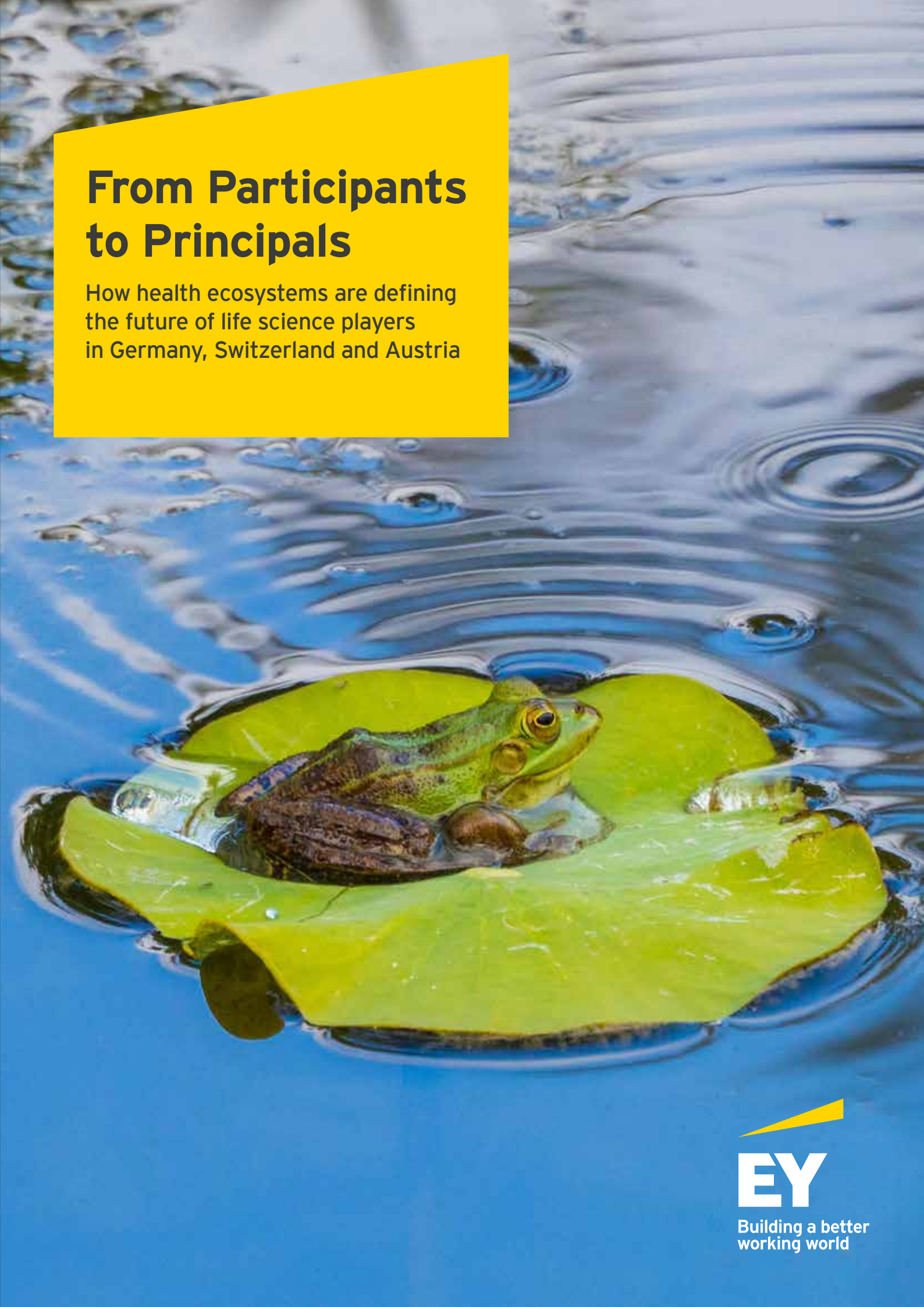

From Participants to Principals

How health ecosystems are defining the future of life science players in Germany, Switzerland and Austria

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Executive summary

From blockbuster medication moving to incorporated patient outcomes and generating an iterative process for drug and technique development – the life science industry is in massive transition.

As mentioned in EY's *Progressions 2018 – When the human body is the biggest data platform, who will capture value?*[1] report, health is being reimagined in the wake of scientific change and customer expectations to create "health technology."

This transition, which is being driven by patient demands, will ultimately be delivered through the creation of ecosystems that utilize data to create tailored solutions. Yet how ready is the pharmaceutical industry to lead this change or to cope with its impact? And what do companies stand to gain or lose by adopting different strategies toward ecosystem creation and management? Do firms want to invest in creating these tools themselves or utilize the knowledge and expertise of others to gain access?

Patient and payer demands – improved health care at lower costs

This change in the way pharmaceutical companies operate is a result of new patient and payer demands, which are closely aligned with a value-based approach and improved health outcomes. Furthermore, it might be a consequence of new platforms – health and wellness centric – becoming part of our life, established by "nontraditional," e.g., technology, players.

Patients are no longer satisfied with out-of-the-box solutions and increasingly demand tailored treatments that are specific to their physiological needs. This is shifting the industry toward new areas such as personalized medicine, application-based health care monitoring and telemedicine, activities that can only be achieved through the collection and analysis of large data sets.

1 http://www.ey.com/Publication/vwLUAssets/ey-when-the-human-body-is-the-biggest-data-platform-who-will-capture-value/$FILE/ey-when-the-human-body-is-the-biggest-data-platform-who-will-capture-value.pdf.

Payers also want to see their costs reduced, with the long-term health of the population prioritized as a means of saving costs. This development incentivizes the creation of a value-based payment structure that rewards health outcomes, and must also be monitored and analyzed to identify optimal treatments for patients and to align with the needs of physicians and policy-makers.

Life sciences players want to better understand patients, their relevant stakeholders, behaviors and ways to drive predictable health outcomes. These new demands can be met through interconnected ecosystems that allow firms to access a variety of health data, analyze it and distill the information that can be used to improve treatment. This trend is, in turn, shifting where the value created by pharmaceutical companies lies.

Ecosystems in GSA: varied development through varied strategies

Life sciences firms in Germany, Switzerland and Austria (GSA) have started to work on this transition, and many are currently investing in ecosystems to deliver value to the patient. These ecosystems are still at an early stage of development and are in many cases product-related. Firms have not yet coalesced around a single strategy, with the industry split between Participants, Pilots, Profiteers and Principals.

To date, pharmaceutical firms have had most success developing ecosystems in areas of drug development and patient access, bringing new methods of data collection and analysis to help improve clinical trials and connect with patients. Firms have also made improvements to the manufacturing process by preparing for the development of further automation. Yet, despite these improvements, the industry remains underinvested, focusing on non-capital-intensive improvements, with the traditional pipeline still favored over ecosystem development for large-scale investment. This is a sign that, currently, the majority of firms are using Participant and Pilot strategies to grow and manage these systems.

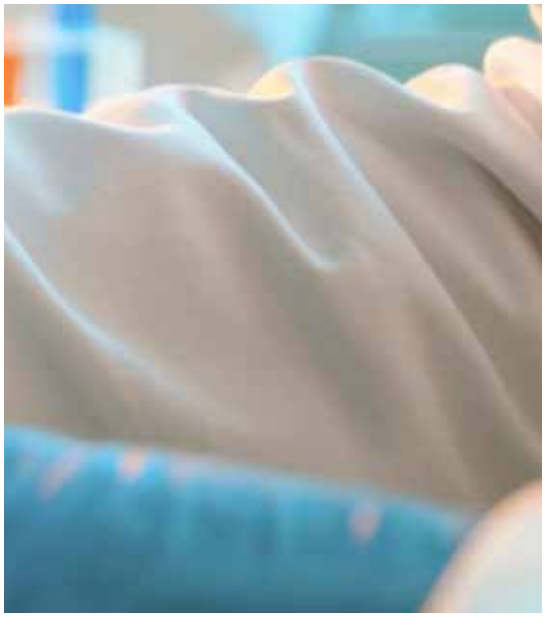
Meanwhile, new entrants to the health care market, such as technology firms, have invested in different areas and are making substantive gains in the space of data collection, management and analysis. Global players such as IBM and Microsoft have been quick to move into the areas of data storage and analysis by serving as partners to traditional firms, while disruptors such as Amazon and Google have sought to challenge directly by combining health analytics with wearables and home-based appliances, and smaller firms and specialty enterprises with advanced capabilities have attracted significant outside investment.[2] They are making progress capturing critical components of the new value chain by owning the interpretation of data. This poses a challenge for traditional pharmaceutical players.

2 L. Beaver, "Amazon sets aside drug ambitions – Google considers bid for Nokia's digital health business -Optum revenue hits double digits," *Business Insider*, April 18 2018, M Reardon, "Google's Nest eyes Nokia Health assets," *CNET*, 18 April 2018.

What ecosystems will mean for the industry
Ultimately, these ecosystems will grow into far more comprehensive solutions that alter drug development, manufacturing and delivery, while also changing the role of traditional functions within pharmaceutical firms. Ecosystems that align different players from different industries on a defined health purpose will compete with each other yet also serve as the anchor for industry convergence.

Once mature, leveraging ecosystems will allow for research to be automated, manufacturing to be personalized and pharmaceuticals to become tools of data collection themselves, greatly increasing the amount of health data available. This will require firms to not only invest heavily in new capabilities to utilize that information, but also restructure themselves to properly create and manage those systems, as current structures are not adequate to handle the data that will be captured.

This restructuring will impact how pharmaceutical firms operate. Business development and licensing will transition away from securing a pipeline of products, and toward securing the capabilities to develop ecosystems and create new disease-, health- and lifestyle-related revenue streams. Marketing and sales will also change, as firms gain the ability to target specific practitioners, and develop tailored solutions for them and their patients.



Projecting to 2030 – how can pharma capture the value of ecosystems?
The success pharmaceutical companies have in making these changes in turn will shape the size of the pharmaceutical market and the share owned by traditional firms.

- As shown by our econometric model, by 2030, the economic value added from the pharmaceuticals industry, i.e., pharmaceutical sales, licensing and the health IT tools used to create and deliver products (hereafter referred to as the pharmaceutical market), in GSA will be worth almost €130 billion compared with just €62 billion in 2015, according to Eurostat and Swiss Federal Statistical Office data, with ecosystems at the core of that value creation. Ecosystems themselves, in the form of health IT, will house over €30 billion in value and will also be responsible for delivering a large share of the near €95 billion in value of pharmaceutical sales.

- For firms to maximize their potential in the market and capture over 70% of the total value of the near €130 billion created, the adoption of a Principal strategy will be needed, signifying a major push into establishing and owning digital-enabled platforms and data analytics tools. Only by investing heavily in the ability to derive value from the data ecosystems capture will traditional pharmaceutical companies be able to own the key sections of value creation. If they do not, and either continue along their current path of investment or adopt a Profiteer strategy that favors external partners over internal development, their share of the market could fall as low as €70 billion, with new entrants capturing an extra €20 billion that could have been won by pharmaceutical firms, had these taken a more direct ecosystem ownership and development strategy.

Introduction

Interconnected ecosystems can lead to significant value in the ownership of health data and the platforms that can best access consumers.

The pharmaceutical industry is a key economic sector in GSA, employing more than 172,000 people across the region.[3] With domestic pharmaceutical sales of almost €39 billion and total exports of over €135 billion, the industry not only represents a source of economic growth, but also an area of international expertise.[4]

The region's firms comprise some of the world's largest pharmaceutical companies, with champions such as Roche, Novartis, Merck KGaA, Boehringer Ingelheim, Bayer and Fresenius not only structurally important to the GSA region and their respective national economies, but also to the global health care industry. GSA also hosts specialized players that provide platform businesses for larger firms, with companies such as Qiagen, SYGNIS and Siemens Healthcare also playing important roles in the makeup of the region's health care market.

However, the traditional health care system to which these firms have become accustomed is changing.

Those who pay for health care – governments, insurers, companies and patients – are increasingly concerned about rising costs. Patients are also more focused on improving their own overall health thanks to better care with a holistic approach, higher recovery rates and fewer side effects. The European health care landscape is therefore increasingly shifting away from a system based upon the sale of products toward one that delivers, and is rewarded for, improved patient outcomes.

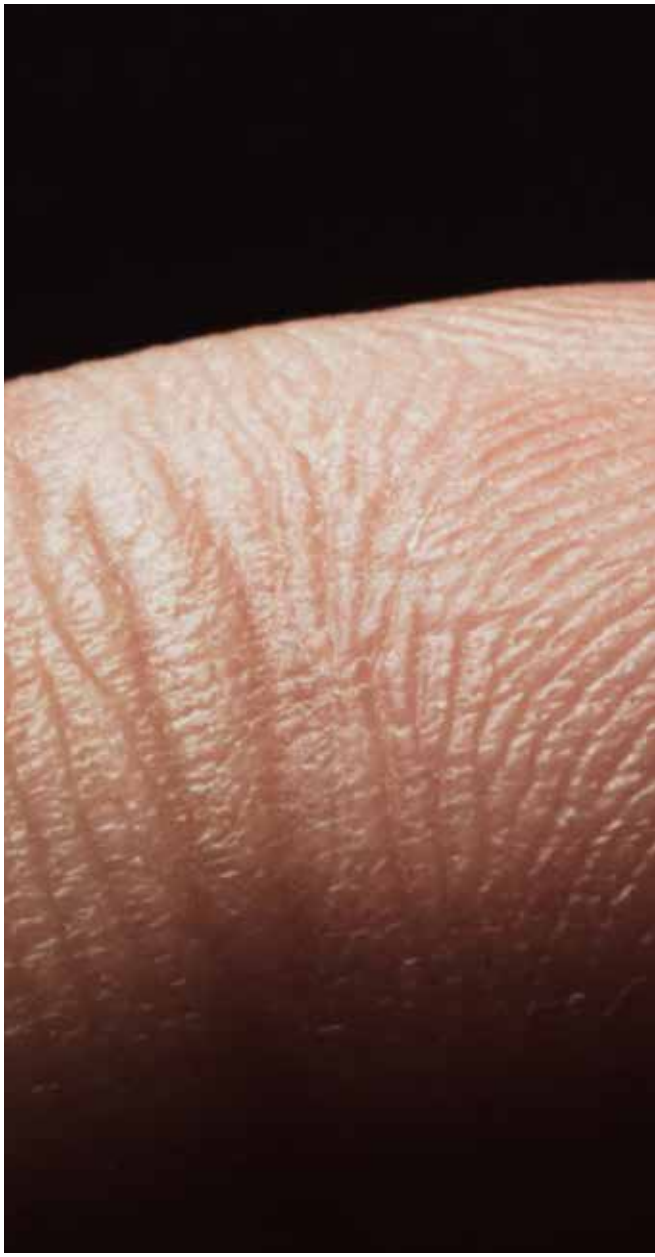
This change in the way patients and payers view their optimal health outcomes is driving widespread change in the development and delivery of pharmaceutical products. While drug development and delivery was once a lengthy process dominated by a few key players, with clinicians operating as conduits for the collection and transfer of health data from the patient to pharmaceutical producers, patients are now increasingly demanding access to more information, and asking for the ability to customize how and when they are treated. To accomplish this daunting task, pharmaceutical firms are looking to create and use interconnected ecosystems. These ecosystems, which bring together a range of partners to collect and share data, will allow firms to not only share information directly with the patient and other health providers, helping to deliver a more impactful outcome, but also create room for improvements in the development of future drugs.

This is a radically different approach to the product-centric system of the past and creates significant value in the ownership of health data and the platforms that can best access consumers. These ecosystems create space for new firms to enter the market, particularly those with expertise in data analytics and management.

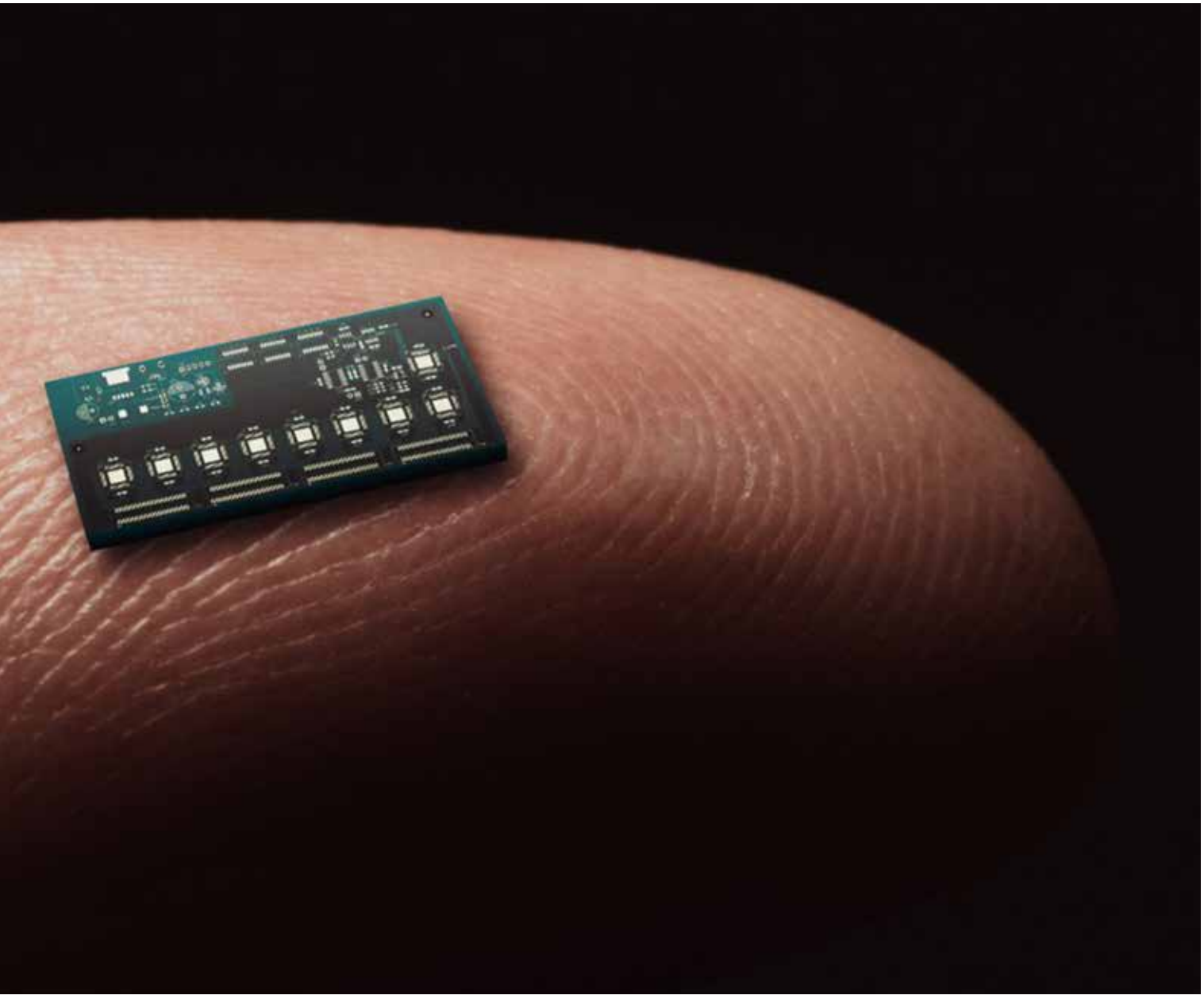
What do these changes mean for the pharmaceutical industry within the GSA region? Are pharmaceutical firms in GSA prepared to design, orchestrate, lead and sustain ecosystems? What transitions need to happen internally for firms to successfully develop and manage these ecosystems? Will the pharmaceutical firms of the region be able to make those changes – and thus be at the forefront of ecosystem development – or will they see their global standing eroded by new market entrants? What are the different strategies pharmaceutical players can employ to engage with ecosystems, and what do these strategies mean for how firms share value with other actors?

3 "The Pharmaceutical Industry in Figures Key Data 2017," *European Federation of Pharmaceutical Industries and Associations (EFPIA)*, accessed 22 May 2018.
4 "The Pharmaceutical Industry in Figures Key Data 2017," *European Federation of Pharmaceutical Industries and Associations (EFPIA)*, accessed 22 May 2018.

