

A background image showing a dense network of neurons with glowing blue cell bodies and intricate, branching dendrites and axons against a black background.

Digital deals: spotlight on life sciences

Inorganic strategies are
driving the digital agenda
in life sciences

February 2017

**Is your capital
strategy healthy
enough to seize
the best digital deal
opportunities?**

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Key findings

Across the life science sector, and particularly in pharma, digital innovation is fueling transformation, new opportunities and new challenges. The pace of change means organic strategies alone are not sufficient to build the necessary digital capability. Our recent survey showed that 70% of life sciences CFOs plan to use inorganic approaches to execute their digital strategy. In the last two years alone we have seen over 100 digital deals involving life science companies.

In analyzing these deals, we see clear patterns emerging:

- ▶ The focus of deals fall into three main categories – digital therapeutics, real-world data and advanced analytics.
- ▶ Chronic diseases have experienced the most deal activity.
- ▶ Innovation and product development are at the heart of nearly half of deals observed.
- ▶ A wide variety of deal structures are being employed with the vast majority (approximately 74%) being non-equity-based partnerships rather than traditional M&A.
- ▶ Digital disruption is affecting all areas of the life science value chain.
- ▶ 70% of life science CFOs plan to use inorganic approaches to execute their digital strategy.

Understanding your digital ecosystem, selecting the right partners and structuring deals to protect intellectual property and extract maximum value are keys to success in navigating the digital economy.

Questions you should be asking

1. How is digital affecting your business?

2. Have you identified the gaps in your digital portfolio?

3. Do you know who you want to partner with? Which deal types suit your current, and future, business model?

4. How will you measure the success of your digital strategy?

5. How will you integrate digital solutions into your organization and be confident of delivering the business benefits as well as the adoption of a digital culture?

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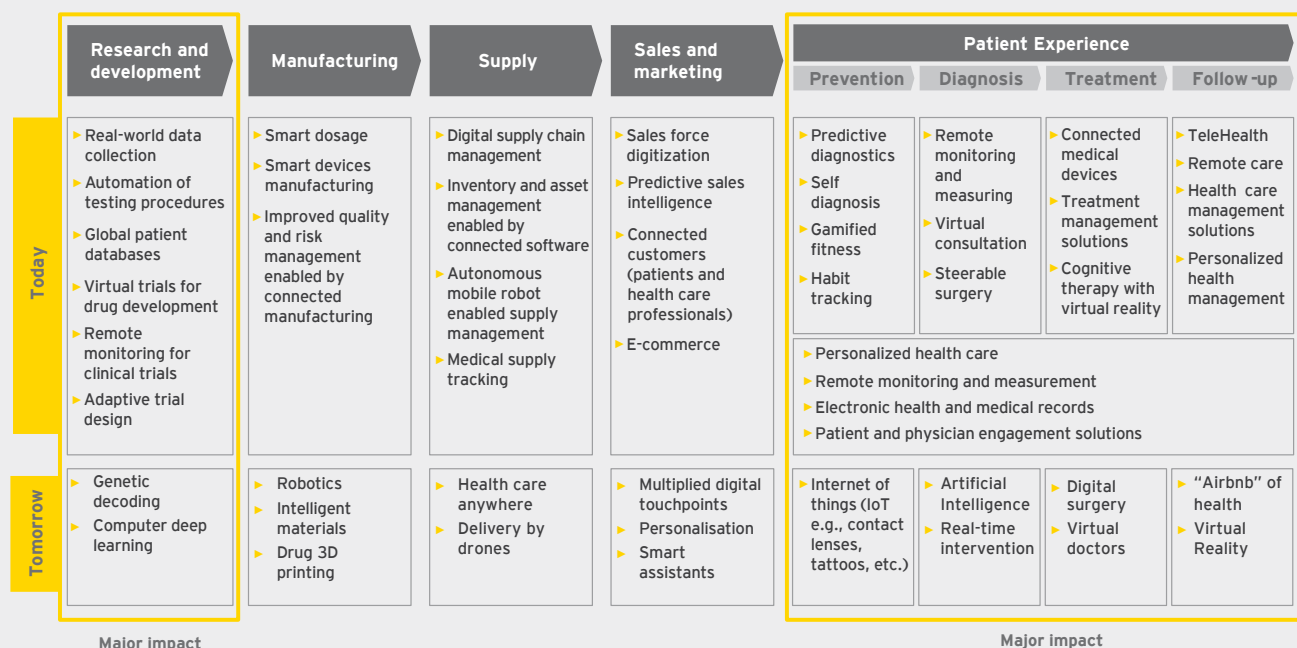
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Digital innovation is disrupting the life sciences value chain

