and analytical capabilities, are all serving to push the healthcare industry towards an ecosystem defined by collaboration, quality and consumer value.

There are two megatrends in particular that are impacting pharma: the broadening demand for healthcare products and services, and severe cost pressures. Aging populations, urbanisation and growth in emerging markets are all putting a greater strain on healthcare systems around the globe. For pharma, this means a huge influx of new customers and greater demand for medicine. However, spending increases for drugs are triggering public and private efforts to reduce prices and tightly manage utilisation. In particular, for chronic diseases, governments are also seeking more comprehensive treatment programs, including wellness and prevention, along with more advanced approaches to population management.

Digitalisation and the explosion of data are further rewriting the playbook for pharma. New technology – including cloud, mobile technology, analytics and social media – can drive better patient education, engagement, and results. Wearables, biosensors, regulator-approved mobile apps and devices, and remote monitoring engage patients by providing the tools they need to receive treatment, and the feedback necessary to maximise drug effectiveness.

Electronic health records (EHRs) and emerging digital technologies on the provider side are catalysing new partnerships between healthcare systems and pharma companies, with the goal of leveraging patient data to demonstrate health outcomes and differentiate products in a real-world setting. Such technology can also transform the drug development process by improving patient recruiting and enhancing clinical trials.

An increasingly patient-centric focus is catalysing new forms of collaboration

As market forces push pharmaceutical and life science companies closer to patients, a number of factors are converging to catalyse collaboration across the health sector. They include rising drug costs; increasing competition in key therapeutic areas such as oncology, diabetes, multiple sclerosis and rheumatoid arthritis; inefficient and outdated clinical trial models; shifting provider regulations and incentives; and a new emphasis on patient-reported outcomes.

The sum of these factors is beginning to exceed the number of remaining obstacles—such as a compliance issue and an unwillingness to share data—as health organizations prioritize optimal patient outcomes over conflicting business incentives.

In the New Health Economy[1], the blurred lines of demarcation between traditional health industry business models are giving way to a wide open marketplace in which data sharing, customer input and disease management is linked directly to consumer choice and payment.

New collaborations pairing traditional drug makers with healthcare systems, healthcare providers and purchasers, patient groups and technology firms are reconfiguring three crucial business operations: drug R&D, regulatory submission and product commercialization. All of these collaborations have one thing in common: they aim to use newly available consumer health data to uncover the truth about drug value and its relationship to health outcomes. The need to collaborate also stems from a growing concern that drug development doesn't adequately address patient needs and medication adherence outside of the clinic. Personal health information might well be the new currency of drug development and commercialisation.

Pharmaceutical and life sciences companies must therefore look outward to anticipate, identify and act on new opportunities in drug development and commercialization. Many novel biopharma collaborations are already underway, with wearables firms[2] such as Fitbit and MC10 Inc.'s biostamp, or genetics companies such as 23andMe. Others are partnering with purchaser and patient groups. In the following section we will elaborate on such collaborations involving biopharma companies, new entrants and consumer groups.

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New entrants

In the era of big data, organizations are realizing that bigger isn't always better; being able to access and communicate relevant data as they relate to individual business objectives or specific audiences is the key to demonstrating value. New entrants are disrupting healthcare delivery by using consumer technology as a point of entry.

In 2014, global biopharma company UCB announced a partnership with electronics company MC10 Inc. to develop the latter's Biostamp device — a clinically-focused, flexible biometric sensor patch with the potential for a temporary tattoo-like form factor — for use with UCB's drugs to treat movement disorders such as Parkinson's disease and restless leg syndrome. The UCB/MC10 Biostamp research collaboration will test the Biostamp with patients, to track movements in the home and around the clock. UCB hopes analysis of the Biostamp data can optimize treatment for patients with movement disorders.[3]

In addition, organizations such as Teva Pharmaceutical Industries Ltd. are collaborating with new entrants on implantable drug delivery microchips for patients[4] and telehealth services[5]. Teva also formed a research incubator with Philips Healthcare aimed at developing new medical technologies to support drug therapy. And Google's life sciences group — Google X — launched a wearable device designed specifically for patients participating in clinical trials.[6]

New entrants[7] bring not just technology, but new business models to bear on care delivery and consumer health. Biopharmaceutical companies, through collaboration, can leverage the speed and innovation of emerging technology, device and diagnostic firms to merge the consumer experience into the health ecosystem.[8]

Consumers

Consumer expectations in healthcare have shifted in the last five to ten years, due in part to experiences in other industries.[9] Easy access to health information, increasing costs, and a desire to understand—at a physical and biological level—what's happening in their bodies has led to stronger opinions about how, where and when to deal with illness.