This report will seek to answer these questions by discussing the drivers of change – the demand by patients and payers to receive more impactful outcomes – and the strategies firms can choose from to engage with the phenomena of ecosystems, and identifying how companies will adapt their processes for pharmaceutical development, manufacturing and delivery over the coming decade to meet patient demands. Onto this picture of the future of the industry will be overlaid how pharmaceutical companies are currently leveraging these ecosystems within GSA, the strategies already in use, and where they are facing increasing competition. The report will conclude by forecasting what the region's market might look like by 2030, and how it could be divided between legacy firms and new entrants to the market, based upon the current strategies displayed, and what changes in strategy could mean for how the market is divided.



Ecosystems, which bring together partners to collect and share data, will create room for improvements.



01

Drivers of change – keeping people healthy, improving patient outcomes at lower prices

Pharmaceutical firms are required to form partnerships with other health care providers, as well as companies specializing in the development of data collection tools to enable health instead of curing the sick.

Medicine has never been an exact science. Unlike other fields in which experiments can be conducted in pristine lab environments and devices act on relatively uniform objects, the health care sector is designing products for the human life and body, with all of its inter- and intra-individual variabilities and varieties. Additionally, pharmaceutical companies must balance the drive to create products as efficiently as possible with the need to avoid any flaws that would cause harm to patients. For these reasons, development cycles are long, and most medicines are only specific to population groups large enough to generate statistically relevant results.

Today's patients, however, are demanding more out of their drugs and the companies that manufacture them. Patients want to not only understand more about their treatments and their effects, but also to receive tailored treatments that are specific to them and their physiological needs. These two new demands are shifting the industry toward new areas of personalized medicine, application-based health care monitoring and telemedicine.

This unfolding change in how patients view their health, and what they expect to receive from their health care providers, is fundamentally altering how the pharmaceutical industry functions and where the value it produces is being created.

Patient and payer demands are forcing the industry to rethink how to deliver improved health outcomes.

To meet these demands, ecosystems in the health sector are emerging to capture and share information. Wearables, genetic sequencing, telemedicine and other innovations are creating or sharing vast amounts of data and shrinking the gap between patient and pharmaceutical company – allowing for medicine to become personalized in a way that had never been possible in the past, improving patient outcomes while lowering costs, and shifting where the value that pharmaceutical companies create is delivered in the health care process.

The traditional model – curing the sick

Pharmaceuticals have traditionally been developed along a linear timeline, in which research organizations develop a molecule or specific treatment, refine it over a period of years through distinct stages of clinical testing and then manufacture and market it as one product, geared for specific ailments or disease indicators. Firms are then reimbursed on a pay-per-pill model, with a price negotiated with payers.

This system lends itself to the large-scale manufacture of identical products and leads pharmaceutical companies to gravitate toward long-life products first under patents, and then as generic medicines. It is a system that does not necessarily utilize information about how the products are used – walling off real-world evidence (RWE) from the manufacturing process.

The measurement for the success of this process is unidirectional. It is geared toward curing an ailment, but not necessarily toward enabling the patient or wider community to be healthier. It is a relatively inflexible model, although it should be noted that this model has been shaped by the technical limits of gathering information in a pre-digital age and the caution with which regulators justifiably act in response to new ways to experiment with new drugs on human subjects.

310

million wearable devices were projected to be sold during 2017.

Enabling health

Patient demands, as well as those of payers (governments and insurers), are looking away from this structure based upon curing acute sickness or managing chronic diseases, toward a wider view of improving a patient's overall health through a mix of preventative diagnostics, personalized care and continual monitoring. This satisfies the patient demands of better care and better lifestyles, and meets payer needs to bring down health care costs overall.

This shift requires pharmaceutical companies to be involved in multiple aspects of the patient's health, taking an active role in managing the use of pharmaceuticals, their impact on patients, and how they view the role of medication within their own health care environment. Pharmaceutical companies are moving from being product providers only to becoming solutions-oriented, active participants in health care services.

Yet to accomplish this change, firms must develop new touchpoints with patients and health care providers. Creating the systems to do this requires pharmaceutical firms to form partnerships with other health care providers, as well as companies specializing in the development of data collection tools. Collectively, these new platforms form ecosystems, which allow for data transfer directly to and from the patient.

It is these ecosystems, and the tools used to shape them, that will increasingly create value within the pharmaceutical industry.

What patients demand

Ecosystems will be shaped primarily by what patients demand and what technology allows: personalized quality of care and on-demand access to care. Personalized quality of care relies on the improved ability to gather data from patients so that health care professionals can distinguish an individual's needs compared with their population group for which traditional treatments are developed. There are two areas where such advances have been remarkable in recent years: the rise of wearables and mobile phone apps, and inexpensive genetic sequencing.

Continual monitoring – wearables and apps

Devices that allow people to monitor their health and motivate them to get healthier account for one of the fastest growing sectors in consumer products. The segment for health and fitness apps on mobile phones has grown by over 330% in the last three years, according to new research.[5] The global number of wearable tech devices sold in Q4 (such as Fitbit wristbands that track heart rate and step count) increased from 29 million units in 2015 to 33.9 million in 2016 – a year-on-year growth of 16.9%, with forecasting firm Gartner projecting that 310 million wearable devices would be sold worldwide in 2017 alone, a 16.7% increase on 2016.[6] In Germany, a survey found that 31% of citizens over the age of 14 are using fitness trackers, while in Switzerland, health insurance providers increasingly offer health apps to patients to encourage healthy lifestyles.[7]

In Germany, a survey found that 31% of citizens over the age of 14 are using fitness trackers.

5 "Health and Fitness App Usage 'Grew 330% in Just 3 Years,'" *Net Imperative*, 13 September 2017.
6 P. Lamkin, "Fitbit's Dominance Diminishes But Wearable Tech Market Bigger Than Ever," *Forbes*, 3 March 2017; "Health and Fitness App Usage 'Grew 330% in Just 3 Years,'" *Net Imperative*, 13 September 2017.
7 S. Dehmel, B. Mützwe, and C. Krösmann "Gemeinsame Presseinfo von Bitkom und BMJV: Fast ein Drittel nutzt Fitness-Tracker," *Bitkom*, 9 February 2016.; S. Knoll, "Gesundheitsdaten auf dem Smartphone wecken Begehrlichkeiten," *Schweizer Radio und Fernsehen*, 23 March 2017.

Fitness trackers and apps are typically employed in general health monitoring but are increasingly used for management of chronic diseases. Wearable devices offer RWE and can help trace environmental and individual factors that influence the effectiveness of a drug. Patients with type 1 and type 2 diabetes can now more actively manage their health with the apps mySugr, SugarPoint Kids and SiDiary.[8] Beyond the scope of these disease-specific apps, a growing number of players – start-ups for the most part – have created apps that allow for symptom evaluation and diagnostic support, such as, Ada, Babylon and Gyant.

To create these apps and successfully analyze the health data they collect, pharmaceutical firms must either enter the field of health care technology and analytics themselves, moving beyond their core business, or must develop ecosystems with partners in that area, leveraging existing skills and capabilities.

Personalized medicine

Patients are now able to receive (and are therefore asking for) pharmaceutical products that are tailored to their specific physiological needs.

Personalized medicine is made possible by the rapidly decreasing cost of gene sequencing in recent years. The first-ever effort to sequence an entire representative copy of the human genome cost somewhere between US$500 million and US$1 billion in 2000. By 2006, the cost of the process had fallen to about US$20 to US$25 million and, by the end of 2015, it stood at only US$1,500, or roughly €1,200.[9] With continued innovation in methods for sequencing, it is likely that the cost will continue to fall, to the point where sequencing a genome will be less expensive than pharmaceuticals based upon genomic data.

Personalized medicine holds the promise of being much more effective than traditional pharmaceuticals, with fewer negative side effects, faster results and better outcomes. However, the ability to use genomics in pharmaceutical development and delivery is dependent on pharmaceutical companies being able to store, analyze and protect vast amounts of highly sensitive data: a representative sample of the human genome has about 3 billion base pairs and personalized medicine requires comparing an individual with the rest of their population group. Creating systems that can store, share and protect that data is also a critical driver in the development of these new ecosystems and another factor pushing pharmaceutical companies into work processes more often associated with technology firms.

On-demand access to care

Patients are also seeking technical solutions to one of the most elemental parts of health care: access to doctors and medical professionals. Known as telemedicine, this process of communication reduces barriers to health care delivery.

On-demand access to care is already available in the GSA region. Medgate in Basel, run by doctors, has the largest telemedicine center in Europe.[10] They offer medical consulting on a constant basis; Swiss patients can choose their health insurance provider and are connected directly through to Medgate. Patients provide their personal data and symptoms, including photographs of affected areas when needed. The medical team then discusses treatment options with the patient and can directly write prescriptions.[11]

While regulatory barriers remain in place, particularly in Germany, where telemedicine is only possible after the patient has physically met with the doctor, patient demand for such convenient solutions is growing.[12] And there have been some signs of the barriers being lowered, such as in the German federal state of Baden-Wuerttemberg, which recently saw the launch of a pilot project for telemedicine. However, a seamless and region-wide provision of on-demand access to care will hinge on the development of partnerships between pharmaceutical firms and health care providers and practitioners.

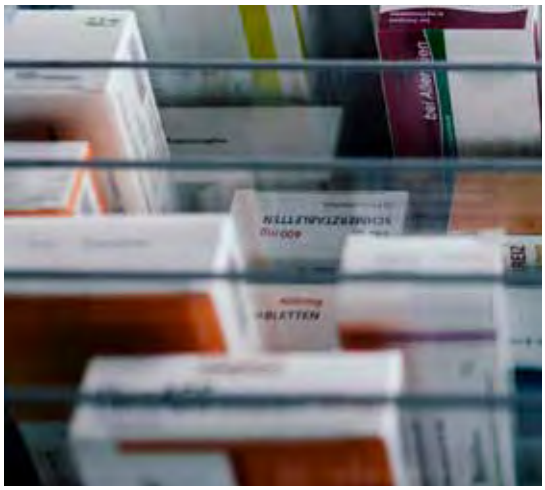
8 "Die besten Diabetes Apps," *CHIP*, 3 December 2015.
9 "The Cost of Sequencing a Human Genome," *National Human Genome Research Institute*, 6 July 2016.
10 N. Battenfeld, "Telemedizin auf Schwyzerdütsch: Ein Besuch bei Medgate," *Wir Techniker*, 18 August 2017.
11 "Telemedicine Center," *Medgate website*.
12 "Telemedizin in Deutschland: Interessanter Markt für US-Unternehmen," *Heise Online*, 4 February 2018.

What payers want – a healthier population at lower costs

Beyond the changing demands from patients in terms of treatment and access, the pharmaceutical industry faces pressure from public health payers who are seeking lower costs for the sector.

Cost pressures on the pharmaceutical industry call for the development of more efficient means of manufacturing and distribution. This also leads to the concept of value-based medicine, where firms are not rewarded for what they sell, but instead according to what those sales produce in making patients healthier. The improvement in the health of the overall patient population can be measured in a variety of ways, from hospitalization rates, to survival rates or the number of treatments needed. Those metrics are used to determine compensation for pharmaceutical providers. This type of payment structure is already being tested within GSA, with Merck, Novartis and Fresenius all seeking to utilize this model for aspects of their pharmaceutical products.[13]

Before a value-based health care system can be implemented, firms must first have access to data that provides real-world evidence (RWE) and know which treatments are working best. Without a wider ecosystem in place to monitor patients after treatment, outcomes remain unknown and restricted to rigorously controlled clinical studies. Pharmaceutical firms are therefore forced to create networks to facilitate RWE collection and analysis. Networks must include patients, doctors and hospitals – which are closest to RWE – as well as data analytics teams and R&D teams who will use the data for the next phase in the product cycle.[14]



Value-based care is undoubtedly a growing trend within the industry and an important driver of change. As countries age and governments look to control costs, there will be tremendous pressure to find ways to eliminate waste. The ability to track evidence via patient engagement, monitoring apps and closer contact with doctors via telemedicine permits value-based care to move into the realm of reality, and payers will soon be demanding evidence of efficacy before committing to pay high fees for pharmaceutical products.[15] These pressures will force pharmaceutical companies to adapt or be left behind by those who do.

13 J. Miles, "Going Digital In Life Sciences: What Does That Really Mean?," *Digitalist Magazine*, 25 May 2016; M. Alsumidaie, "Novartis Brings on Digital in Patient Centricity Trials," *Applied Clinical Trials*, 12 April 2017; interview with a senior executive from a German life sciences firm.
14 M. Alsumidaie, "Novartis Brings on Digital in Patient Centricity Trials," *Applied Clinical Trials*, 12 April 2017; interview with a senior executive from a German life sciences company.
15 C. Bowie, "Outcomes-Based Medicine Demands Real-World Evidence," *Pharmaphorum*, 12 October 2016.

02

Ecosystems: what, how and who?

What is meant by the term “ecosystem”? How are ecosystems different from current practices? How will they be created and what should be the strategy for pharmaceutical firms in GSA?

As patient and payer demands force companies to produce better health outcomes at lower cost, ecosystems will be created. Only by pooling knowledge and capabilities with other health care providers can pharmaceutical firms deliver the desired results.

What is an ecosystem?

Looking at nature, an ecosystem comprises all the plants and animals that live in a particular area together with the complex relationships that exist between them and their environment. Consider a garden pond forming an ecosystem with frogs, flies, fish, water lilies, but also the gardener – and you.

Ecosystems in the life sciences industry can be described as networks in which information can flow between different actors within the pharmaceutical value chain or health care environment. Unlike the traditional model of buyers and sellers in bilateral economic relationships, ecosystems recognize that

Ecosystems create more value than the sum of their individual participants.

buyers (in this case, patients) can offer value to sellers (pharmaceutical firms), and that those who do not traditionally operate in this sphere (data analytics and technology companies) can also provide useful inputs. These ecosystems operate with the unified purpose of creating and sharing value by leveraging data-driven platforms.

Although ecosystems are often equated with the adoption of innovative technologies, they are not necessarily digital and do not need to include technology partners. They are instead any mechanism by which the relationships between actors become dynamic and multidirectional, creating more value for each actor involved through new types of interactions.

An example of this structure is a partnership between a hospital and a pharmaceutical provider that allows the company to receive RWE on the use of its drugs, which can be fed into the development of new pharmaceuticals. The patient receives a better quality of care, the hospital develops more refined treatments for its patients and the pharmaceutical company gains access to data by which it can improve its product.

How do they work?

Ecosystems can and will take a variety of forms, but most can be broken down into those that are: (1) patient – pharma; (2) pharma – third-party provider; or (3) patient – pharma – third-party provider. Starting small, ecosystems will rapidly and continually grow in terms of both number of participants and the number of connections between them. Within these linkages, information flows between two or more connection points, providing each actor with data to which they would not otherwise have access. These actors may be grouped around entities – such as a pharmaceutical company, telemedicine organization or a health tracker all working to treat a specific patient – or around therapeutic areas – as with multiple pharmaceutical companies operating in tandem in distinct stages of the treatment process. As outlined in "Progressions 2018," these ecosystems can themselves be interconnected, with data shared among partners that can create value. Ecosystems typically have a digital foundation and rely on new digital tools to capture and share information that was previously not captured. These tools can take the form of smartphone applications that collect health data or complex logistics techniques that allow a warehouse in Germany to track inventory, ensuring uninterrupted supply.

Most ecosystems therefore rely on specific digital capabilities to function, with data management, security and analytics as key areas of system development. Other aspects of digital technology, such as machine learning and artificial intelligence for processing large sets of health care data and converting them into meaningful insights, are also components of ecosystems. These tools have already been deployed in telemedicine and patient communication, where innovations such as chat bots are facilitating the development of patient-hospital ecosystems.[16]

16 Interview with a senior executive from a Swiss pharmaceutical company.

Becoming part of an ecosystem – buying or building capabilities

Taking an active part in the creation and evolution of an ecosystem requires that pharmaceutical firms take advantage of new digital tools, many of which fall outside of their core competence. Pharma companies are therefore forced to use one or a combination of three different models for ecosystem creation: (1) to purchase firms with those capabilities or license their technology so that they house the system, (2) form partnerships or joint structures with firms capable of producing an ecosystem or deriving value from its data or (3) develop their own internal capabilities.

Forming a strategy

Before elements of, or enablers for, an ecosystem can be built or bought, however, firms need to first identify in which areas they would like to pursue their role in an ecosystem and where they would like to derive the most value from it. Many firms in the pharmaceutical sector in GSA have expressed an interest in leveraging ecosystems around patient data and activation, but before those systems can be of any strategic value to the firm, or produce meaningful material benefits, the long-term objectives must be well defined. This takes the form of a strong strategy for ecosystem engagement, which outlines a company's focus, as well as the tactical steps it can take to achieve its goals. This type of clear strategy will then help to guide ecosystem participation and help the firm derive the most value from the ecosystems it creates, by minimizing duplication of effort and enabling easier management decisions.

Firms seeking to actively take part in ecosystems without a clear strategy or purpose will find themselves deriving less value from those investments, as value creation within ecosystems largely hinges on having a clear vision for how to use and incorporate them.

Licensing and M&A – buying what you cannot build

When attempting to leverage ecosystems using the tools or knowledge of a third-party provider, licensing technology or purchasing the firm that creates it are two of the most common solutions pursued by big pharma.

Licensing technology – the software as a service model

Licensing software can be the least intensive and often quickest path toward ecosystem participation. As smaller firms and major health care providers develop their own elements of ecosystems, pharmaceutical firms will be increasingly able to license software technology, either by paying royalties for its use or by gaining exclusive rights for its use within a particular health care area. This produces a more flexible licensing model than those previously used for pharmaceuticals, as the technology lends itself to differential pricing depending on the frequency of use and number of users.[17]

Many of these new licensing models will be put into practice with the involvement of nontraditional health care firms, given that start-ups, technology companies and financial institutions are all interested in providing services to pharmaceutical companies in the GSA region.[18] For life sciences firms, partnerships are likely to develop in areas outside of their traditional competence, particularly in the storage of, and access to, big data, as well as in artificial intelligence. Platforms such as IBM Watson Health are early examples of the likely model for partnerships.[19]

Partnerships have flourished in areas such as storage and analysis of large data sets.

Selling services that facilitate the active engagement in ecosystems can be regarded as a novel, secondary business model, fueled by a growing number of companies seeking to take on more active roles in their respective ecosystems. German firms such as Siemens are already in the process of making this transition, with the Siemens Healthineers platform designed to facilitate information sharing

17 A. Dodt, "Lizenzen, Rechte und Geld," *Medizin Elektronik*, 12 September 2016.
18 M. Kröher, "Können Daten Wirklich Heilen?," *Manager Magazin*, 21 September 2016.
19 A. Norman "Your Future Doctor May Not be Human. This is the Rise of AI in Medicine," *Futurism*, 21 January 2018; M. Kröher, "Können Daten Wirklich Heilen?," *Manager Magazin*, 21 September 2016.

between different third-party providers.[20] This platform already has more than a half-dozen partner organizations, and other major pharmaceutical firms are likely to imitate the approach as they attempt to position themselves as intermediaries in data transfer, creating a new business model in the process.

Mergers & acquisitions – absorbing market entrants

M&A provides another means of assuming a more active role in ecosystems, as pharmaceutical firms seek to incorporate new technologies built by smaller, more agile and disruptive firms. In the pharma sector, M&A activity has shifted away from traditional research-based organizations toward firms that provide new digital products, data and tools that help large pharmaceutical organizations either better control internal functions, manage and analyze data, or interact with consumers.

In the GSA region, Merck KGaA, Novartis, Bayer, Fresenius and Roche are investing in firms that possess digital capabilities that can be used to drive additional value for the patient. The purchase of MySugr by Roche is an example of this type of ecosystem absorption. By purchasing the firm, Roche gained a complete ecosystem for type 1 diabetes care and can now leverage the capabilities of MySugr to help it develop similar tools for other disease areas.