Life science organizations are undergoing a paradigm shift as digital technologies impact their business across each step of the value chain. Digital innovations across the health care ecosystem are fueling transformation, opportunities and challenges. To overcome these challenges, traditional players will have to work with technology and data-management firms, plus partner with health care providers and payers.

Emerging digital technologies and a blurring of industry boundaries means that companies from other industry sectors can challenge pharma's dominance. This is leading to disruption that goes far beyond previous digitalization waves and adoption of enterprise-wide solutions. These evolving technologies will allow the life science sector to leverage data, focus on patient-outcomes and ultimately move to beyond the pill solutions.

Figure 1. Digital disruption is occurring across the value chain, but is currently most pronounced in R&D and the patient experience segments.



Why are research and development (R&D) and the patient experience the most impacted by digital disruption?

Digital innovation is helping to address some of the life science sector's biggest challenges - to reduce drug development cycle times, to improve attrition and become increasingly patient centric. Digital technologies will help R&D select the right therapeutic targets, the right compounds to develop and the right patients to test them in. Innovative solutions will improve patient and physician engagement in response to changing patient expectations.

Why is pharma relatively slow to adopt new or un-validated digital technologies?

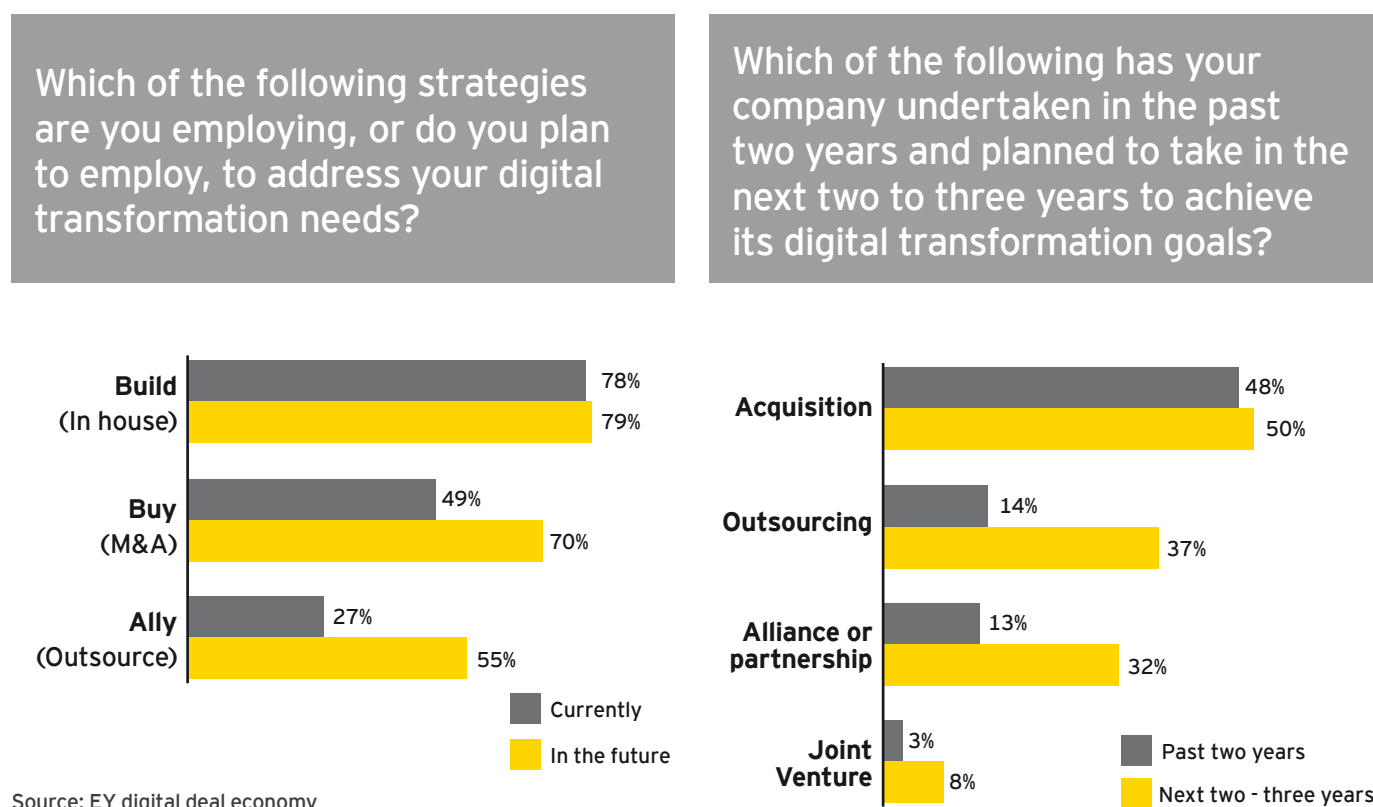
Rates of digital technology uptake vary across the sector, with biotechnology companies being the most advanced, mirroring their innovative culture and operational nimbleness. They are early adopters of artificial intelligence, epigenetics and personalized medicine. Medical technology firms and contract research organizations (CROs) are both rapidly adopting digital technologies. For medtech these include robotic surgery and precision diagnostics whereas CROs have focused on enabling software solutions such as cloud-base electronic trial master file (eTMF) and regulatory submissions. It is pharma that currently lags behind. This immaturity exists despite many years of infrastructure outsourcing and successful digital transformation of software solutions e.g., clinical data management, customer relationship management (CRM) and enterprise resource planning (ERP) platforms. We have focused this report on pharma's journey to adopt digital innovation.