Patients are pushing for further inclusion into drug review processes, to ensure that new drugs are truly addressing their needs in meaningful ways. In the US, officials from the Food and Drug Administration (FDA) have suggested that the next Prescription Drug User Fee Act (PDUFA) reauthorization, in 2017, will codify patient input as part of FDA's review process.[10]

Consumers are also pursuing an agenda that can sometimes run counter to conventional methods of drug development and approval. Demonstrating that a tumour shrank, or that a biomarker was successfully targeted by a drug during clinical trials doesn't necessarily mean that a patient will feel any better. In chronic obstructive pulmonary disease, for example, the ability to accomplish daily tasks—such as lifting children, or using a hairbrush—without succumbing to breathlessness, can be more important to patients than a clinical efficacy number.

Collaboration with patient groups has paid off, for patients and pharmaceutical companies. The Cystic Fibrosis Foundation's (CFF) collaboration with Vertex Pharmaceuticals, for example, continues to bear fruit. Kalydeco, a blockbuster drug for cystic fibrosis patients first approved in 2012, was discovered at the CFF and developed by Vertex. At the same time, Kalydeco's price of about US$300,000 a year has fuelled broader concerns about the rising cost of medications.[11]

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Leveraging consumer and patient health information

An increasingly comprehensive understanding of the patient experience and journey is necessary to define health outcomes and to measure the impact of medicines on peoples' lives over time. While there's nothing close to a one-stop-shop for patient data and information—yet—a variety of organizations have succeeded in piecing together disparate data. The results are building progressively vivid representational models of people as they manage their health, access care and continue living, or die.

The critical first step in considering a data-sharing collaboration is understanding which data, and what kind of access, are unique to a potential partner organization. Medical records housed with provider groups and health systems are not the black boxes they once were; the growing quantity of EHR data now accessible for research has enabled new analytical capabilities and data linkages for constructing a more detailed portrait of patients and disease progression. Other data sources, including patient registries created by public and private groups, are organized primarily around specific disease areas. The data housed in these registries vary dramatically according to patient population size, data type and accessibility. A clear strategy and set of objectives is needed to determine which data are most valuable to an individual organization.

New technology that captures biometric data aims to further integrate the patient experience into drug development and illuminate health outcomes research. Drug company partnerships with wearable technology firms—such as UCB's collaboration with MC10, Inc., or drugmaker Biogen Idec's partnership with Fitbit and PatientsLikeMe in multiple sclerosis[12]—are in the pilot stage.

These pilot programs may later transition to core product services as more companies focus on health outcomes as a key measure of product value. Validated accelerometers that measure precise body movements[13], for example, are pro-

ducing reliable data in the clinical setting. But it's an open question whether activity trackers will become meaningful tools to support and define health outcomes.

> Give us, healthcare payers, new medicines that are clinically and economically better than what's already available

What this means for your business

The message that healthcare payers, particularly in mature markets, are sending out is clear: give us new medicines that are clinically and economically better than what's already available – medicines that decrease mortality or morbidity, make the care pathway more efficient or reduce the total resources a patient consumes. And give us hard, real-world data to back up your claims. As pressure builds to link patient health outcomes with the cost—and value—of new therapies, biopharmaceutical companies must transcend the traditional divide between drug R&D and commercialization. Evidence generation should continue after a drug receives FDA approval, as clinical safety and efficacy measures give way to real-world performance and demonstrated patient outcomes.

As such, collaborating strategically can maximise the dollars spent in drug development, fill evidence gaps in specific patient populations and demonstrate a drug's cost and comparative effectiveness. We suggest four areas for consideration in navigating the way forward:

Place new bets with pilot programs. New entrants are flooding into healthcare. Advances in digital monitoring and biometric sensor technology can shed light on patient experiences and identify remaining unmet need.

Get the purchaser perspective. Collaborating with insurer groups and health systems provides access to the patient data used by these groups to make coverage decisions.

Embrace patients as partners. Consumers are asserting themselves when it comes to data ownership, but will contribute health information if they understand the benefits. The US-based biomedical research facility National Institutes of Health lists 39 disease-specific patient registries open for research.[14]

Anticipate regulatory change. Regulators are exploring new ways to integrate patient experiences into drug review decisions. Working with patient data as regulations evolve will deliver a competitive advantage over companies that wait for new laws to take hold.

Collaboration through finding common sources of value is key

While biopharma companies have dabbled in external collaborations for years, what is different now is the accessibility and quality of the consumer data that underlies new partnerships which help biopharma companies capture and explain the value of products. New technology is accelerating the pace of innovation in biopharmaceuticals by democratising access to data and empowering consumers to manage their health.

As a result, new definitions of innovation and value are needed to remain relevant in a rapidly changing healthcare system. In turn, collaboration is critical for accessing and analysing the data needed for an increasingly personalised product offering and the price tag that such a product commands.

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