As the value of active participation in ecosystems becomes more abundant and acknowledged, M&A activity will become a key enabler to rapidly achieve a meaningful position. Joe Jimenez, former CEO of Novartis, has described data ownership as the key to obtaining power within the system, and firms such as IBM have invested billions on acquiring firms that compile patient information data.[21] This is not yet a major trend within the GSA health care market, as concerns over data privacy have minimized the financial gain of such ventures, but it is likely to become a key driver as access to data becomes more valuable with the continued development of ecosystems.

Pharmaceutical companies within the GSA region, such as Novartis, are also starting to implement new funding models for smaller firms, with the use of venture capital a growing trend.[22] In this area, life sciences firms face strong competition from nontraditional players such as Google, with its investment arm, Google Ventures, investing roughly half its capital into health technology firms.[23]

Forming partnerships

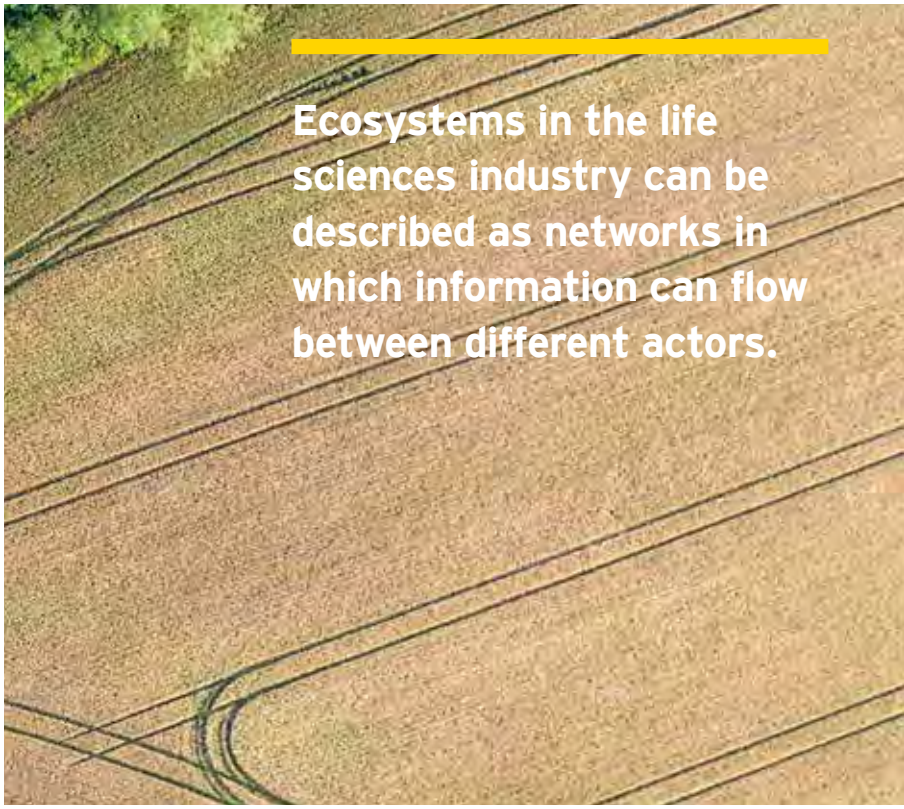
While licensing and M&A activity allows firms to own large components and control significant portions of an ecosystem, partnership models are yet another way of securing additional skills, capabilities and access to wider ecosystems.

These partnerships, such as the arrangement recently established by JP Morgan, Amazon and Berkshire Hathaway, create new entities that invest in ecosystems. This archetype of ecosystem engagement is used in two distinct ways as firms define more clearly which areas of the ecosystem value chain they intend to control. First, firms use such partnership models when they seek to actively engage in an ecosystem, making it a useful approach for topics deemed of interest, but not critical to

20 Siemens, "Siemens Healthineers will mit einem digitalen Ökosystem die Digitalisierung der Gesundheitsversorgung Voranbringen," *Siemens Healthineers Press Release*, 20 February 2019.
21 "Digital Disrupters Take Big Pharma 'Beyond the Pill,'" *Financial Times*, 24 April 2017.
22 S. Neville, "Pharma turns to big data to gauge care and pricing" *Financial Times*, 11 July 2017.
23 S. Baum, "Report: Alphabet venture arm GV, Khosla Ventures claim top sports in health care investment ranks", *MedCity News*, 6 July 2017.

the firm's strategy. Second, firms can also use this approach when working with large and established players, as M&A activity or an exclusive licensing deal is less likely to be available. Thus, such models give pharma companies access to the knowledge of other firms and allow them to tap value from their ecosystem involvement.

This can be seen in Novartis's partnership with Science 37, which has seen it create a platform for the development of 10 "site-less" clinical trials and plans to use the type of digital tools, such as wearable technologies, set to become staple components of many health ecosystems.[24]



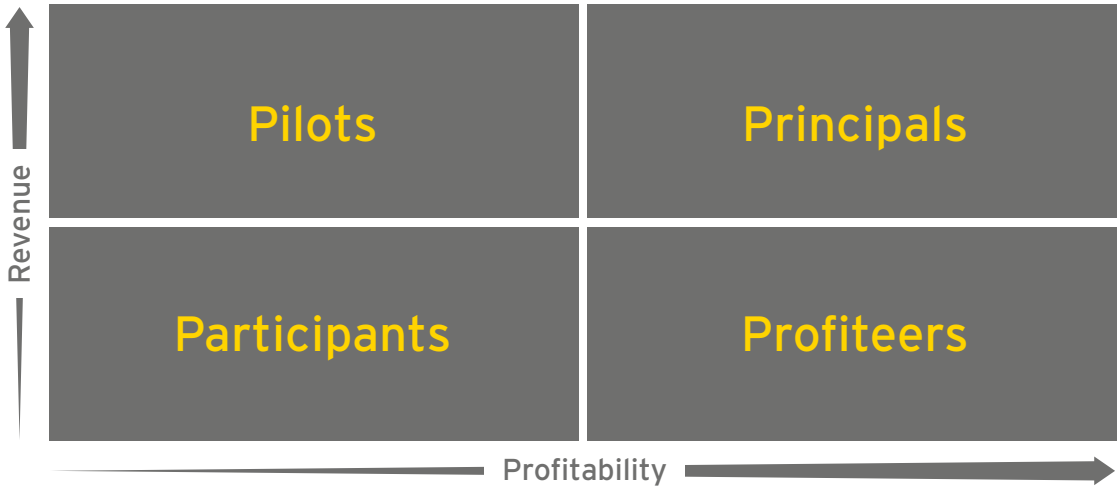
Ecosystems in the life sciences industry can be described as networks in which information can flow between different actors.

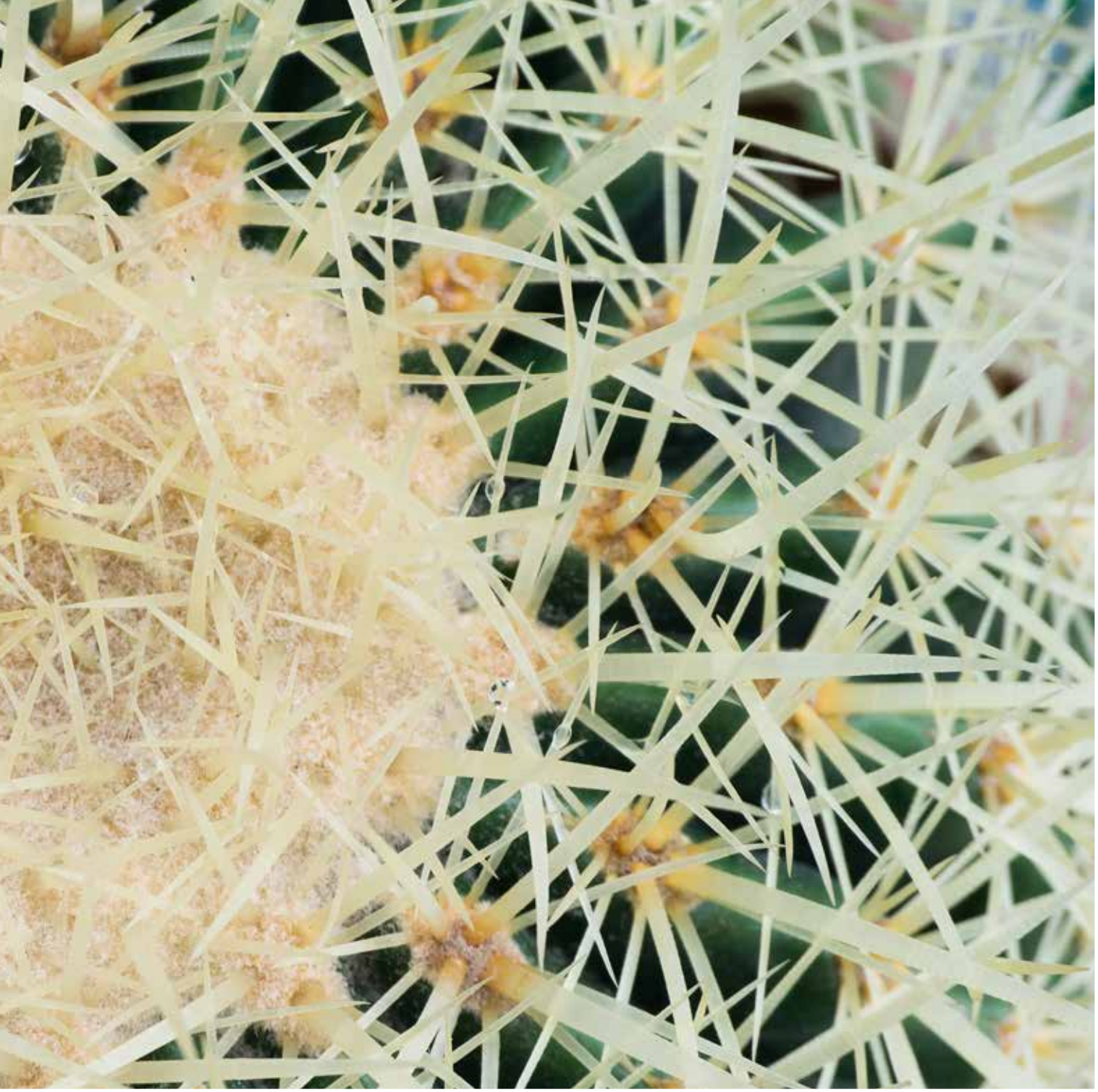
24 B. Adams, "Novartis becomes deeper Science 37 partner, as pair aim for 10-trial launch," *Fierce Biotech*, 7 March 2018.

03

Choosing a strategy – how to manage and invest in ecosystems

Graphic 1: Positioning in the ecosystem

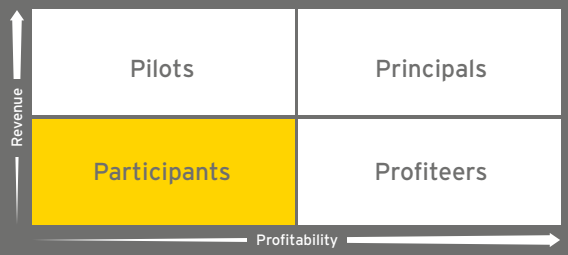




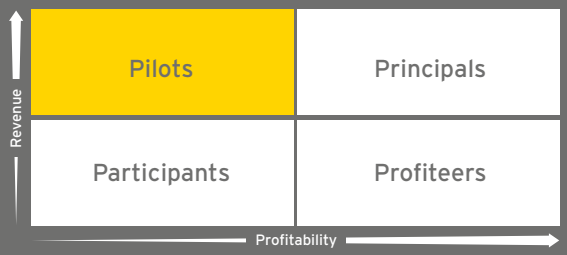
Ecosystem strategies can be gauged upon two axes – the ability to drive revenue and improve profitability – thus creating a matrix that displays a firm's position in relation to how it leverages ecosystems. Revenue is an indication of the mastery of systems and value they create, with firms that invest in systems more likely to tap revenue streams from their use. Profitability indicates the management of processes and systems, allowing the organization to fully align existing capabilities to improve efficiency and exploit synergies (Graphic 1).

This matrix thus allows firms to locate their strategic alignment within one of four groups based upon the assessment of their role in ecosystems: Participants, Pilots, Principals and Profiteers.

Success for Participants is about remaining focused on their core business and its unique advantages.



Pilots achieve success by partnering their internal capabilities with the skills of external partners or newly purchased entities, using their knowledge and experience to influence a wider share of an ecosystem.



Participants – going with the flow

At a minimum, players are Participants in one, if not a number of, ecosystems. Often, firms in this position create customer value using specialized intellectual property and monopolistic positions, e.g., a blockbuster innovation protected by a robust patent. While this positioning might be reassessed over the course of the life cycle, Participants thriving in a wider ecosystem can find themselves in a comfortable and highly successful role from a commercial perspective.

Success for Participants is about remaining focused on their core business and its unique advantages. This is a non-capital-intensive approach, which favors being involved in the system without taking an active role in its development. Nevertheless, Participants often build solutions that utilize existing capabilities of other ecosystem players in a limited and pre-defined way, thus trying out concepts and learning how a more active role in the ecosystem could be of value.

Firms decide to settle for a Participant strategy when they do not see the value added of a more active role in an ecosystem as a driver of revenue or profitability. The ecosystem is simply the environment for existing business activities and a means to meet the linear demands of known other actors.

The benefit of this strategy is that it keeps firms nimble and able to adjust to new developments quickly, while freeing up capital and management to focus on other areas of development. Typical Participants are, e.g., companies that produce and supply intermediates and are therefore able to feed on linear one-to-one relationships at reasonable costs, or companies with a clearly established and protected USP. This has thus been the typical strategy of big pharma in the past era of blockbuster drugs.

Pilots – testing the top line

Firms that still rely on their core business, but have started singular initiatives or satellite projects to test opportunities for revenue generation and growth through more active collaborations in ecosystem creation, can be regarded as Pilots.

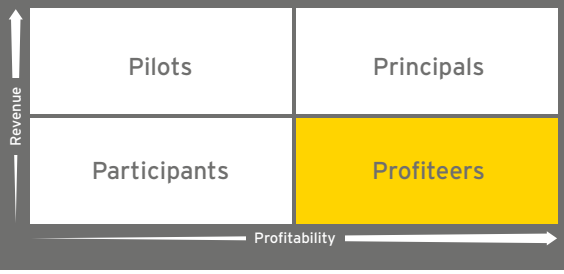
Success for Pilots is about venturing out beyond the classical product focus toward developing solutions that allow them to cover a larger part of an ecosystem. These firms contain silos of ecosystem exploration and engagement, and use them to produce value in handpicked business areas. This is achieved by partnering their internal capabilities with the skills of external partners or newly purchased entities, using their knowledge and experience to influence a wider share of an ecosystem. While these satellites may contribute to revenue, the lion's share of the firm's business is carried by traditional business models.

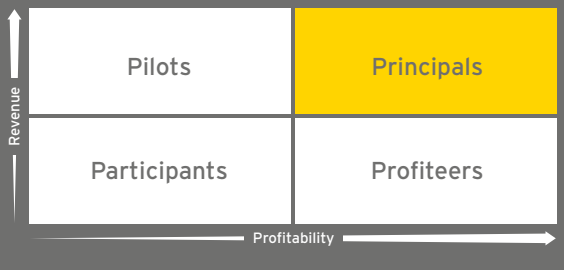
Firms seek to use this strategy if they identify areas of an ecosystem that are strategically important yet beyond the scope of their internal capabilities. This strategy allows for selected development, with companies able to define which processes are critical and warrant investment.

The benefit of this strategy is that it allows firms to balance ecosystem engagement and risk by limiting the scope and depth of active ecosystem participation. Typical Pilots are innovation-driven companies faced with patient needs in a complex environment and seeking to move beyond their linear business ties. Otsuka's partnering with Proteus to develop Abilify MyCite, an antipsychotic medication with a microprocessor integrated in the pill and read out by a sensor and an app, is a good example of a traditional pharma company acting as a Pilot by setting up such an ecosystem.

Success for Profiteers lies in identifying and using partner organizations to provide the services needed to complement traditional business activities.

Long-term value for Principals is the ability to replace the falling value of stand-alone pharmaceutical products with the value encapsulated within integrated systems.





Profiteers – driving efficiency

Profiteers are focused on maximizing the gains from business processes and do not seek to develop ecosystems themselves, but instead to manage their use as a means of ensuring higher levels of profitability. These companies possess strong management capabilities and an understanding of how elements of an ecosystem can be selected, used and switched to complement existing practices, although they choose to focus resources on their traditional value-add within the sector. Profiteers thus rely on partners to help them efficiently pursue their business, improving profitability without significantly impacting revenue generation.

Success for Profiteers lies in identifying and using partner organizations to provide the services needed to complement traditional business activities. Profiteers take advantage of the skills of others – e.g., a variety of contract manufacturing organizations, through partnerships or service models – and do not engage in M&A activity or large capital investments. This is a non-capital-intensive approach to ecosystem engagement. Instead, it requires firms to actively oversee the use of opportunities within an ecosystem in order to drive more profitable outcomes.

The benefit of the strategy is that it allows companies to make use of their role in an ecosystem to reduce cost, without this involvement becoming central to creating value. Typical Profiteers include generic manufacturers and over-the-counter producers whose core operations focus on bottom-line optimization. Their engagement in ecosystems is thus motivated by efforts to capture meaningful commercial and supply chain savings, helping these firms to stay competitive.

Principals – securing sustainable growth

Principals drive the interconnectivity and evolution of ecosystems through their business and management capabilities. These firms possess a strong vision of how ecosystems can be leveraged across functions and have implemented initiatives in most, if not all, areas of the firm that are generating measurable returns.

Success for Principals is a function of the uncompromised focus on customer needs, the continual drive for innovation and the agility of ecosystem-focused management and process capabilities across the organization.

To succeed with this strategy, firms must possess a unified vision for, and understanding of, the ecosystems and be well positioned to manage complex systems. Firms must also have the capacity to design, drive and adapt processes to fit cross-functional purposes. This continual learning experience is an investment- and management-intensive approach toward the creation of value.

The benefit of the strategy is that the journey never comes to an end, for true Principals never stop creating and pursuing new opportunities in known and unknown ecosystems. As Principals seek to own the areas of value creation within ecosystems, the long-term value of this strategy for firms is the ability to replace the falling value of stand-alone pharmaceutical products with the value encapsulated within integrated systems, which leverage health data to improve the outcomes produced by traditional medications.

An ideal Principal is thus a major pharmaceutical and health care company that can increase the value of its products and services by improving its connectivity and leveraging health data to lower costs in drug creation and in delivery of personalized services. Currently, at a time of conscious and systematic exploration of ecosystems by the pharmaceutical industry, the Principal remains beyond the immediate reach of most players in the

industry. Some companies, however, have started moving in this direction. For instance, one company headquartered in GSA is active in pharmaceuticals, MedTech, hospitals, home care and adjacencies. This allows it to continually increase the coverage of indication-specific ecosystems on the one hand and to network into new ecosystems beyond its own reach on the other.