Our research shows that 70% of life science companies plan to use M&A to build digital capabilities over the next two to three years with the pace of change and competitors coming from non-traditional sectors

A business model supported by an adaptable and agile capital strategy has to be adopted for digital transformation to be successful. In the life science sector it is essential that the deployed capital for digital transformation is not achieved at the expense of pharma investment in R&D since one of the benefits of the digitalization will be the discovery of innovative treatments and novel ways of providing personalized health care.

Evidence from across the sector clearly shows that companies can no longer solely pursue organic growth activities to meet their digital ambition as the pace of change from digital innovation is simply happening too fast.

Figure 2. EY's "Digital Deal Economy" study reveals health care executives believe acquisitions and outsourcing to third parties will be a key enabler for achieving digital transformation in the future sector



It is important to understand your digital portfolio and identify where the gaps are in your capabilities and digital technologies. Should you "Build or Buy"? With limited capital and time, pharma is turning to mergers and acquisitions (M&As), joint ventures and partnerships or alliances. This is confirmed by the recent EY study (see Fig 2) which demonstrated that M&As have become as important as building internal, or organic, capabilities. The study also clearly showed that partnerships and alliances will be twice as important going forward as they are today, and that joint ventures will become commonplace. **But do you know where the digital technology opportunities are and who you should partner with?**

Deal goals and outcomes

Delivery of a “digital therapeutic” or a more “open-ended” collaboration to drive innovation