Evolving engagement in ecosystems – from Participants to Principals or Profiteers

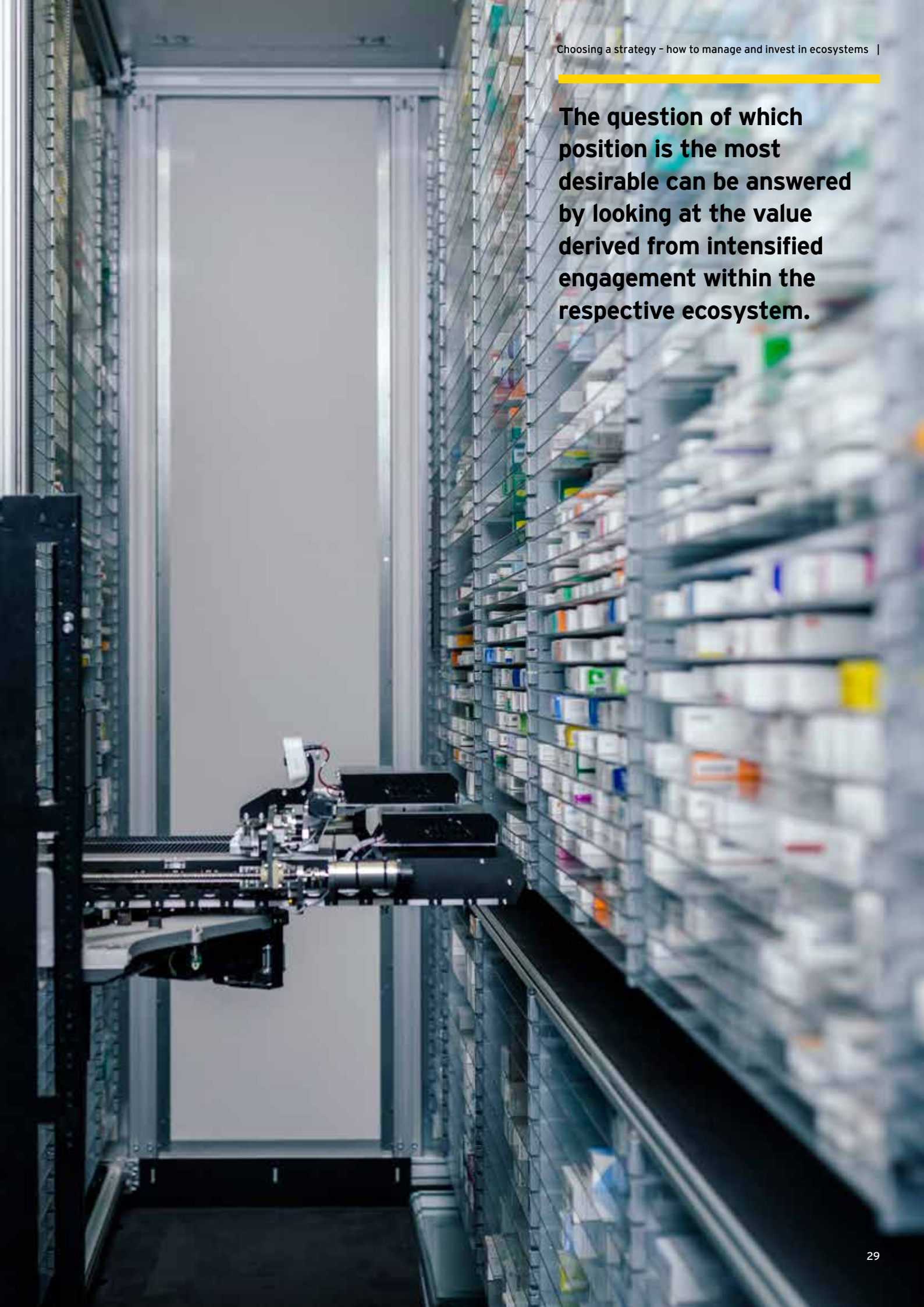
While these strategies each represent potentially sensible roles for life sciences companies to take on in an ecosystem, companies embarking on the journey to engage in ecosystems almost universally do so from the position of a Participant. From that entry point to ecosystem engagement, two pathways emerge for firms wishing to adopt other potential strategies.

The question of which position is the most desirable from a strategic and, ultimately, commercial point of view can be answered by looking at the value derived from intensified engagement within the respective ecosystem.

The strategic decision to explore top-line gains from ecosystem engagement will let firms screen, define and pilot individual activities targeted at connecting with partners beyond their initial remit, making them Pilots. Based on successful pilot projects and the ambition to multiply this success, while making the additional revenue sourced from these collaborations profitable, companies can move toward becoming Principals. The objective of this development is to create a sustainable and adaptive stream of both revenue and profit, which can be materialized even if the company's initial product or service offering remains unchanged.

Conversely, firms can also choose to continue to focus on traditional operations and only use these systems as a means of creating efficiency gains. This ambition leads to a transition from Participant to Profiteer, with firms that adopt such a strategy unlikely to make any further realignment toward the Principal position, given the sizeable gap in investment between Profiteers and Principals in terms of ecosystem engagement and development.

The question of which position is the most desirable can be answered by looking at the value derived from intensified engagement within the respective ecosystem.



From left

Jürgen Peukert
Partner, EY Life Sciences Advisory Leader
for GSA
Ernst & Young GmbH

Sebastian Graf von Strachwitz-Helmstatt
Partner, EY Life Sciences Advisory
Ernst & Young GmbH

To what extent do you see the need for a value- and outcome-based approach changing the traditional pharmaceutical business model?

Sebastian Graf von Strachwitz-Helmstatt: Pharma 1.0 to Pharma 3.0 can be seen as a transformation from a blockbuster- to an outcomes-based model. We are, however, entering a new decade of change, as patients will become the primary drivers for the pharmaceutical industry as they gain access to new capabilities and treatments through ecosystems. These ecosystems will drive value for patients by supplying the information necessary to provide them the right diagnostics and treatments. In the past, pharmaceutical companies simply prepared individual products and ran them through the supply or value chain and on to the patient. In the future, they will need to create a solution and value around this information flow in order to meet patient needs. What is key here for companies seeking to accompany this transition is the technology and digital assets that pharmaceutical companies need to gather and analyze the necessary information.

How is growing demand for the capability to analyze and manipulate large data sets impacting how pharma firms invest, partner and engage with the marketplace?

Sebastian Graf von Strachwitz-Helmstatt: Data is the new gold in the pharma industry, particularly as pharma players define what information they need to know and how to engage with the stakeholders, patients and care givers involved. The challenge is to run a business that turns data into information that is relevant to continually optimizing the business approach and creating value for the patient, which means having the right algorithms, analytics and sales channels. With this in mind, current initiatives are helping life sciences players to define business models and an approach to turn data into actionable information. At EY, we use a data platform called Embryonic in our life sciences projects, which is a cloud-based platform that utilizes proprietary algorithms to read millions of data points, to visualize financial and non-financial relationships between traditional and innovative disruptive business. We have found that the industry is still struggling to find answers to key questions, such as what information is needed to play an active role in an ecosystem, how to capture and share the relevant data and how to interpret the algorithms to understand its value in order to make the right decisions.

Analytics has become – together with AI – a continual learning process. It is a cycle, a self-developing routine, which needs to be adjusted and carefully monitored to generate the right information. This has implications for traditional business activities as well. As digital sales channels supplement traditional channels, individuals such as sales representatives will have the ability to choose and interact with health care practitioners in a more intense way than in the past, targeting specific practitioners and creating unique ways for them to improve service offerings for their patients. That is what data analytics can help with, and companies need to make it a routine process within the organization. But this will take time, it cannot be done from one day to the next.

What can pharma companies do to make themselves more capable at managing these systems so that they end up as the dominant partner or leader of these new ecosystems?

Jürgen Peukert: As the transformation from a "solo player" to a participant or orchestrator of an outcomes-based ecosystem is a complex endeavor, there are different aspects to be considered: first, the strategy and cultural impact; second, capital allocation and capability building; and third, organizational readiness and evolution.

Interview

On the one hand, it is about the strategic positioning of firms over time, about the health-outcomes that consumers, patients and society want to drive, with aligned ecosystems building new revenue streams and platforms. On the other hand, it is about defining how much to invest into the traditional business model, how to protect the key capabilities in its R&D, market access and commercial execution layer, and whether and how this "traditional business" is threatened by upcoming ecosystems, rather than just traditional competitors.

Irrespective of which pathways you look into, some of the most complex questions that need to be answered are how to drive health outcomes, which information is essential and how to capture data along this process – to engage with consumers and patients. You also need to know what to do with the insights from data so that you can create value by making products and services that improve health and wellbeing from the perspective of individuals and society. As we outlined in our study "Progressions 2018," EY believes that there will be different archetypes of company service, with some players still serving as the breakthrough innovators, others as lifestyle managers, others still as organizations active in acute "industrialized" treatment and chronic diseases – often referred to as "disease managers" – and some focusing on efficient production and availability in the market. Most of them, if not all, will be connected through digital platforms as enablers. So, as a first step, it really comes down to the strategic positioning, as all of those companies currently are more or less product-related innovators. But if we take a closer look, we find that the scope of transformation is much broader.

The transformation to ecosystems and related platform businesses means a completely new world for business development and licensing, and for strategic marketing and commercial operations, as much as for IT, compliance and risk management – and last but not least, for tax and accounting. The impact is going to cut across all divisions and functions, and extend beyond the firm, possibly also leading to alliances with other life sciences players and in many cases with players from other industry sectors, such as technology, financial services and insurance companies. This new world is outside the traditional business and experience most big pharma companies have. This means that the issue will need to be considered from an organizational readiness perspective, not to forget culture and change: how to make a deal happen, how to design contracts accordingly, how to execute initiatives in a way that ensures that they are always compliant in terms of both patient safety and data security, how to share insights and value to maximize the benefits for all relevant stakeholders. These are all questions that firms need to be prepared to answer so they can define how they intent to set up, operate and optimize their organizations.

Many organizations have already understood that they might not be able to tackle this transformation in a traditional way. Different organizations are adopting distinct responses to their own respective challenges, without a standard pattern emerging. The transformation needs to be purpose-led and is about creating value for everyone who "docks onto the platform" – value for society in the form of a perceptible improvement in health outcomes and a better working world.

Are there aspects within the internal culture of pharmaceutical companies that need to change for them to properly come to grips with what these systems will mean?

Jürgen Peukert: Yes! Even if a life science player has the right strategy, understands the best-fitting organizational set up and capabilities needed, moving into connected, platform-based ecosystems is still a huge step that entails significant change. More than this: it leads to a new culture as companies are on a journey to consider and implement diversity in many dimensions – some of which are even subject to reporting and legal requirements. It is the ability to collaborate beyond companies and borders that will prove critical. The purpose of what they are doing in an orchestrated ecosystem becomes a company's foundation.

Understanding the purpose and translating this into the organizational DNA is essential. Traditional KPIs need to be adjusted and redesigned to a certain extent, both within firms and the wider ecosystem, and this will have a significant impact. It is important as well to be transparent, as this will be another source of value creation, given that data delivers the evidence for the outcomes. Such evidence of outcomes is needed to engage stakeholders as proof of value of relevance to patients. The key challenges are transparency, KPIs and the diversity that is needed to form well-functioning ecosystems, as success is not only about the right organizational model and its agility. What you measure is what you get.

04

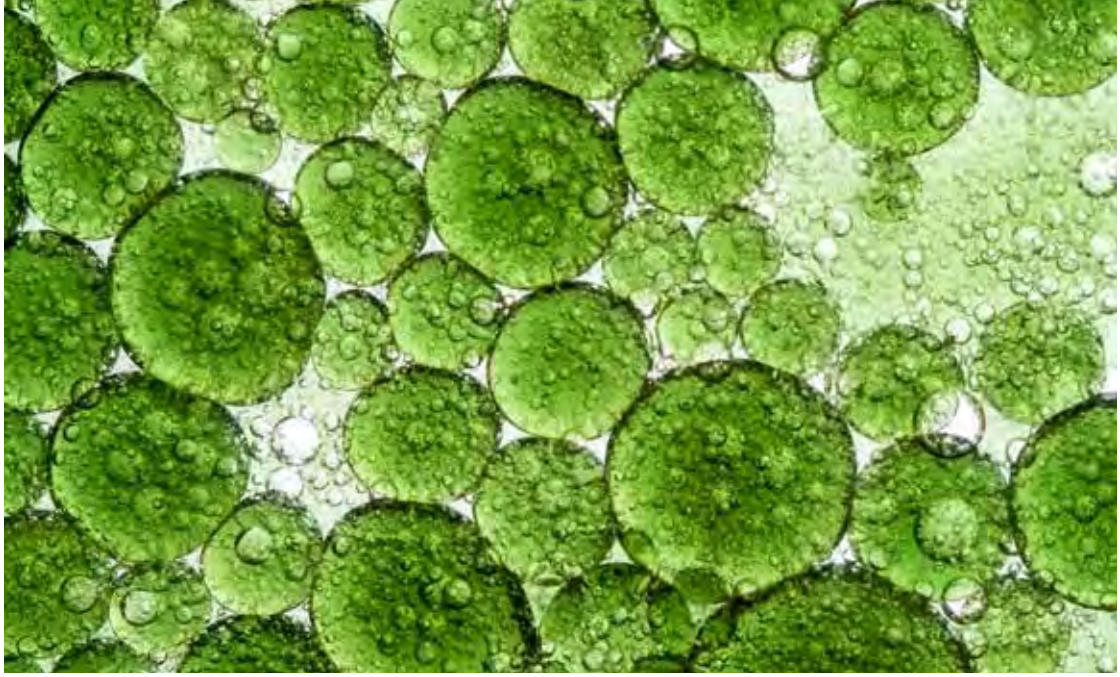
Enacting strategies: current pharmaceutical ecosystem development in GSA

Analytics, artificial intelligence, robot process automation – disruptors are most successful entering the market. And non-pharmaceutical firms are making long-term bets on their future success in the health care sector.

Pharmaceutical companies throughout the GSA region are currently at different stages of development of ecosystem involvement, with some already having clear ecosystem penetration strategies, while others still prefer to merely participate without proactive engagement. There has thus been no unified model within the region on how to best leverage ecosystems based upon individual capabilities and needs.

As well as using the above matrix to assess the current progress in the GSA pharma sector from the perspective of the pharmaceutical firms themselves, ecosystem development can also be seen from the perspective of new market entrants.

This section will thus not only look into how and where established firms are engaging with ecosystems, and what that says about the strategies they are currently using, but also where disruptors are most successful at entering the market, and where non-pharmaceutical firms are making long-term bets on their future success in the health care sector.



Big pharma – a plurality of strategies to engage with ecosystems

Large pharmaceutical companies have traditionally operated in the health care space unopposed, by specializing in different therapeutic areas. The drive for improved patient outcomes has changed that by creating space for new technologies to be utilized in the development and delivery of treatments. The sector can now be divided into areas where the role of traditional pharmaceutical companies is largely unchallenged, those that are so innovative and uniquely disrupting the market that they compensate for the first-mover advantage of the existing firms, and areas that sit between the two. This raises questions about which type of firm will achieve the greatest market share.

Clinical trials and commercialization strategies are an area of relatively advanced ecosystem engagement.

Areas of greatest success – where the role of drugs cannot be replaced

As the dominant market force within the industry, pharmaceutical firms within GSA have been able to see this transition coming and have, in some areas, adapted to these market shifts. Through a mixture of organic growth, establishing partnerships and aggressive investment, firms that have embraced the Pilot, Profiteer and Principal strategies have attempted to leverage their market position in some way into a competitive advantage, predominately based around their existing structural advantage, which is the research, supply chain and commercialization.[25]

The areas that have seen the greatest investment and development from traditional firms are clinical trials, patient outreach and other commercial improvements, and methods of production and distribution, with ecosystem silos in this area a hallmark of Pilot firms, while Profiteers have made the greatest use of managing partnerships responsible for the development of these functions.

R&D: Bringing digitization to clinical trials

Ecosystem development is relatively advanced in clinical trials, especially among large pharmaceutical firms in the GSA region, with many firms using a Pilot approach. Already, 9 out of the 20 largest pharmaceutical firms, including Roche and Novartis, have electronic health partnerships to track patient data (including those within clinical trials), allowing them to begin using advanced analytics. This can potentially provide a stepping stone to the development of personalized medicine as ecosystems advance.[26] Firms across the region have a stated objective of using real-world evidence (RWE) as inputs in drug development, and appear to be relying on a partnership model in order to help establish the ecosystems necessary for the capture and use of that data.[27] These ecosystems are now allowing them to better identify the best-suited patients for clinical trials through enhanced site selection, while also allowing remote monitoring of patients, making clinical trials more flexible and efficient.[28] Investigator-sponsored trials, which allow firms to incorporate the clinical work of other groups to help improve patient outcomes, have also emerged through the creation of trial ecosystems, as has the use of innovation hubs to help pool pharmaceutical knowledge from smaller firms. While still underutilized, both represent recognized areas of ecosystem potential.

25 Interview with a senior executive from a Swiss pharmaceutical company.
26 M. Kröher, "Können Daten wirklich heilen?" *Manager Magazin*, 21 September 2016.
27 "Optimizing Clinical Trials with Digital Technology," *Sanofi*, 26 January 2018.
28 M. Alsumidaie, "Novartis Brings Digital Patient Centricity Trials," 12 April 2017.

Within the realm of clinical trials, the majority of firms have adopted Pilot strategies, as these systems remain isolated and often draw on the management capabilities of partner organizations. As a result, their R&D functions benefit from improvement in the clinical trial completion rate, while accelerating the process. The CEO of Novartis, Dr. Vas Narasimhan, believes that these technologies could reduce drug development costs by 10-25%.[29]

Many firms are aiming to transition from a Pilot approach in R&D toward a Principal strategy, as these systems will ultimately represent large cost savings for firms also beyond R&D by complementing companies' functional areas in adjacent functions such as manufacturing, medical and commercial.

Commercialization: Connecting with patients and partners – activating customers and consumers

With the exception of Profiteers, firms are beginning to use their status as the provider of pharmaceutical products to increase their profile and outreach with patients, an area where they have traditionally had a relatively minor footprint.[30] Pharmaceutical firms within GSA now have electronic portals and applications that manage patient communication and physician journey and deliver health advice to the customer, opening up a new data stream for firms to access in their drive to improve patient outcomes.[31] These interactions are also used as a means of steering patient behavior to more refined methods of treatment and serve as a key form of patient activation.[32]

These initiatives to reach out to patients and consumers form the basis for developing more advanced outreach-insights conversions through the application of robotic process automation (RPA) and artificial intelligence (AI). Critically, though, these initiatives tend to be developed in-house and owned by the respective firms, representing a different method of engagement and management compared with clinical trial ecosystems. As an example, simple automation of commercial dashboards might be enhanced with the help if external technologies and algorithms available in the ecosystem.

Firms within the GSA region have yet to fully monetize patient outreach programs, with companies in each strategy quadrant choosing instead to focus on qualitative metrics, such as patient activation and retention, for now.[33] However, monetization in some form will come in time, as these applications and tools can help reduce inefficiencies in the development process or support value-based payment plans. For now, however, these applications remain non-promotional, are designed to improve internal and external processes and are not driven by revenue goals.[34]

Initial efforts by other commercial functions to leverage ecosystems can also be seen, with risk sharing agreements and innovative pricing models being explored by European pharmaceutical companies, including those located in GSA. Access to those ecosystems for wider commercial functions, such as sales and marketing, however, often requires the management of multichannel communication, and as an area where internal capabilities and experience is limited, this access tends to be constrained. Though such structures are still in the early stages of development, and only in sporadic use, the willingness to pursue multichannel promotional communication by Pilot firms demonstrates belief in the potential of ecosystems to create commercial value.

9

out of the 20 largest pharmaceutical firms already have electronic health partnerships to track patient data.

29 "Novartis's new chief sets sights on 'productivity revolution,'" *Financial Times*, 25 September 2017.
30 Interview with a senior executive from a Swiss pharmaceutical company.
31 D. Tryler, " Roche Acquires Digital Diabetes Management Platform," *PMlive*, 4 July 2017.
32 Interview with an Austrian executive at a major European pharmaceutical company.
33 Interview with a senior executive from a Swiss pharmaceutical company.
34 Interview with a senior executive from a Swiss pharmaceutical company.

Upstream processes have been prioritized over downstream efficiency gains.

Supply chain: Preparing for the rise of robots

Ecosystems engagement can already been observed in the upstream aspects of pharmaceutical production and distribution, with firms investing in the technology to create inputs digitally, and to monitor the production and distribution cycle in real time.[35] This use of Automation 4.0 technologies and aspects of lean logistics represents a step forward in the planning process, if not the actual methods of production. However, the modification of production mechanisms has yet to occur, with the upstream process prioritized over downstream efficiency gains in internal systems.[36] This again illustrates the appetite of firms to explore Pilot strategies, while the systems remain siloed and are not yet driving value across multiple business segments. For Profiteers, such as over-the-counter producers and generics companies, this is an area where ecosystems involving contract manufacturing organizations (CMO) have taken on more management intensity.

To create upstream tools, firms have not only relied on the development of internal capabilities, but are also partnering with businesses specializing in software development. Downstream tools, such as smart delivery methods and, ultimately, continual manufacturing capabilities, will all become areas of investment for Pilots and Profiteers, but as of yet, are not areas of significant internal development for the industry as a whole due to their capital costs. The widespread development of Principals, therefore, cannot be expected at present.

The upstream concentration of investment for ecosystems, and its prioritization over downstream tools, is particularly important, in that it is indicative of a key trait of current GSA pharmaceutical practice: the propensity for non-capital-intensive investments.

Fitting into the matrix – many Pilots, few Principals

The current methods and direction of development sees the majority of firms within the region using the strategies of Pilots: while some have made significant investments into strategies and tactics to engage with ecosystems, few firms have demonstrated robust internal management capabilities to derive maximum value, and thus profit, from these systems, placing them on the left-hand side of the matrix.

Although firms within the GSA region have shown varying degrees of readiness to adapt to and engage with ecosystems, significant room for growth exists in systematically embracing ecosystem engagement in areas of strategic importance as well as in driving the convergence of different pilot strategies with the aim of approaching a Principal position. Pharmaceutical firms thus face the challenge of both increasing their level of ecosystem penetration, particularly in areas of strategic value, while also managing the use and maintenance of the systems internally to maximize their potential.

The importance of this cannot be understated, as a key strategic goal for the industry is already being left unmet by the current level of ecosystem penetration and management.

35 Interview with a senior manager at a German pharmaceutical firm.
36 Interview with a senior manager at a German pharmaceutical firm; interview with a senior executive from a German life sciences company.

Nontraditional players

The market is increasingly opening to new competitors that look at the health care space from a different angle, based upon mastering the techniques of health care analysis, but without a background in health care itself.[37] Nontraditional pharmaceutical firms are seen particularly in the areas of preventive health care and chronic diseases.[38]

Breaking into the business

While the traditional business model of the industry is built around uniform products, disruptors are already relentlessly focusing on delivering pharmaceutical outcomes created from personalized therapeutics, which are powered by advanced analytics and methods of production that allow for small batch manufacturing, such as continual manufacturing and smart delivery methods. Regionally championed by firms such as BioNTech, which has already raised near €800 million in funding, these firms seek to challenge the traditional production methods of the industry and aim to deliver improved outcomes from increased patient data inputs.[39]

Disruptors have also adopted a model of providing non-drug-based therapies. Centered around software applications to provide advice, monitor a patient's health or access health care professionals, this model is seeing firms navigate around traditional health care organizations. Within the GSA region, start-ups, such as those located within the Health Innovation Port, are making significant strides in this area.[40]

The last business model that is beginning to emerge from nontraditional players is health care analytics. As patient data is collected through the diffusion of digital tools throughout the health care system, firms that specialize in interpreting that data are entering the market and either selling their expertise to established firms that own substantial amounts of patient information or partnering with organizations actively using that data to treat patients. These new entrants are new species to the ecosystem and enrich the choice of skills, capabilities, technologies – and potential partners for established players. Globally, funding for firms operating in this space reached US$1.1 billion in 2017, demonstrating the belief in their future market potential.[41]

Beyond the pill

As pharmaceutical companies are not yet fully used to working "beyond the pill," the influx of new firms in nontraditional areas has disrupted not only the wider health ecosystem, but also the activities of pharmaceutical firms.

In areas surrounding the pharmaceutical industry, this has already taken place in the realm of telemedicine, where regional insurers such as Allianz are investing in the digital procurement of health care services, and regional start-ups such as Clucare are working on chat bot functions that can arrange appointments for users with medical professionals.[42]

Advances have also been made around chronic diseases through prevention mechanisms such as nutrition and behavioral tools.[43] Applications already exist that allow patients to monitor their blood levels and regulate the flow of drugs to optimize their treatment regimen.[44]

Centered around software applications to provide advice, monitor a patient's health or access health care professionals, this model is seeing firms navigate around traditional health care organizations.

37 M. Alsumidaie, "Novartis Brings Digital Patient Centricity Trials," 12 April 2017.
38 Interview with a senior executive from a German life sciences firm.
39 "Europe's biggest private biotech company raises $270 million," *Reuters*, 4 January 2018.; USD to EUR conversion of .832663 was used, https://www.xe.com/currencyconverter/convert/?Amount=1&From=USD&To=EUR.
40 The Health Innovation Port is an incubator for start-ups in the health technology space. Founded by Philips and based in Hamburg, its aim is to help develop companies aiming to enter the digital health market. Interview with a senior executive from a Swiss pharmaceutical company.
41 L. Beaver and A. Aouad, "Digital Health Briefing: Amazon Job Posting Raises More Healthcare Speculation — Change Healthcare Acquires Ndsc — Venture Funds' Interest In Ai Grows," *Business Insider UK*, 20 January 2018.
42 S. S. Biesdorf, U, Deetjen, M. Möller, "Eine Vision für ein digitales Gesundheitssystem in Deutschland," *McKinsey*, April 2016.
43 "Wir Sind Hip," *Health Innovation Port*, 2018.
44 Interview with an Austrian executive at a major European pharmaceutical company.

This trend has manifested itself in the business decisions faced by Participants, Pilots and Profiteers, which find themselves increasingly relying on the capabilities of these firms, either as partner organizations or as targets for M&A activity. These external systems are a sign of growing competition, but also new opportunities for engaging the ecosystem, with these firms forced to either insert themselves into these externally owned systems or purchase them so that they can be internalized.

Data analytics and storage

Access to health data remains an area in which traditional pharmaceutical firms are at an advantage over new market entrants, given their longstanding relationship with patients and health care providers. Yet in storing, analyzing and using this data, large pharmaceutical firms, both in GSA and globally, are seeing their business position disrupted by the expertise provided from nontraditional players, both large and small.

Larger new entrants to this market, such as Microsoft and Amazon, have made themselves key partners for many traditional pharmaceutical firms in the GSA region by offering data storage services, allowing them to become the warehouses for health data through cloud-based technologies, which creates ease of access for practitioners and patients, among other services the companies provide.[45] IBM has also entered this space, using its Watson technology to farm out its data analytics platform and artificial intelligence capabilities to pharmaceutical firms in the region, thereby providing a key component of the new outcomes-based value chain.

New entrants have proven adept at collecting health data and attracting users to digital health platforms.

The prevalence of large technology players in this space is one reason for the heavy use of partnerships by traditional firms exploring data analytics. Major pharmaceutical companies in many instances have pre-existing relationships with these firms, which has in turn made it easier for Pilots to essentially outsource this function to the ecosystem and for Profiteers to manage processes that are undertaken by these firms. The close relationships enjoyed between large technology firms and big pharma has in many ways created the reliance currently seen by firms across this industry on external providers for data analytics.

Smaller firms worldwide are also increasingly seeking to analyze health data and are finding capital to back their efforts: Google Ventures invested roughly one-third of its resources into health analytics start-ups in 2017.[46] GSA also has experienced this market force with Verily, formerly a division within Google X and increasingly a player within this space in Europe through its work with Sanofi.[47]

These firms, both big and small, are already able to use existing patient data to determine optimal treatments, define clinical trials and identify suitable trial patients. They are serving as a critical middleman within the development and management of these systems and, in doing so, they are essential and active parts of the health care ecosystem.

Competing for patient data

While big pharma has made important gains within GSA in terms of connecting with end users and activating patients, and while some pharmaceutical

45 M. Kröher, "Können Daten Wirklich Heilen?," *Manager Magazin*, 21 September 2016.
46 S. Baum, "Report: Alphabet venture arm GV, Khosla Ventures claim top spots in healthcare investment ranks," *Med City News*, 6 July 2017.
47 Interview with an Austrian executive at a major European pharmaceutical company.

companies are not concerned about a perceived barrier in trust between themselves and patients, they have undoubtedly been disrupted by the ease with which new entrants have been able to attract patients and capture health data.[48]

Traditional players are slower to react to the demands of end users, given their large organizational structures, and have previously struggled in system design. Smaller firms have already proven skilled at adapting their platforms to fit patient demands and produce more continual change.[49] This has allowed new market entrants to become effective at releasing applications that monitor a patient's health and use that data to provide advice or direct them into different methods of treatment.

Patient activation remains an area of improvement for many within the health care industry, and one now dominated by third-party-produced applications.[50] Thus, in a marketplace where access to patient data and to the patients themselves is a key aspect of health care, the ability for new entrants to activate users quickly on the one hand is a disruptive force with long-term developmental implications, while on the other hand, it will serve as a powerful new capability at the disposal of the entire health care ecosystem.

Five key lessons for enabling ecosystems

This varied development between pharmaceutical firms and new market entrants demonstrates some important insights for how ecosystems can be enabled as they mature in the future:

- Before looking to advance and technically enable and automate an ecosystem, firms should produce a viable product that meets with the approval of patients, relevant stakeholders and partners, and obtain proof that it delivers value. This work can be "manual"; what is important is that it creates confidence in the approach taken and that the essential information is obtained from ecosystem interactions. Once proven, firms can turn to the business of advancing the platform.

- Advanced analytics and artificial intelligence are critical areas of ecosystem development and poised to be a significant source of value creation in the long term. Exploring the potential of these capabilities and identifying ways in which they can support and develop existing business operations is critical for firms, and will be key drivers to engage with ecosystems.

- The ability to store, secure and analyze patient and health data will remain a major area of value creation for pharmaceutical firms over the coming decade. These abilities will be far easier found in the ecosystem than built internally.

- Robotic process automation and artificial intelligence will not only shape manufacturing and distribution, but also sales, marketing and medical functions. Preparing for those changes, planning out investment and identifying the right suppliers will be significantly sped up through the outreach to the ecosystem.

- An easy first-mover entry point into actively engaging with an ecosystem for pharmaceutical firms is to identify a limited-scope approach around one product, be it in the area of running clinical trials, activating patients or improving commercialization.

48 Interview with a senior executive from a Swiss pharmaceutical company.
49 Interview with a senior executive from a Swiss pharmaceutical company.
50 Interview with a senior executive from a Swiss pharmaceutical company.

"Full **customer ecosystems** will probably **remain** the area more dominated by **traditional pharmaceutical companies**, potentially in partnership with major technology firms."

Sander Ruitenberg
Worldwide Franchise Digital Head,
Immunology,
Hepatology & Dermatology,
Novartis

What are you and your team currently doing to develop client facing systems and portals?

At the moment, my team is working on a chat bot program, which will use artificial intelligence (AI) in order to be more responsive in our communication with patients and to build out a full ecosystem in support of patients.

How are you engaging with technology partners, both current and potential?

As a firm, Novartis maintains long-standing partnerships with some of the large technology players, for example with Microsoft, Salesforce and IBM Watson. Within these relationships, I often look to understand where they are in their own developmental journey, and work to find the right fit for our collaboration with them within the larger digital ecosystem I am working on. As a global company, these large technology firms play an important role, as they can meet the scale an organization such as Novartis requires.

From the perspective of how I deal with smaller partners, start-ups if you like, these relationships tend to be more based around individual, and in some cases, localized, solutions. In my role within Immunology, Hepatology & Dermatology, I have started looking at some potential smaller partners, but have yet to create any formal partnerships.

When evaluating these new platforms and systems, what metrics do you use to determine their success or impact?

While, as a firm, Novartis looks at market growth and market share across all of our franchises and brands, I do not make direct links between these systems and those business metrics. I can't, and in most cases shouldn't, as it isn't in the nature of these platforms to directly impact those metrics.

My aim is to try to improve how to segment patient communities because this enables my team and I to optimize how we communicate and to improve patient engagement. I am also looking at what will allow us to use health data in new ways. I of course want us to be fully compliant with national and international regulations but am also open to exploring new ways of working with health data, for the benefit of the patients themselves and to enable real-world evidence, which can be used to help other patients and can support pharmaceutical research.

In the future, I think this can also impact public sector payers, as it may be able to demonstrate that the health benefits we can provide as a firm go beyond our drugs themselves and, may provide an indirect health benefit to other patients, lowering overall health costs.

In creating patient-facing digital ecosystems, in your opinion, what are the disadvantages and advantages for nontraditional pharmaceutical firms?

Their advantage is that they can change quickly and can launch products within a much shorter time. Given that they tend to be smaller institutions, they also have faster decision-making processes, are more closely connected to technological innovation and are able to stay closer to customer feedback and react faster. This allows them to continually update themselves and their platforms, keeping them nimble and agile. In the area of regulatory compliance needs however, the new companies have a steep learning curve, though some are learning to do it quite well.

Interview

In which market areas do you think disruptors might have an advantage against traditional health care companies?

Disruptors may have the advantage in the creation of individual application-based solutions that, while owned and operated by these smaller firms, can connect to larger ecosystems as well.

Full customer ecosystems will probably remain the area more dominated by traditional pharmaceutical companies, potentially in partnership with major technology firms. However, these might develop to become plug-and-play systems, whereby large parts are owned by pharmaceutical companies but are open and accessible to the app-based solutions run by smaller players, making them a key structural trait of these health ecosystems.

When trying to acquire the skills necessary to develop and operate these new systems, do you think Novartis is looking to follow an organic or acquisition-based model for growth?

There will be areas where the firm wants to own products and platforms as Novartis, and these will require the buildup of in-house capabilities. While this is speculation, our CEO has increasingly focused on areas of data science, and this could be one of those areas that Novartis seeks to increasingly develop internally and build up competence.

Then there will be certain areas where the firm might not be able or want to own the whole thing ourselves and, in these instances, I think we will look to strategic partnerships. Lastly, there will be other areas where the company doesn't want to be involved at all and just wants to be able to connect to those systems, and in this realm, I envision that third-party providers will create solutions outside of the system.

Regardless of how the firm chooses to partner and develop within these areas, our internal IT infrastructure and digital capabilities are evolving quite rapidly. While there are certain levels of innovation and creativity that aren't suited to being housed within the firm, I believe that the company is working to make sure that we have the right capabilities in-house to make the best assessments and decisions on how to view a platform's suitability or a partner's strategic fit with our priorities.

What will these ecosystems look like in the future?

Current areas of ecosystem development represent only a fraction of the value that will ultimately be created for patients through innovative connections between pharmaceutical firms, medical professionals, patients and new market entrants in the health care sector.

In the next decade, pharmaceutical firms will navigate a complex and changing environment. Ecosystems will evolve as technology matures and management capability and willingness to oversee multi-stakeholder engagements increase. As these traits grow, the value that ecosystems can create will increase in both breadth and depth, for traditional firms as well as new market entrants. This section provides an overview of the likely contours of ecosystems from 2018 to 2030. Attention in ecosystems is not limited to the means of interacting with patients and stakeholders along the pathway to health and cure. The focus is also on how core functions and processes can be streamlined and optimized, and related costs and value shared.

51 S. S. Biesdorf, U, Deetjen, M. Möller, "Eine Vision für ein digitales Gesundheitssystem in Deutschland," *McKinsey*, April 2016.

Changing drug development

Within drug development, ecosystems will mature to both simplify and accelerate the pharmaceutical research process.

Automated research

In drug research, ecosystems will be enhanced through the use of artificial intelligence in the form of deep neural networks to recognize which drugs could be repurposed and positioned across different systems and conditions, outperforming current electronic testing methods.[52] These ecosystems will ultimately allow for the digital testing of thousands of different combinations of pharmaceutical ingredients to determine the most efficient formula, replacing costly time in the lab. This will dramatically lower the amount of time necessary to test a medication, helping to get pharmaceuticals to market faster and at a lower cost.[53]

Systems that automate research are poised to become a major cost saver for Rx businesses.

Automated research has the potential to make a sizeable budgetary impact within the GSA region. In 2014, €5.8 billion were spent on R&D in Germany, with an additional €5.3 billion spent in Switzerland during the same year.[54] Even a 10% reduction in cost would save companies operating in the area over €1 billion per annum.

To establish these systems, firms will first need to identify which research areas are of the greatest strategic importance to them and use that information with the analytical capabilities of partner organizations, or skills created internally. Once identified, and connection points are established, this acceleration of the product creation process will improve patient outcomes by increasing access to higher-quality products.

Algorithms that scan through hospital records and patient data will more efficiently search for potential trial participants, lowering the failure rate of clinical site selection, which currently stands at 30%.[58]

Clinical trials – intelligently chosen and remotely monitored

Clinical trials will also see rapid advancement in ecosystem development, delivering increased value to the patient through improved quality and cost effectiveness. By optimizing data collection, patient selection and trial protocols, ecosystems will enable pharmaceutical firms in GSA to streamline what is traditionally a cost center.

Clinical trial ecosystems will function through the communication of information between pharmaceutical firms, patients and third-party health providers, and will be formed through the actions of pharmaceutical firms. Ecosystems in this area are unlikely to function without the management activity or participation of traditional pharmaceutical firms.

Through these systems, wearable technologies and other means of electronic monitoring will be connected to firms' internal systems, eliminating the physical barriers previously associated with clinical trials, reducing the amount of time and money needed to conduct a study.[55] It is estimated that these new "virtual trials" could soon represent up to 25% of all clinical trials in the United States.[56] A similar impact would be likely for firms in the GSA region. For a company such as Roche, which currently operates over 32,000 clinical trial sites, this will significantly reduce the costs associated with performing trials.[57]

These ecosystems will also extend to participant capture and the formulation of trial protocols.

Algorithms that scan through hospital records and patient data will more efficiently search for potential trial participants, lowering the failure rate of clinical site selection, which currently stands at 30%.[58] Ecosystems will also allow firms to more easily shape trial protocols and model their effects, improving study design and streamlining modifications.[59] By partnering with technology companies for big data expertise, firms are in fact already able to model trial outcomes. Companies such as Sanofi have begun this process, collaborating with TriNetX, a US technology firm, to analyze patient populations to determine optimal clinical trial protocols.[60]

52 https://pubs.acs.org/doi/abs/10.1021/acs.molpharmaceut.6b00248.
53 B. B. Mesko, "Learning from Science Fiction," *Boehringer Ingelheim*, 2017.
54 "Industry Overviews: The Pharmaceutical Industry in Germany," *Germany Trade & Invest*, 2018.
55 S. Neville, "Pharma Turns to Big Data to Gauge Care and Pricing," *Financial Times*, July 11, 2017; J. Crowley and A. "The Transformative Power of Healthcare Technology M&A in Life Sciences," *Accenture Strategy*, March 2015.
56 Medidata, fourth quarter 2017 earnings call, get info from their site.
57 "Research & Development: Who we are and How We Work," *Roche*, Updated 2018.
58 T. Ohr, "Paris-based Inato Raises €1.3 Million to Lower Drug Prices through Better Clinical Trial Recruitment," *EU-Startups*, 15 November 2017.
59 M. Alsumidaie, "Novartis Brings Digital Patient Centricity Trials," 12 April 2017.
60 "Optimizing Clinical Trials with Digital Technology," *Sanofi*, 26 January 2018.

Changing manufacturing

Ecosystems will soon allow firms to monitor each stage of the manufacturing process and provide instantaneous feedback on the quality and quantity of that product, delivering value to the patient by allowing for personalized medicines to be produced at an affordable cost.[61]

Industry 4.0

Firms benefit from this overarching ecosystem by obtaining tools that allow for intelligently automated manufacturing, which can more easily respond to flexible demand, thereby relying heavily on the SaaS model of ecosystem development.[62] These systems will create an open flow of information horizontally (across machines) and vertically (transferring information from the factory floor to management systems).[63]

Industry 4.0 is the modularization and digitization of the production process and uses a constant flow of data inputs to create smaller batches of pharmaceuticals that can be adapted to fit the regulatory demands of different markets and regions. This will help reduce issues associated with overproduction and tie the production of pharmaceuticals to specific market needs. It will also impact quality control, by allowing for continual monitoring throughout the production cycle.[64]

European companies, including those within GSA, are already making significant strides toward making use of manufacturing ecosystems, with Europe representing 35% of the global output of pharmaceuticals made with the support of Industry 4.0.[65] This investment is a necessary building block for the industry before more complex ecosystems can be created, such as those for personalized medicine. Ecosystems are critical for developing economical personal medicines.

Personalized production – the path toward personalized medicine

Personalized medicine will draw on ecosystems that combine gene sequencing and an individual's genetic code with pharmaceutical production. This is done by forming connection points between CRISPR (Clustered Regulatory Interspaced Short Palindromic Repeats) technologies, analytics programs and manufacturing facilities. This type of ecosystem can already be seen in the work done by firms within the GSA region, such as BioNTech, which is developing personalized oncology treatments. Bayer has also established a joint venture with CRISPR Therapeutics to pursue similarly tailored products for hematology and ophthalmology.