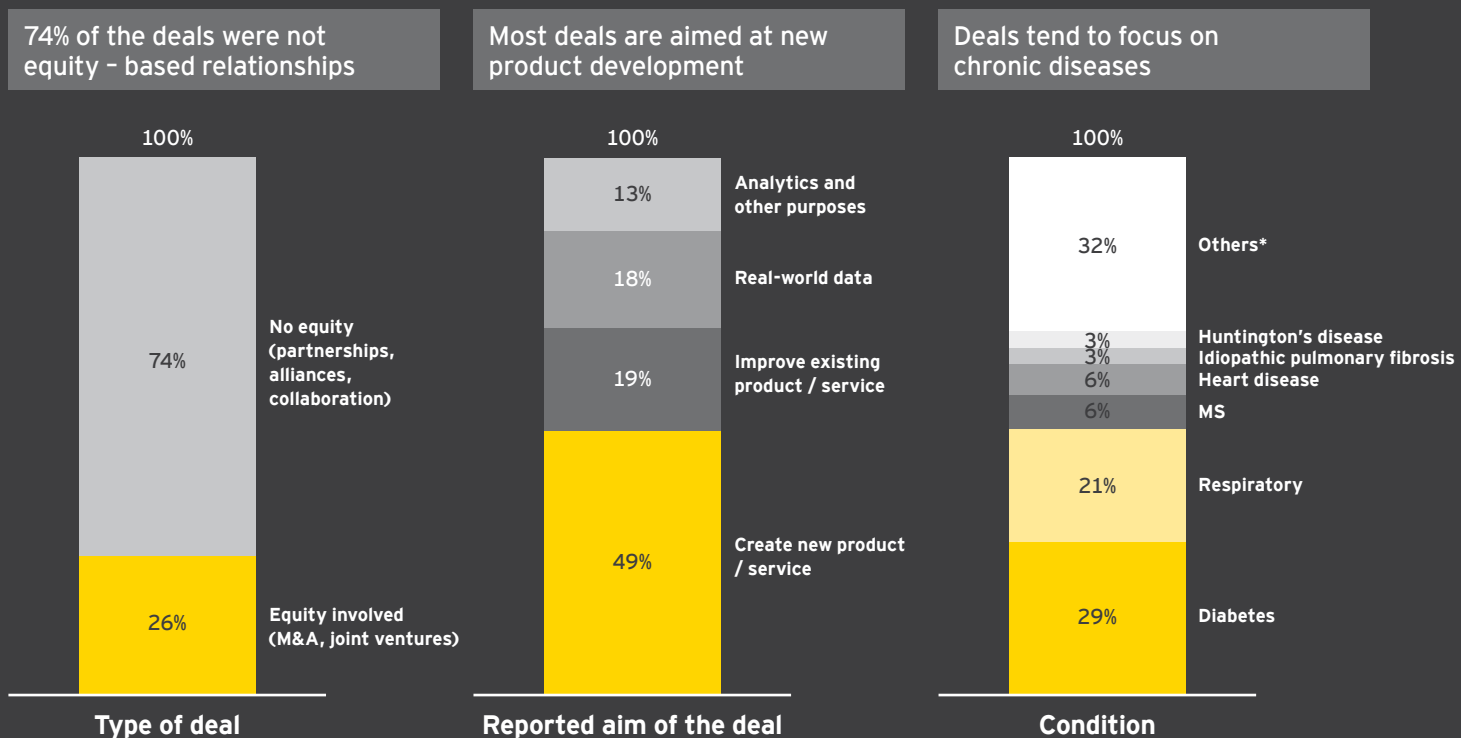
EY has analyzed over 100 deals that pharma has made with a digital focus in the last two years. There are several notable findings observed when the deals are parsed by deal type, objective and disease area (see Fig 3). **The majority of these deals (c. 74%) do not involve equity** and consist of a mix of partnerships and collaborations. The 26% of deals that involve equity are joint ventures and M&A. The deal type is dependent on how close to commercialisation a product or service is. Generally more mature deals and those involving equity follow on from successful pilot proof of concept or proof of value studies.

Innovation and the creation of products or services are at the heart of these deals (c.49% of them), and the aim of a further 19% is to add an innovative aspect to an existing product or service, e.g., connecting an existing medical device to a health care platform by addition of a smart technology. The remaining 32% of deals have been established to either **gain access to health care datasets or real-world data** (18%) or to access technologies (13%), such as advanced analytics and cognitive computing. These can be utilized to mine internal and external data sources, un-locking value, and provide detailed insights for evidence-based decision making.

Most deals are focused on chronic disease especially diabetes and respiratory which make up c.50% of the analyzed deals. The target of the remaining deals can be summarized as:

- ▶ Therapeutic areas where there are new products in development or recently launched medicines;
- ▶ Disease areas where adherence is poor and a health care platform would support either treatment or disease management;
- ▶ When there is a need to gain an understanding or monitor progression of disease symptomatology.

Figure 3. EY analyzes of recent digital deals reveals their rationale is predominantly creating a new product or service



Source: EY research

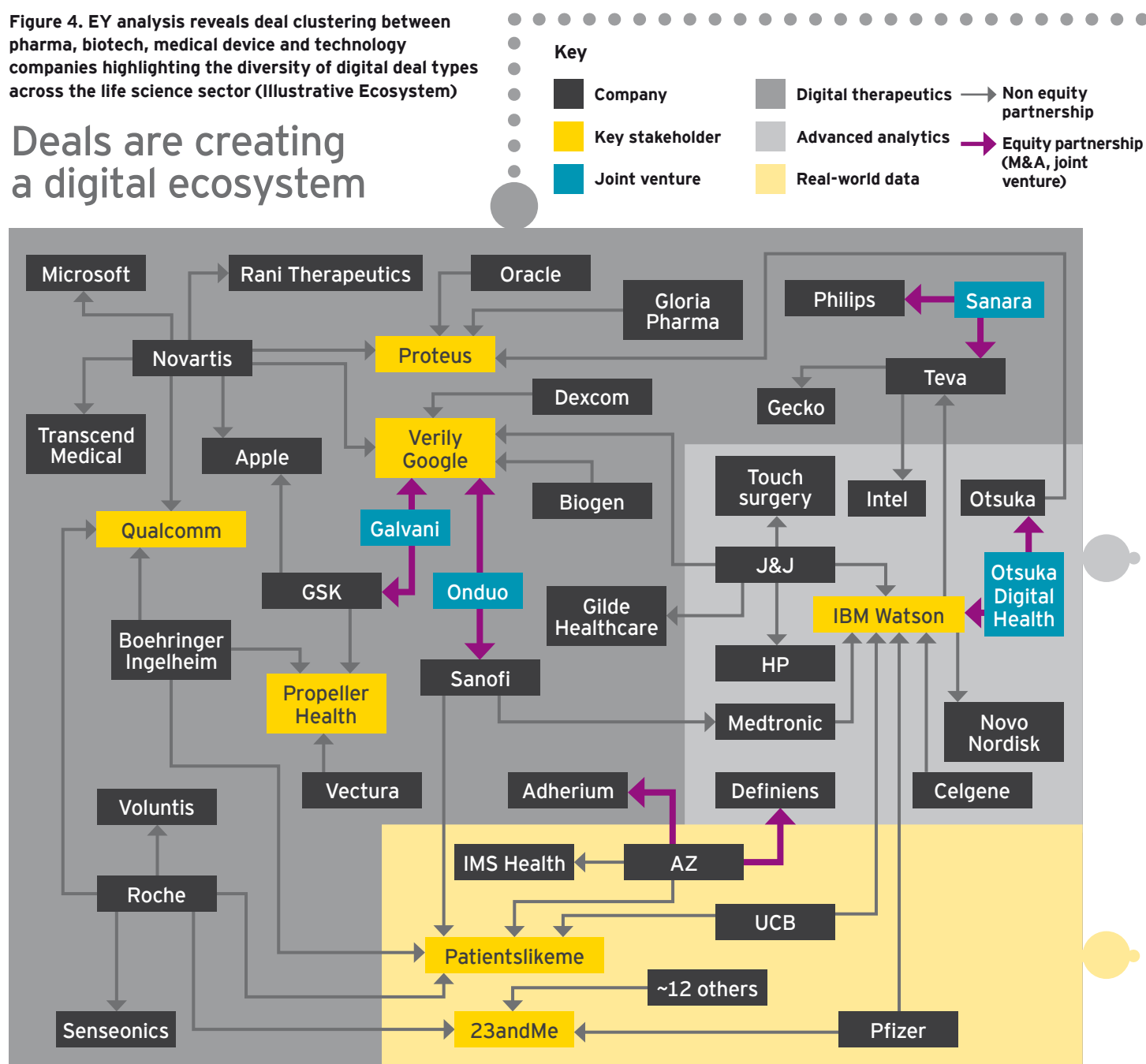
* Others include: Parkinson's disease, cancer, mental health, epilepsy, glaucoma, dry eye disease