Ecosystems are critical for developing economical personal medicines.

Work by the Research Center Pharmaceutical Engineering in Graz, Austria, suggests that the future of personalized medicine will be in 3D printing pharmaceutical products, as the method allows for an even smaller production scale.

Turning the engagement with these ecosystems into value and returns will therefore require firms to not only invest in the partnerships necessary to collect and analyze the data required to create personalized medicine, but also in the physical hardware to produce such products. Such ecosystems are therefore likely to evolve from non-capital-intensive structures focused around information sharing, with firms then acquiring the necessary means of production once a commercially viable ecosystem has been created.

European companies, including those within GSA, are already making significant strides toward making use of manufacturing ecosystems, with Europe representing 35% of the global output of pharmaceuticals made with the support of Industry 4.0.[65]

Digitized production plans and robotic warehouses

The processes associated with warehousing and distribution will also change through ecosystems, delivering value to patients through speedier product delivery and improved distribution. This will occur through two areas of development.

The first is in the creation of automated upstream systems that improve the planning process. All activities that take place prior to distribution,

61 "Werum Is Paving the Way for Digitization and IoT in Pharma and Biotech," *Werum Pharmaceuticals*, updated 2018.
62 "About Us," *Novartis-MIT Centre for Continuous Manufacturing*.
63 "Werum Is Paving the Way for Digitization and IoT in Pharma and Biotech," *Werum Pharmaceuticals*, updated 2018.
64 "About Us," *Novartis-MIT Centre for Continuous Manufacturing*.
65 S. Milmo, "Europe Leads the Way in Continuous Manufacturing," *Pharmaceutical Technology*, 2 November 2017.

including the production plan, will be created digitally and then transferred into the distribution process. This development is not capital intensive but does require firms to build up internal competence or partner with external providers.[66] Potentially a US$17 billion cost to the industry by 2020 due to the rising need of cold chain logistics, the advancement of processes to manage upstream distribution could bring significant cost savings to the industry.[67]

Pharmaceutical companies are not yet investing in the means to fully automate distribution.

The second pathway is in the downstream cycle, for which firms will eventually seek to automate as much of the distribution process as possible. This will require the large-scale use of robotics, so that small batches of medicine can be produced, stored and transported without the need for significant human involvement. This transition will be extremely capital intensive, with few firms currently making significant investments in this space.[68] Given the costs involved, before firms make this step, they will first seek to access the vast range of necessary capabilities and technologies the ecosystems provide to improve upstream systems.

Changing drug delivery

Ecosystems will also play a role in changing the very nature of pharmaceutical products, by altering what medications can do, through the use of increased data flows to create a continual stream of information between patients, doctors and manufacturers.

As these systems grow and develop, they will ultimately form the thread that ties each of the involved stakeholders together by sending the data collected from the end user back to the company, where it can be used not only to improve the health outcomes of patients but also to alter the development of new medications. This not only will save costs, by reducing the feedback loop within product development cycles, but will dramatically alter the patient experience by placing them into an evolving process instead of consuming the same products and hoping they continue to be effective.[69]

Drugs that can talk

Pills have started to become outfitted with technology and the means of communicating with wearable technologies or other devices through microscopic sensors.[70] Otsuka's Abilify MyCite with an integrated sensor is the first example of the new class of "digital pills," approved by the US Food and Drug Administration in 2017. As these become more abundant and more sophisticated, the pills themselves will even be able to monitor their overall impact on the patient, serving as another tool in the collection of patient data. Pharmaceuticals are also already being transformed into diagnostic tools,

66 Interview with a senior manager at a German pharmaceutical firm.
67 A. Jacques, "2017 Trends & Transformations in the Pharma Supply Chain," *Pharmapro*, 29 December 2017.
68 Interview with a senior manager at a German pharmaceutical firm.
69 D. Dimitrov, "Medical Internet of Things and Big Data in Healthcare," *US National Institute of Health*, 31 July 2017.
70 M. James, "Intelligent Pills: A new 'dawn' in healthcare?," *Bio Centre*, Updated 2014.

whereby they can be used to replace traditional medical exams or medical devices, opening new areas to pharmaceutical products.[71]

These integrated solutions will be created either through internal programs, joint ventures or through traditional M&A activity, depending on the interests of the firm in leveraging the ecosystem. Even wholly owned solutions, however, will function in a multi-stakeholder environment, as the information will continue to flow from patients to doctors, either directly or through systems operated by the pharmaceutical company or its partners.

Beyond the pill – portals, platforms and personalized medicine

The most clearly defined component of a shift toward new models of health care is in the advancement of wearable technologies. Wearables are in some ways already here, with insulin pumps a prime example of this technology in use. Ultimately, these products will be able to detect bodily functions and environmental factors, analyze them internally and relay that information to remote systems for data collection.[72] When fully developed, these wearable or embedded devices might even be able to serve a preventative function and warn of any impending issue, particularly for conditions such as epilepsy.[73]

Through wearable technologies, the means of health care communication will change. Currently, a patient must seek out a medical professional to receive advice on how to use or alter medication. Through the creation of integrated digital tools, chat bots will be able to analyze data and offer personalized solutions or perform tasks based upon that data. Chat bots will likely transform into fully electronic "personal health assistants" that serve to both help patients and improve company visibility into how their products are used and work in the field.[74]

Much of this data analysis and communication will be performed on the platforms and portals created to allow users to interact with health information. Application-based health monitoring is already on the market, with platforms such as MySugr, a fully owned subsidiary of Roche, combining passive data collection through smartphone sensors and wearable technology with context-aware feedback displayed on the app. As wearables become more advanced, the creation of health-centered applications will expand, with portals likely to combine interactive incentives, through a gamification of data entry, with personalized feedback to the end user.

The transitions where pharmaceuticals become diagnostic tools has already begun.

Platforms will also increasingly be used to connect users with other users. Peer-to-peer communication will allow consumers to share experiences and pool health information.[75] These platforms can also act as secure and accessible data storage sites. Some firms such as Microsoft and HereIsMyData, a Dutch collaboration, are already moving into this space.[76]

The ecosystems providing these platforms are an area of immense competition, as they represent a market segment more open to nontraditional players. For pharmaceutical firms, the value in these systems will be in understanding the patient data and in being able to manufacture products that assist optimum treatment. While traditional pharma is likely to face little competition in the creation of the pharmaceuticals themselves, to create these systems and control the area of greatest value creation, firms must either partner with, or purchase, companies specializing in that data collection, or patient activation through apps of medical devices. Otherwise, firms will be forced to produce those systems internally, at great cost, and in a competitive marketplace.

Wearables will become a market segment hotly contested between traditional firms and new players. Both will seek to control the health data captured by these systems.

71 H. Bodkin, "Smart Pill that Reads Gut Gasses Spells End to Colonoscopy for Thousands," *Telegraph*, 8 January 2018.
72 N. Heintzman, "A Digital Ecosystem of Diabetes Data and Technology," *Journal of Diabetes Science and Technology*, 20 December 2015.
73 R. Metz, " A Sleek Wristband That Can Track Seizures," *MIT Technology Review*, 28 November 2014. "An Update on SmartWatch: An Innovative Monitoring, Detection, and Reporting Solution for Seizures," *Epilepsy Foundation*, 2016.; "Pharma Digitalization: Challenges and opportunities in transforming the pharma industry," *European Pharmaceutical Review*, 30 May 2017.
74 R. Dillmann and S. Kahl, "Digitalisierung in der Pharmaindustrie," CHEManager, 13 April 2017.
75 "Patientslikeme: How Patient Experience Can Change the World," *Health*, 28 August 2018.
76 D. Dimitrov, "Medical Internet of Things and Big Data in Healthcare," *US National Institute of Health*, 31 July 2017.

Changing marketing and sales – from payers to patients

Ecosystems will also transform internal functions, such as marketing and sales, with firms needing to adapt how they approach selling their products.

Pharmaceutical firms must shift some of their marketing focus toward patients and physicians and create closed-loop marketing to stay in continual contact with the right message in the right format at the right time.

Traditional marketing for the industry targets health care professionals, and sales efforts focus on major payers. However, the use of ecosystems to increase patient interaction creates an environment in which pharmaceutical firms must shift some of their marketing focus toward patients and physicians and create closed-loop marketing to stay in continual contact with the right message in the right format at the right time. This will create value for patients by making them increasingly aware of their pharmaceutical treatment options, and improving patient activation, which impacts other areas of ecosystem creation.

This applies not only to traditional pharmaceutical products, but also to the new platforms being created to develop relevant health ecosystems. Health care applications will become key tools in the marketing apparatus of pharmaceutical companies, helping to increase brand and product awareness, and opening sales channels directly to the consumer.[77]

Marketing to patients and physicians will lead to questions of legal and ethical restrictions.

Access to data on which doctors are more prone to prescribe new medication is likely to lead to more targeted marketing campaigns, while the proliferation of digital applications that allow companies to interact with consumers will create new demand for digital advertising based upon segmentation via behavioral elements and targeting – although governments may ban such tactics.[78] Direct messages to the consumer are also likely to become increasingly important, with evidence-based messaging campaigns via applications targeting individuals with relevant conditions as a new channel for an older approach to pharmaceutical marketing.

As for the mechanics of system creation, these ecosystems are likely to be under the control of the industry, though built with tools from external partners, as companies are the natural repository for the data on who is prescribing and consuming their products. As a result, this aspect of ecosystem development favors the strengthening of internal capabilities over relying on external expertise.

Critically, in Germany, legal restrictions currently limit direct marketing to patients, reducing the short term need for this type of ecosystem exploitation. German pharmaceutical firms are therefore more likely to invest in generic forms of patient communication, such as raising awareness of health issues, while companies in Switzerland and Austria could have more leeway to engage in direct-to-consumer marketing and sales.[79] Either method, however, is likely to be built upon internal systems and capabilities, and not housed externally.

77 A. Oertel, "Marketing Automation: Wie Pharma Digitalisierung nutzen kann," *Health Relations*, 27 September 2017.
78 "The Future of Healthcare Is Digital," *The Millennium Alliance*, 2 February 2018; A. Oertel, "Marketing Automation: Wie Pharma Digitalisierung nutzen kann," *Health Relations*, 27 September 2017.
79 A. Oertel, "Marketing Automation: Wie Pharma Digitalisierung nutzen kann," *Health Relations*, 27 September 2017.

Changing demands on legal and compliance functions

The presence of digital ecosystems that not only connect companies in the delivery of goods, but also make use of health data, will likewise fundamentally reshape the work undertaken by legal and compliance functions in pharmaceutical and technology firms that seek to develop or use ecosystems.

The EU has already passed a new directive on data protection. In parallel, the EU commission is working on future ways to protect data as an asset. The General Data Protection Regulation (GDPR) entered into force in May 2018 and provides patients the ability to access their health data and deny firms its use. Germany, Switzerland and Austria have all enacted their own legislation to regulate the use of data and provide for its systematic capture within the health system, creating a method for firms within GSA to access patient information.

However, while the new law has created a legal structure for the use of electronic health information, allowing it to be shared between providers, the security of that information is still an issue of national debate.[80] For example, the German Federal Insurance Authority (BVA) has since criticized fitness apps for lacking safeguards for quality assurance and data security risks, with some health insurance providers no longer offering these apps as a consequence.[81] While this is currently a small concern, as the size of these systems grows, and more complex information is shared, the potential for concerns over data security to impact the quantity of health data stored and shared will grow with it.

This uncertainty will impact the legal responsibilities of pharmaceutical firms within GSA. Future legislation within all three countries must address the anonymization of data, while regulations for the international transfer of data must also be established.[82] For firms in the GSA region, which are under more stringent data privacy controls than their counterparts in the United Sates, this alone represents a major legal hurdle going forward.

The legal structure of how these new ecosystems are pieced together must also be constructed, with the risk burden between firms in particular yet to be properly defined. Issues such as constructing and measuring the outcomes of value-based health care, the insurability of autonomous or networked systems, information asymmetry between patient and insurer and the liability for any misuse of data or delivery of improper treatment remain unclear. These topics, among others, will be the main focus of legal departments within GSA-based pharmaceutical firms in the coming years, as they must be resolved before the new ecosystems can maximize their commercial value.[83]

Legal and compliance teams will therefore play an increasingly visible role in risk management and risk transfer going forward as ecosystems mature. Even firms such as Participants and Profiteers, which do not work within mature ecosystems, will need to effectively shield their organizations from the financial risks of data ownership or use.

Risk sharing will become hotly contested in a health environment that utilizes ecosystems.

80 New E-Health Act: "Patients have control over their data", *Medica Magazine*, 5 August 2016.
81 Weiterentwicklung der eHealth-Strategie, strategy & and German Federal Ministry of Health.
82 Industrie 4.0 – Rechtliche Herausforderungen der Digitalisierung, *Bunderverband der Deutschen Industrie*, 17 November 2015.
83 Industrie 4.0 – Rechtliche Herausforderungen der Digitalisierung, *Bunderverband der Deutschen Industrie*, 17 November 2015.

"You can see players are **developing new forms** of **health care delivery** and starting to **form ecosystems** through **easier interactions** between their clients and patients."

Dr. René Buholzer
CEO of Interpharma

From your perspective, what has been the focus of the Swiss pharma industry in the creation of ecosystems?

We are convinced that the current framework with existing regulation is not sustainable, as it fails to address future needs. Health care firms have started to collaborate with each other and different actors but there is no broad movement tackling this challenge. There are some individual groups trying to do this, but there is no wider discourse yet around the topic of ecosystems in Switzerland, which would be necessary for true progress.

Data privacy is a big issue for the region. Do you see any regulatory advantages or disadvantages for firms that are based in GSA?

The focus is still very much on data protection instead of which data policy we need and want. We will see how the debate evolves, but historically Switzerland has a long and solid track record for protecting individual rights in a free market economy and is therefore well positioned. In addition, Switzerland has a very fragmented health system, with 26 different cantonal actors, all of which play a critical role in determining how the system functions. This creates the potential for different approaches. Fragmented markets can be a disadvantage for firms, but have also a huge advantage for a real-world trial and error approach. In addition, the Swiss marketplace is not only small but well connected between regulatory actors and the industry and with an above-average discussion culture. This allows actors to run pilot projects and conduct testing within an advanced health care system that is open to innovation.

Are you seeing firms in Switzerland starting to think about how they are going to compete with nontraditional market players?

Partly. The new CEO of Novartis has been very vocal in articulating that the industry needs to be more data driven and digital. Recent M&A activity testifies that Roche is investing in data platforms to develop real-world evidence for cancer research. Overall, it seems that, apart from research in the pharma industry, the health care industry is not as advanced as other sectors in taking advantage of digitization. One possible reason for this is that the stringent regulation distracts attention from management and can act in some ways as a barrier to market entry, keeping new firms from quickly or directly competing in this space.

I am personally convinced that the Swiss pharmaceutical industry is up to this challenge. I am, however, more concerned about the readiness of the health care system as a whole and the potential impact for the speed and delivery of innovation, particularly for doctors and other actors involved in health care delivery. Discussions on ecosystem creation are currently centered around cost containment and not how we as a sector adapt to technological developments and new innovations that can improve quality and effectiveness of care.

In terms of disruptors who could enter the sector, are there any Swiss champions that you see well positioned to compete with traditional pharmaceutical firms?

On the one hand, we could mention the obvious candidates that are successfully interacting with consumers, such as Alphabet, Google and Amazon. My personal opinion is that these firms are more likely to begin their foray into the health space by focusing on healthy people, which is to say prevention-based tools and ecosystems. Conversely, the pharmaceutical industry is dealing more with ill people, for both chronic and acute care, and I think those two elements will potentially over time grow together. Further, you can see players are developing new forms of health care delivery and starting to form ecosystems through easier interactions between their clients and patients.

Interview

What kind of partnering has been most effective in allowing for ecosystem development?

It is incredibly challenging to reform a complex and fragmented system that is highly regulated without causing some unintended consequences. When you change some aspect of the system, as these new ecosystems will do, there are potentially many players that would have something to lose and would feel the need to defend the position that they have established over time. This makes any reform process difficult and slow.

We, at Interpharma, are trying to approach this issue with a "do-tank." Essentially, this is a bottom-up initiative to give all stakeholders who are willing to innovate in the form of a concrete pilot project a platform to create these relationships and share the learnings for a sustainable health care system. There are already pilot projects that have been undertaken by our member companies and other stakeholders along the value chain (pharmaceutical companies, insurers, hospitals, medtechs or other actors) but the connection and the leverage for the system was missing. I am convinced that there is a lot of potential for improving efficiency, delivering better outcomes for patients and improving collaboration.

What stage of development are these initiatives in?

We are at an early stage, but there is a lot of will to move this conversation forward within Switzerland. To tackle the issue not via theoretical concept papers but with concrete pilots is clearly timely. We are talking to all stakeholders in the health care system to make sure that we have a multi-stakeholder approach, which is key for the multiplication and scalability of the pilots in a later stage of the project. But not surprisingly, to engage in such an open co-creation process needs a lot of courage and commitment. This impacts the speed at which the initiative is moving forward; but it is the only way to systematically form lasting ecosystems that will deliver improved outcomes.

06

The future of ecosystems: looking ahead to 2030

The strategies that pharmaceutical firms in GSA employ now will shape where they stand in the next decade, after new market entrants and pressure from patients and payers have had time to impact the traditional business model.

Looking ahead to 2030

Pharmaceutical firms are still at an early stage of ecosystem engagement. The future of the industry – where value will be created and who will capture that value – is still to be decided. The strategies that pharmaceutical firms in GSA employ now will shape where they stand in the next decade, after new market entrants and pressure from patients and payers have had time to impact the traditional business model.

Forecasts of future industry trends cannot predict how individual companies will fare. It is possible that a firm misses the growth of a new market segment but expands its share of an existing part of the value chain. However, overall patterns of industry growth, and value captured by the pharmaceutical industry, will apply to the majority of firms within the sector to varying degrees.

€130 billion: approximate size of the GSA pharmaceutical market in 2030.

Market scenarios

To determine what is at stake for the industry in the GSA region, a model was constructed to identify the future economic value of the pharmaceutical market in the region. The model was formed by using Eurostat and Swiss Federal Statistical Office data on the size of pharmaceutical value added in each GSA country, along with the breakdown of key data from pharma firms' annual reports, to construct an outlook for sales, licensing and health IT. Growth rates were then established based upon growth data from 2000–15, with small increments added to account for the positive impact of ecosystems. This then produced the size of the GSA pharmaceutical market in 2030.

Scenarios were developed using M&A activity as a guide for investment, to demonstrate where current strategies might lead and how changes in strategy could impact the value derived from these systems, as firms seek to use and build ecosystems.

Size of the pharmaceutical market in 2030

In 2015, the wider pharmaceutical market (i.e., economic value add) in GSA was roughly €62 billion, according to Eurostat and Swiss Federal Statistical Office data, with the majority of the value housed within pharmaceutical sales. Health IT, and the tools that will be used for ecosystem engagement, were a relatively minor component.

By 2030, the pharmaceutical market in the GSA region will stand at almost €130 billion,[84] with the industry set to more than double over that 15-year period. **In Germany, the largest market, this will see the amount of value produced by firms jump from 32 to slightly under €65 billion, followed closely by Switzerland, whose market will rise from just under 27 to roughly €60 billion, while the value produced by Austrian firms will grow from 3 to over €5 billion (Fig. 1).** This increase in market size will see growth strongest in areas such as data analytics and non-pharmaceutical based health care applications. The pharmaceutical market in 2030 will therefore be divided between revenue produced by traditional pharmaceutical sales, which will in many ways be impacted by ecosystems and the value housed within the broader networks themselves.

84 The 130 bn figure represents the value add produced by Germany, Switzerland, and Austria (GSA). It is not a sales figure for what was sold within the three countries, but is instead the amount of value produced within each country, which is the sales price minus the cost of inputs. Note: the figure only represents value created within the country, and does not include value produced by firms overseas (i.e. the value produced from a GSA company with a factory in China is not included). Value added is a measure of GDP for the industry, and is the size of the production or output market.

Figure 1. The pharmaceutical market in GSA region by 2030 in billions – divided by country (2018, €)

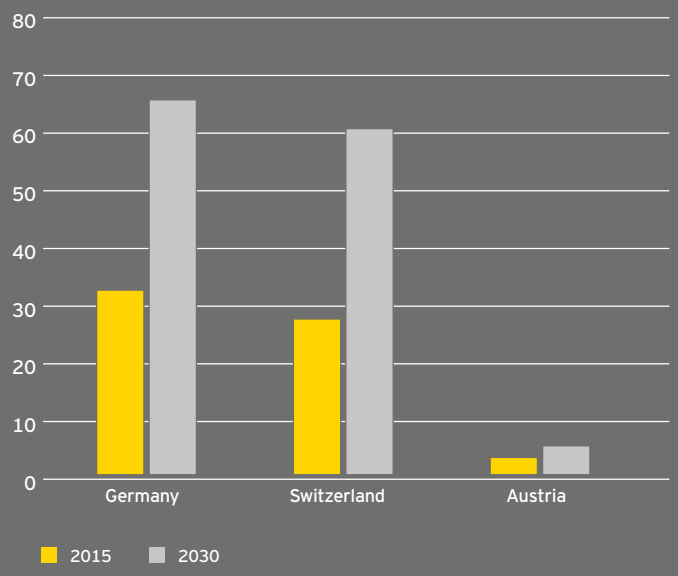
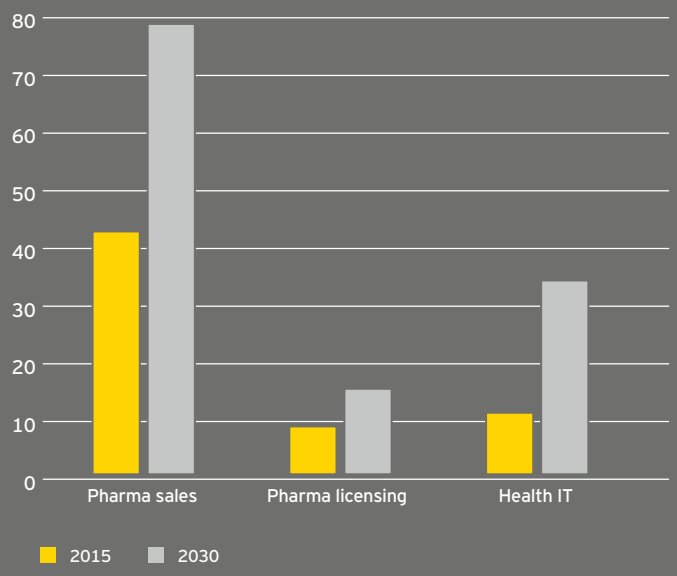


Figure 2. GSA pharmaceutical sector projections in billions (2018, €)



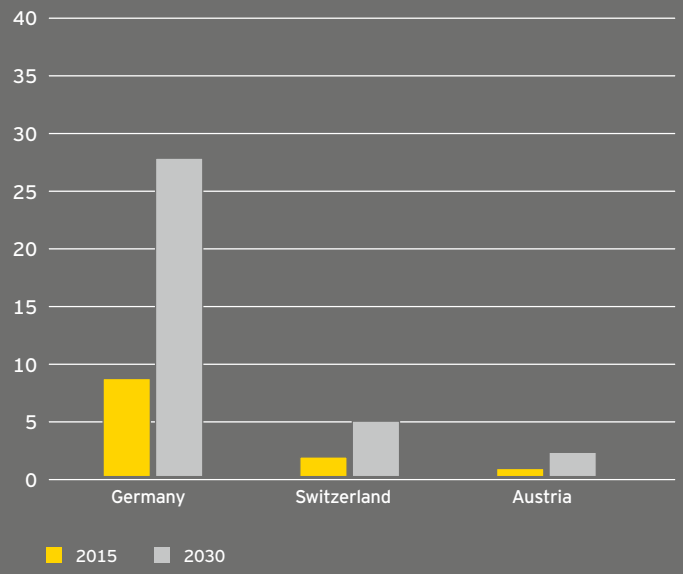
While traditional pharmaceutical sales still represent the lion's share of the industry in 2030 (Fig. 2), this segment of the market will be shared by the firms involved within the pills ecosystem. Growth of the Health IT sector will be remarkable: in Germany, annual growth rates of 8.20% will increase the added value produced to €27.6 billion. For Switzerland, the numbers are 6.90% and €4.8 billion, and for Austria, 7.80% and €2.1 billion (Fig. 3). Firms that are able to deliver tailored and improved outcomes will account for much of the value-add of the treatment. Systems housed internally, and the analytical tools they represent, will also witness robust growth, increasing in value by over 200% by 2030.

For pharmaceutical firms to make the most of this future marketplace, the value created through the engagement in ecosystems must be captured, or else new market entrants will control the areas of data capture and analysis, and the value those systems create.

The potential for pharmaceutical firms to do so varies depending on the strategies they employ and the management structures used to oversee these ecosystems. The following three scenarios provide an indication of the market potential for traditional pharmaceutical companies, depending on the pathway they take toward the development of new ecosystems.

- The "Profiteer Entrenchment" scenario (1) represents reduced investment in ecosystems by traditional firms leading to a 5% decrease in market share.
- The "Varied Development" scenario (2) represents a continuation of current trends.
- The "Becoming Principals" scenario (3) represents an increase in investment and desire for ecosystem ownership, management and creation leading to a 10% in market share.

Figure 3. Health IT sector by country until 2030 in billions (2018, €)



Scenario 1: Profiteer Entrenchment model – 55% of market control

While the pharmaceutical industry is in large part currently looking to leverage ecosystems, there is no guarantee that this process will continue at pace in the future. A scenario is possible in which the pharmaceutical industry takes a more detached approach to engage in ecosystems, permitting those areas to be run primarily by new market entrants. With such as strategy, traditional firms in GSA could expect to capture roughly 55% of the total value produced by the pharmaceutical industry in 2030, with the majority of that coming from the continued production of pharmaceutical products and other traditional business areas.

This scenario would be characterized by a continuation or lessening of current investment patterns in initiatives to engage in ecosystems. Investment would instead be channeled into traditional business areas such as pipeline development, and partnership models to develop individual solutions. The scenario would also be marked by an entrenchment within pharmaceutical firms toward traditional structures and practices, with limited desire to own the non-pharmaceutical components of a value-based health care model. Pharmaceutical companies in this scenario would use ecosystems to meet market needs, but the revenue produced by those systems would flow to the firms that create or own the ecosystems. Thus, traditional firms would earn more revenue on the back of a growing pharmaceutical market, but they would only be able to capture a limited amount of the value created by these systems.

The chart below shows how this leads to roughly 55% of the total value within the pharmaceutical market, which equates to €72 billion being captured by traditional firms. Of this, €55 billion is brought in

Scenario 1 would be characterized by a continuation or lessening of current investment patterns in initiatives to engage in ecosystems.

by pharmaceutical sales, with only €17 billion created through licensing and health IT (Fig. 4).

While this scenario sees the industry capture a smaller share of the pharmaceutical market value, the industry remains somewhat protected by its ownership of the final product. Firms with a Profiteer strategy will use new production methods to lower costs and produce more advanced products for consumers, while lowering their investment risks by relying on external partners to create advanced ecosystems. This will enable pharmaceutical firms to become even more efficient within their current operating model.

This scenario is, however, not without risks, because if the industry collectively adopts the Profiteer approach, firms may find themselves producing products that are continually moving downward in the overall health value chain, as the information critical to patients is developed in ecosystems outside of their control. Firms will also find themselves increasingly reliant on partner organizations, as the cost to leverage ecosystems effectively will increase as they mature and become more embedded into the larger health environment. It is likely that some firms will thrive in this scenario by becoming more streamlined organizations, but overall the industry will lose its current dominant position for one of near parity with new entrants.

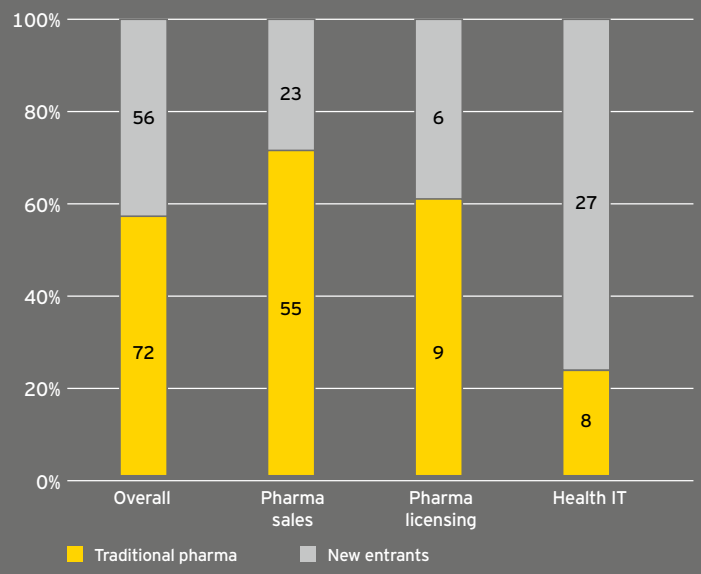
Scenario 2: Varied development, varied results – 60% of market control

While the above scenario envisions pharmaceutical firms focusing on traditional operations, the possibility also exists for the industry to remain divided on how to approach the development and use of ecosystems, with a continuation of the status quo resulting in a myriad of strategies used by the pharmaceutical industry, leaving it exposed to external market forces. New market entrants will then assume a dominant position in the ownership of ecosystems and the value they create.

This scenario would see large pharmaceutical firms continue to operate mainly as Pilots, with only a few firms adopting the Principal and Profiteer strategies. This would signal a lack of pharma industry consensus on how to best handle the patient and payer demands through the use of these integrated tools. As a whole, incumbents would invest in the network of ecosystems, though to varying degrees, and predominantly through M&A activity and external partnerships, leaving the majority of ecosystem leverage to nontraditional firms.

The prevalent use of Pilot strategies would allow some firms to derive revenue from the use of the ecosystems in which they are involved. However, as firms begin to pursue digital strategies, the industry would develop unevenly and new players would find opportunities to set up and manage

Figure 4.
2030: Share of pharmaceutical market in scenario 1



ecosystems themselves. This approach would leave traditional pharmaceutical companies with control of approximately 60% of the value in the market, approximately €78 billion (Fig. 5). Although incumbents would capture a bigger share of the market value than in the Profiteer scenario, this scenario in some ways represents a more precarious position for the industry as it exposes firms to more intense competition.

A continuation of the status quo would allow Pilots to carve out pockets of ecosystem ownership through M&A activity. This in turn would give the industry a greater share of the total market value. Traditional firms, however, would still not be in a dominant position, as the management of these tools remains predominantly in the hands of other businesses. Firms would capture more value from pharmaceutical products, as well as the licensing of different products or ecosystem components, than under the widespread adoption of the Profiteer strategy, but would still be forced to contend with strong competition from new market entrants within key segments, particularly in the control and analysis of data, as Pilots and Participants are unlikely to own those processes themselves.

This scenario therefore presents the possibility of a fragmented pharmaceutical sector within GSA, as the lack of a dominant strategy toward ecosystem engagement allows new players to control key aspects of value creation.

Scenario 3: Becoming Principals – 70% of market control

Although the two previous scenarios underscore the challenges and pitfalls facing the pharmaceutical industry as outcomes-based models are created, a scenario is conceivable in which the pharmaceutical industry is able to maintain its dominant market position and capture roughly 70% of the total market value by 2030 (Fig. 6).

This scenario envisions that, as ecosystems mature, firms that are currently Participants or Pilots transition up the ecosystem development ladder to become Principals in their strategic outlook, allowing them to lead in ecosystem development and exert greater control over the value formed by those systems.

As Principals, the industry in this scenario would alter its investment patterns to not only engage in M&A activity or the creation of new partnership models, but would also internalize the capabilities to manage and create ecosystems. From this position, firms could invest in homegrown systems that provide the greatest return on investment. Firms embracing this strategy would create and manage ecosystems within manufacturing, patient delivery and the sales process. Structural changes, such as retooling business development and licensing teams to focus on technology partners and developing internal mechanisms for data transfers across business

Figure 5.
2030: Share of pharmaceutical market in scenario 2

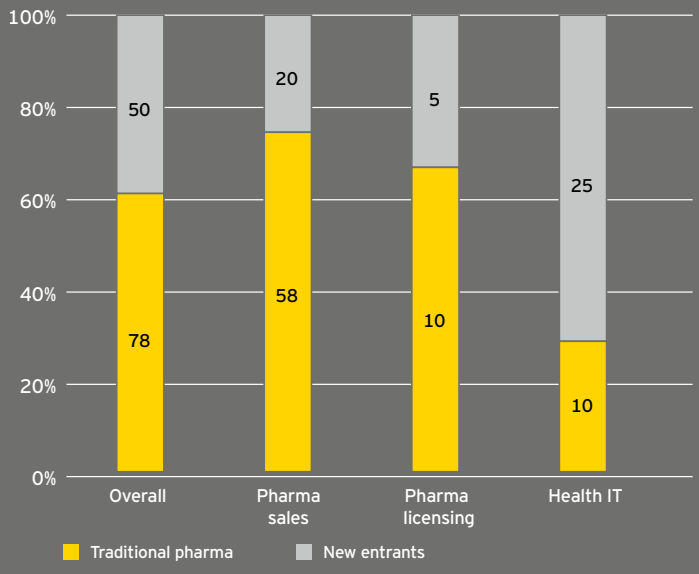
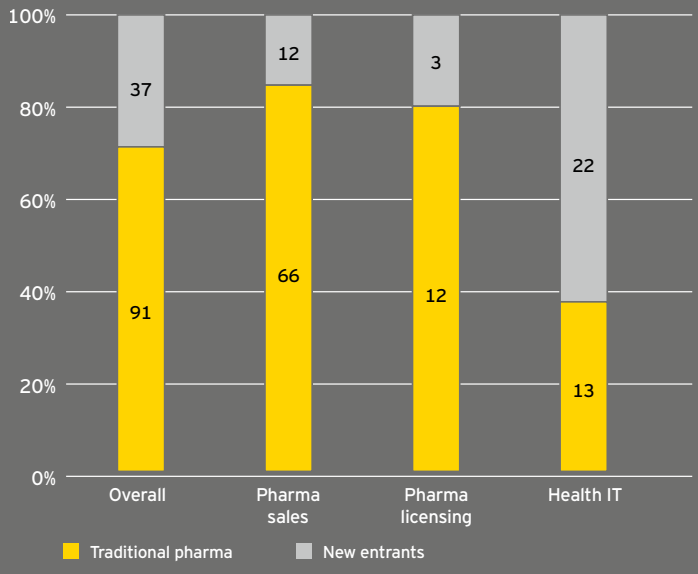


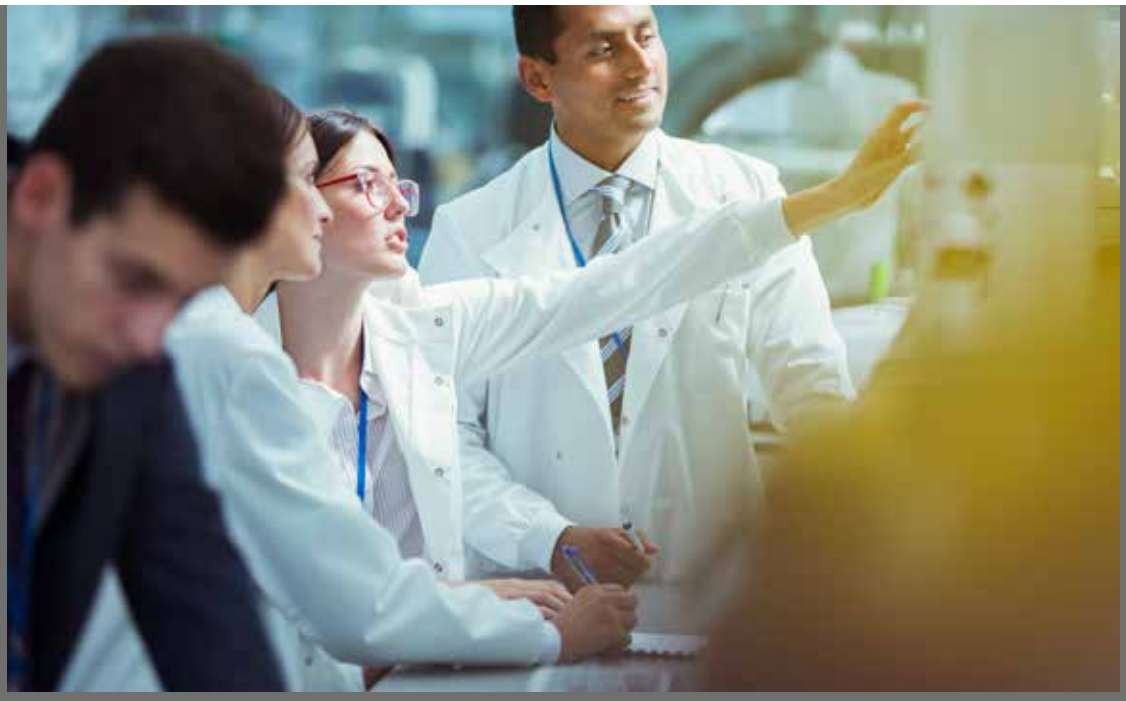
Figure 6.
2030: Share of pharmaceutical market in scenario 3



segments are also key aspects of this process. By embracing the widespread adoption of Principal strategies, the industry would be rewarded with a larger share of the pharmaceutical market. This is manifested not only in the greater amount of revenue generated from health IT, which represents the value housed within ecosystems themselves, but also in the value created by pharmaceutical products, as firms would be in a position to control the mechanisms that enable improved outcomes to be delivered to patients.

By increasing investment in critical areas for the ecosystems, traditional firms would also become less reliant on external partners. While competition from new market entrants is unavoidable, by becoming Principals, traditional firms in GSA would be able to own the processes they believe hold the most value, while allowing new firms to operate elements of ecosystems not deemed central to their strategies. While this scenario too presents risks to traditional firms, as investment in ecosystems is neither inexpensive nor guaranteed to succeed, it is by adopting a strategy that emphasizes both the use and ownership of these tools that they will obtain the strongest position to control the pharmaceutical market going forward.

By becoming Principals, traditional firms in GSA would be able to own the processes they believe hold the most value.



"With digitization and the **use** of these **ecosystems**, we hope the overall **costs will go down.**"

Marco Odoardi
Head of Global Warehousing and Distribution, Merck KGaA

Ecosystems in the pharmaceutical sector are going to impact drug delivery; logistical functions such as warehousing and distribution are also undergoing large shifts. How are these ecosystems being created, from your perspective, and what new tools will you use to make them work?

We have a model with primary and secondary distribution. Primary is the main arm of distribution from our manufacturing sites to selling countries, while our secondary model is what covers the last mile distribution. This is a classic model for many in the industry.

At Merck, we envision two potential directions for how ecosystems will impact warehousing and distribution. One is the planning of production and distribution, or what can be referred to as the "upstream part" of the distribution. Through the use of new tools, activities that take place before the physical distribution can be digitally assisted. This is, and remains, a high value-added activity for us, but it is increasingly getting digital support. These systems are not perfect yet, however, and their development is still work in progress.

Most big pharmaceutical players are running to make this change happen, but without making any structural changes to the current distribution business model. A common objective of all the big firms is to use advanced computing, AI and data analytics, to build smart and computer-aided distribution plans. This is something everyone in the industry is thinking about. Some firms, Merck included, are more advanced, although probably none of us are at the level they would like to be! We are still in the early development phase of these systems.

As regards the "downstream part" of distribution, the physical product transportation and warehousing, the trend points toward robotics and automation. But these innovations are hugely capital-intensive and make business-sense only from a long-term perspective. Payback from these automation investments is rarely quicker than 7-10 years. That means that, as a pharma company, you typically invest in these systems if you have logistic partners with which you share a long relationship or if you have a long-term vision in place. You are not going to invest in these types of innovations otherwise, given the heavy investment involved.

How are you measuring the success of these new ecosystems? What are the improvements your business hopes to gain by using them?

We measure the impact of these systems with four KPIs: environment & safety, quality, service and efficiency. These are the four KPIs that matter for us when we evaluate impact of these tools and processes.

First and foremost, we believe in being a green company and further reducing our CO2 emissions. Ecosystems will hopefully help us to cut down on waste and be more environmentally friendly. As regards safety, you can measure the number of accidents, including those of your logistics providers, so we can see if these tools are improving our workplace environment. With respect to quality, there is a need for all pharmaceutical companies to ensure that products arrive at their destination in perfect condition, which includes monitoring them for temperature excursion. This is another area where we can see how effective the systems are, as we can compare their performance with legacy systems. As for service, classic on-time-and-in-full (OTIF) delivery is our standard measurement.

Interview

In financial terms, efficiency is cost and cash. With digitization and the use of these ecosystems, we hope the overall costs will go down, but we still need to consider in the equation the investments needed to make it happen.

These four metrics will hopefully all improve over time as these digital ecosystems become more advanced and integrated into workflow.

Many of these new ecosystems use tools and skills that fall outside the expertise of traditional pharmaceutical companies. In order to compensate for this, have you partnered with any organizations in order to create these new ecosystems?

For these digital revolutions, you need digital capabilities, which are not native to our industry. We have seen several pharmaceutical companies look for partners who have this experience, with many looking to Silicon Valley for expertise and partnerships. Merck has also done this, though not yet at full speed and specifically not for warehousing and distribution. Instead, our aim has been to build out our own internal competency so that we can fully develop and own these ecosystems. We created an internal center of excellence two to three years ago, and this internal team has now developed a significant base of knowledge and serves as an internal think tank dedicated to these new digital opportunities and how we can leverage tools to create some of these ecosystems.

What do firms need to do in order to improve their own internal capabilities?

While automation of distribution activities is capital-intensive, to digitize and optimize distribution and logistics, one has to invest in capabilities. It is really an investment in people and in resources. For a medium or small company, assembling a dedicated team of 20 highly skilled people over a 2- to 3-year period will enable you to build up the necessary internal capabilities.

07

Conclusion

Ecosystems will be a significant part of the pharmaceutical sector's added value by 2030. Benefitting means to adapt to an ecosystem framework for drug development, distribution and redevelopment.

However, as with all trends, not every firm will benefit equally. Those companies that adapt to an ecosystem framework for drug development, distribution and redevelopment will advance faster than those that do not. Those that move to manage key sections of the ecosystem, rather than partnering with firms that control such portions, will retain more of the growth in-house.

Ecosystem building blocks

Ecosystems can be leveraged at nearly every step of the pharmaceutical value chain. Drug development will require digital technology to collaborate with patients and physicians working with previous versions of drugs for the disease in question. Clinical trials will use algorithms to identify participants. Manufacturing and distribution will run on interconnected ecosystems to minimize wastage of batch runs and inventory. And patient feedback and data collection will be the foundation for the next cycle of discoveries.

Ecosystems will operate across the value chain – and will help to link disparate parts of it.

The choice of when to invest in ecosystems can be as important as where to invest in ecosystems.

For many of these steps, much of the work will be in collecting and analyzing data that the ecosystems generate. Personalized medicine will require analyzing 3 billion base pairs in each individual's genome; fitness apps provide a constant stream of data on heart rate and step count. Both of these mechanisms, which are only two of the ways in which the life sciences industry is connecting with patients, will generate massive amounts of data, from which insights will need to be extracted.

Ecosystem development

Firms face trade-offs in ecosystem development. Partnering with technology firms can help pharma companies accelerate the development process but can also see them lose long-term value, as they become a subscriber to a system instead of an owner. Moving too quickly before internal capabilities are built can leave firms with subpar systems, causing them to lose ground on competitors and forcing them to overinvest. Interviewees from the industry have spoken of the varying levels of commitment needed to create ecosystems at each stage of the pharmaceutical value chain. Some areas, such as upstream development, can be built relatively quickly through operations and personnel moves, whereas downstream ecosystems are capital-intensive.

Each firm faces a distinct set of opportunities and risks in this field. The one consistent finding is that firms must shift internal mindsets toward an ecosystem framework and how to approach bringing these systems into the business model. The traditional pharmaceutical process of drug research, development, sales and distribution – a linear model of a producer selling into a market – needs to be reconsidered. Feedback from real-world evidence, data analytics, new pricing schemes and more flexible production cycles will be crucial for pharmaceutical firms to maintain market share.

In this area, pharmaceutical firms vary widely. There are four archetypes of pharmaceutical companies with regards to their engagement in ecosystems and the strategies they employ.

- **Participants** do not actively leverage ecosystems, but rather focus on exploring the potential of ecosystems in small environments with minimum involvement. Firms start as a Participant when they see the value add of ecosystems not as a driver of revenue or profitability, but instead as a conduit for existing business activities. This is a more passive strategy that is neither capital- nor management-intensive.
- **Pilots** are firms that still rely on their core business, but have started initiatives or satellite projects to test opportunities for revenue generation and growth through more active collaborations in ecosystem creation. These firms use a mixture of M&A and partnership agreements to leverage ecosystems, though the development of those systems is primarily in the hands of external organizations. This strategy seeks to maximize the revenue created by ecosystems in certain areas, but keeps others operating along traditional lines.
- **Profiteers** are firms that believe their strategic advantage lies in their traditional business area and that seek to increase their profitability by leveraging ecosystems, particularly in the area of manufacturing. While this strategy is intensive with respect to management and process optimization, it requires only modest levels of investment.
- **Principals** leverage functioning ecosystems throughout the business, including in traditional segments. These firms seek to operate ecosystems, as well as invest in the creation of their own platforms, in order to use the value created by ecosystems to drive revenue growth, while managing their cross-functionality as a means of improving profitability. Due to its investment- and management-intensity, this strategy is most attractive for large research organizations with diverse product lines.

Currently, pharmaceutical firms in GSA mainly operate as Participants and Pilots, with fewer firms adopting the strategies of Profiteers and Principals. There is thus still a considerable way to travel before firms in the region can be said to have fully developed value-creating ecosystems in all areas and there is still a great deal of value for the industry to capture.

Firms can, however, move between these strategies. While the vast majority of companies will first become familiar with ecosystems as Participants, by altering how they seek to invest in, operate or own ecosystems, they can either transition "up" the matrix to become Pilots or Principals, or can focus on traditional operations and transition to operate as Profiteers.

Ecosystem prospects

Partnering with technology firms is one of the many ways traditional companies can encourage the use of ecosystems, but there is the risk that by handing control of increasingly valuable parts of the product cycle over to other firms, the value those systems create will be lost to the benefit of others.

Ecosystem development or non-development will shape where US$20 billion in new market share goes.

Between 2015 and 2030, the pharmaceutical industry in GSA will more than double to just under €130 billion in value. Under the Profiteer scenario of pharma ecosystem engagement, traditional pharma will control 55% of the value created in the sector, with 45% held by new market entrants through their leverage of ecosystems. Under a scenario whereby traditional pharma adopt Principal strategies, traditional firms will be in a position to leverage 70% of the value created.

The difference between these two scenarios is €20 billion, which will go to either the traditional players in the health care market or new entrants. These scenarios demonstrate that the adoption of ecosystems is not only about pharmaceutical firms competing with each other to meet patient and payer demands, but about how they will compete with nontraditional life sciences firms that seek to capitalize on the health market and have backgrounds in non-pharma aspects of ecosystems.

The strategies firms employ, to either stay as Pilots, refocus on traditional operations as Profiteers or embrace ecosystem ownership and development to become Principals, will ultimately determine how this additional value is divided, either among the industry and/or new market players.

Signposts of ecosystem development

Ecosystem adoption is an evolving trend in the pharmaceutical sector. Signposts that ecosystems growth has hit new thresholds as regards its importance in Germany, Switzerland and Austria would include:

- Development of health data regulations. When pharmaceutical companies in GSA have a more solid legal environment for using health data, investment in the area will likely increase and firms will be more comfortable moving ahead with innovative uses of data.
- Major merger or acquisition by a health data company. If a pharmaceutical firm is acquired by a tech company, it would be a clear indication that the traditional balance of value in the sector has flipped – as well as signaling the interest that technologies companies see in the potential for involvement in pharmaceuticals.
- Outcome-based model adopted by a health care payer. If a major insurer or government agency in any market served by GSA firms moves to an outcome-based system for pharmaceutical payment, the need for real-world evidence would dramatically accelerate.

While this report does not predict when these events may occur, it appears highly probable that they will happen before 2030. When they do, firms without ecosystems will find themselves left behind and scrambling to catch up with an industry that has been transformed.

Appendix 1: Quantitative methodology

This appendix explains how we derived the size of the life sciences ecosystem for Germany, Switzerland and Austria (GSA) in 2030, and the share of that ecosystem likely to be occupied by traditional pharma as opposed to new market entrants. **The ecosystem numbers derived from these calculations are presented in the scenarios in the section entitled "The future of ecosystems: looking ahead to 2030."**

Life sciences ecosystem 2030

We divide the ecosystem into two parts: (1) conventional pharma (further subdivided into sales and licensing **based upon the percentages of those areas in the 2001 and 2016 Novartis annual reports)** and (2) health care IT. Our estimates for conventional pharma are based upon value added in the economy, using industry data for the NACE 21 category (manufacture of basic pharmaceutical products and pharmaceutical preparations). Our source for this data is **Eurostat and Swiss Federal Statistical Office**.[85] We express all local-currency values in constant (2018) terms using **consumer price indices from** the IMF WEO database. We divide conventional pharma into sales and licenses on the basis of a key pharma firm's annual reports, as an industry proxy.[86] Our estimates for health care IT are value-add for the economy, extrapolated from the NACE 62-63 category (source: Eurostat and Swiss Federal Statistical Office). We apportion health care IT as a fraction of this, based upon the size of the health care sector in GDP.

To forecast the size of these ecosystem components in 2030, we derive a CAGR based upon the following. For conventional pharma, we use the NACE 21 CAGR from 2000-2015, adding increments to sales or licensing based upon impacts from the new ecosystem as noted in Table 1.

For health care IT, we use the NACE 62-63 CAGR from 2000–15, adding increments based upon the impacts outlined in Table 2. The health care IT CAGR calculation starts with a baseline growth rate **assumption** for each aspect of health care IT. Then it subtracts from this several constraints to full implementation of each aspect. The final CAGR for each aspect is the baseline minus the constraints. The CAGR for health care IT 2015-2030 is the average across these aspects.

The 2015-2030 CAGR for each part of the ecosystem is the baseline CAGR plus the sum of added increments. The value of the ecosystem in 2030 is the sum of each component where the component's 2015 value had been compounded by the appropriate CAGR.

Table 1: Derivation of Ecosystem CAGR (Germany)[87, 88]

		Pharma (conventional)	Sales	Licenses	IT and other info. services	Health
2015	Share of value added		83%	17%		11%
2015	Value added	23.8	19.8	3.93	74.90	8.46
2000	Share of value added		91%	9%		10%
2000	Value added	16.4	14.9	1.54	39.04	3.86
	Baseline: CAGR 2000-2015 (real)	2.5%			4.4%	5.4%
Increments to CAGR (2015-2030)						
	Pipeline (e.g., lower discovery costs)		0.10%			
	Licensing (due to bigger pipeline)			0.10%		
	Collaborative licensing			0.10%		
	Consumer trust (via verification)		0.10%			
	Personalized marketing		0.10%			
	Health IT (see Table 2)					3.75%
	Sum of increments:		0.30%	0.20%		3.75%
CAGR 2015-2030 (Baseline + increments)			2.80%	2.70%		8.19%

85 http://ec.europa.eu/eurostat/en/web/products-datasets/-/SBS_NA_IND_R2.
86 Novartis 2016 annual report, page 255.
87 Tables 1 and 2 serve as examples of the data used to construct the quantitative analysis. Similar data was also compiled for Switzerland and Austria, and then used to form a comprehensive picture of all three markets.
88 Table 1 shows the data used to calculate the CAGR for the pharmaceutical market in Germany for 2015-2030, with the final row in the table the ultimate figures used. The left-hand column represents the historic CAGR from 2000-2015, while "Sales" and "Licenses" show the respective values each business are contributed to overall value, based upon the percentage breakdown seen in Novartis' annual reports for the corresponding years. Increments, based upon perceived reasons for increases in growth, are then added to the baseline estimate to produce the final CAGR.

Table 2: Derivation of health care IT portion of ecosystem (Germany)

	Data sharing and intermediation	Storage of, and access to, big data	Artificial intelligence	Data tools for health care users (patients)	Average
Baseline growth	7.00%	5.00%	3.00%	7.00%	5.50%
Subject to country constraints:					
Initial access	0.00%	0.00%	0.00%	0.00%	
Anonymization	-1.00%	-0.50%	0.00%	-1.00%	
International transfer	-1.00%	-0.50%	0.00%	-1.00%	
Liability assignment	-1.00%	0.00%	0.00%	-1.00%	
Baseline growth (adjusted)	4.00%	4.00%	3.00%	4.00%	3.75%

Apportioning the 2030 ecosystem

The share of the ecosystem expected to be occupied by the traditional pharma players is calculated for the GSA region as a whole. There are low, medium and high estimates of the traditional pharma shares. **To determine these**, we collected M&A data by the pharma sector and the IT sector, concerning aspects of the "ecosystem," from 2015-2018. The pharma sector's share of the pharma sales subcomponent of the 2030 Ecosystem is based upon the share of M&A activity in this category by traditional pharma. Specifically, it is the average of two different calculations: (1) the share of M&A by value of transaction and (2) the share of M&A by number of transactions (Table 3).

The reason for doing so is that either calculation on its own likely represents an imperfect picture of the overall situation due to data limitations. The pharma sector's share of the pharma licensing subcomponent is an arbitrary 5 percentage points less than its pharma sales share, in acknowledgment that new entrants (whether tech or originating in tech) will make bigger inroads into licensing than sales. This gives us a medium scenario for 2030 **that is a reflection of the current levels of investment in different areas by each type of player**. The low scenario is derived by subtracting 5 percentage points from the medium estimate for each component to account for a more reactive stance; the high scenario adds 10 percentage points to the medium estimate to account for increased ownership of ecosystems by traditional firms.

The pharma sector's share of each of the health care IT subcomponents of the ecosystem (genetics, health care (non-pharma), data analytics) is calculated in the same way as the pharma sales subcomponent (i.e., based on the pharma sector's share of 2015-2018 transactions in our M&A database, where the share is an average based on value of transactions and number of transactions). Low and high estimates are again subtractions/additions of 5 and 10 percentage points respectively. **These percentages, which are applied to the market breakdowns for the overall GSA region, can be seen in Table 4.**

Table 3: M&A deals by sector of acquisition or partner (2015-2018 at constant 2018 US$ million)[89]

		By value			By number		Average
	Tech	Pharma	% Pharma	Tech	Pharma	% Pharma	% Pharma
Data analytics	3383	26	0.8%	23	9	28.1%	14.4%
Genetics	4194	295	6.6%	3	3	50.0%	28.3%
Health care (non- pharma)	1835	1754	48.9%	21	10	32.3%	40.6%
Pharmaceutical	1116	17744	94.1%	11	13	54.2%	74.1%

Table 4: Pharmaceutical companies share of value under the three scenarios

	Pharmaceuticals		Health IT		
	% Sales	% Licenses	% Genetics	% Health care (non-pharma)	% Data analytics
Low	69.1	64.1	23.3	35.6	9.4
Medium	74.1	69.1	28.3	40.6	14.4
High	84.1	79.1	38.3	50.6	24.4

89 The categories represent different areas of investment. "Pharmaceutical" houses transactions traditional to the industry and in existing medical areas, while health care (non-pharma) captures deals that are not part of the traditional operating model, i.e., investment in insurance platforms. "Data analytics" houses agreements for data storage, processing and analysis, and genetics includes investment in gene therapies and sequencing.

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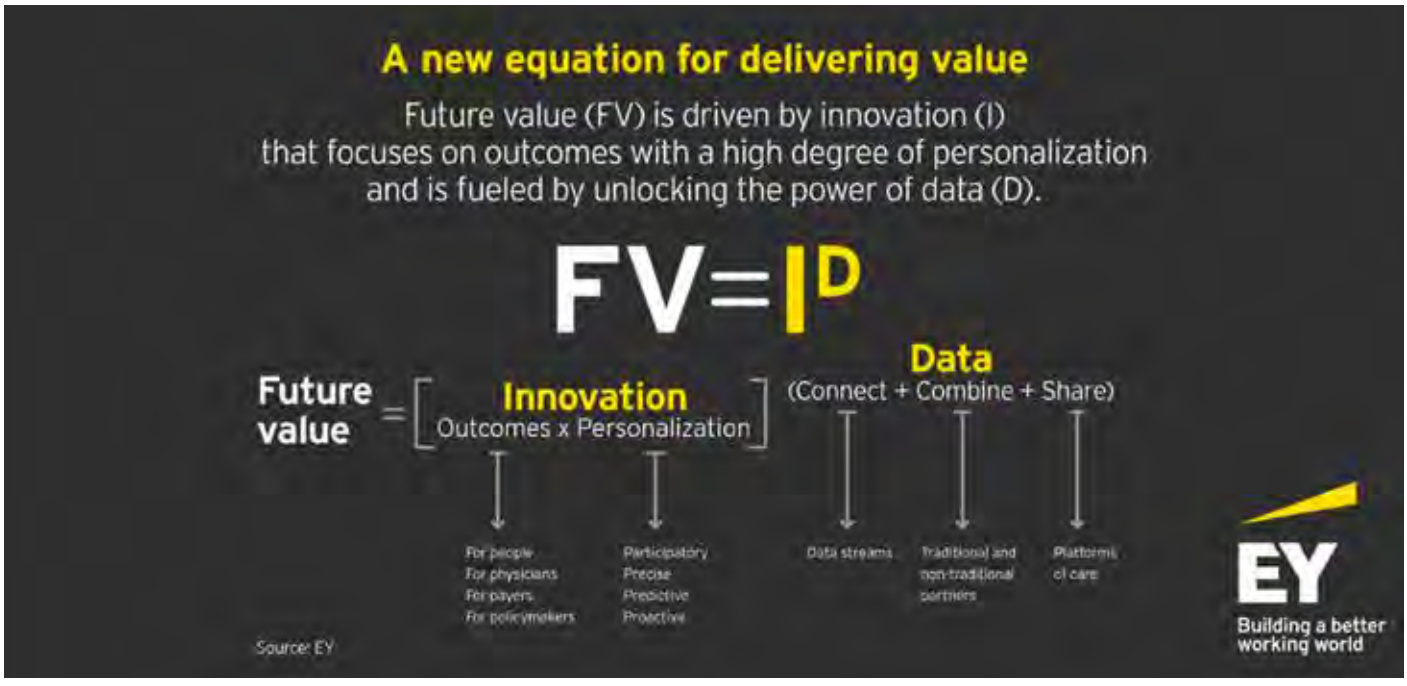
Progressions 2018
Life Sciences 4.0: securing value through data-driven platforms

Increased customer expectations and rapid technological advances are disrupting the health care industry, causing power to shift across traditional stakeholder groups and creating opportunities for new entrants. As the data and algorithms that drive patient-centric health outcomes become the ultimate health care products, organizations that harness data-fueled insights will lead in this new industry paradigm.

Life Sciences 4.0 examines this power shift, creates a future vision for the health care industry and suggests how life sciences companies should respond.

To create value now and in the future, biopharmas and medtechs must adopt agile, data-centric business models presently only seen in other industries. That means life sciences companies must build — or participate in — interoperable information systems that deliver data-driven improvements to health outcomes. And they must form agile, often short-term, partnerships and collaborations.

As competition increases and capital becomes scarcer, we expect to see companies narrowing their focus from diversified business models.



"Embracing Life Sciences 4.0 is both a global urgent need and an opportunity. If companies leverage technology to create platform interfaces and combine their proprietary data with those from other health stakeholders, they can position themselves as powerful leaders and capture sustainable future value."

— Pamela Spence, EY Global Life Sciences Industry Leader

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