A wide variety of deal structures are being employed with the vast majority being non-equity-based partnerships rather than traditional M&A

Deal clustering around key players

Figure 4. EY analysis reveals deal clustering between pharma, biotech, medical device and technology companies highlighting the diversity of digital deal types across the life science sector (Illustrative Ecosystem)

Deals are creating a digital ecosystem



Source: EY Research

Diagram is not exhaustive

Detailed analysis reveals three digital categories that are driving disruptive growth and process improvements

Digital therapeutics

Digital therapeutics are the foundation of pharma's transformation towards patient centricity and providing health care solutions. They have the capability of monitoring disease symptomatology, delivering medicines as well as providing support across the patient journey. A digital therapeutic consists of a number of constituent parts. These include a monitoring or a wearable technology which provides real-time assessment of disease biomarkers e.g., heart rate variability or glucose levels in diabetes. This patient centric information can then either be monitored by patients themselves, by care-givers, or securely transmitted directly to the patients' health care providers. Medicine(s) are delivered by a smart or connected delivery device such as an inhaler or an infusion pump. These can also be connected to a mobile application which provides patients and physicians with a detailed snapshot and longitudinal dataset of the patient's real-world therapy usage and personalized disease progression. A health care management platform provides personalized treatment plans for patient's individual symptomatology and patient reminders to take medicines as prescribed. The result will be improved medication adherence and disease management. Recognizing this, the U.K.'s National Institute for Health and Care Excellence has recognized the SmartInhaler digital platform as the most effective means of improving asthma medication adherence and reducing hospitalizations.

Evolving out of innovative research partnerships are the next generation of digital therapeutics. These miniaturized implantable devices can be programmed to correct the abnormal electrical signals associated with certain diseases. Establishing the requirements for regulatory approval of an end-to-end digital therapeutics will need to be agreed.


Advanced analytics and artificial intelligence

The health care ecosystem sits on a wealth of data. Often this data is hard to access due to outdated IT systems, organisational silos or other technology barriers such as poor interoperability. Emerging technologies, digital solutions and cloud computing now provide the capability to combine multiple complex and diverse datasets (structured, un-structured data and medical images) into a single aggregated dataset. Analytics can provide an understanding of the real-world impact of disease, individual patient profiles, treatment effectiveness, and provide evidence for the true value of a medicine. Mining these datasets can guide clinical practice and help identify new patient segments e.g., rare diseases or poor responders to current treatments. Databases can be greatly enriched with content from pharma's own internal R&D and clinical trial databases. Real-time analytics can be used in adaptive clinical trial design to respond accordingly to real-world signals.

Personalized medicine offers new insights into human genetics and the causes of disease. It will allow health care providers to use a patient's own genetic profile to determine the therapeutically appropriate drug and the optimal dose rather than solely relying on diagnosis and dosing by weight. This personalization is being enabled by advances in bioinformatics analytics, high-throughput cost-effective sequencing of genetic samples, the use of cloud computing to process and analyse huge volumes of sequencing data. Personalized medicine can only be achieved by coupling scientific and analytical technologies requiring collaboration between industry sectors. Having the analytical insights to stratify patient populations by phenotype will allow pharma companies to build predictive models, using artificial intelligence, which when combined with patient level data will be able predict the efficacy of a medicines, and even warn of adverse drug reactions. This deep knowledge can be used to develop physiological models for the selection of new therapeutic targets, to accelerate the R&D cycle time and warn of potential toxicological thereby reducing product attrition.

Real-world data and health care outcomes

These measures provide detailed patient-centric data and customer insights. Real-world treatment effectiveness can be captured from digital therapeutics, as well as the more established sources from health care providers and payers. There is a vast opportunity to create value by using analytics to mine internal and external data sources. These sources not only include health insurance claims, electronic medical and health records, and prescription data but also data relating to health care economics and the societal financial impacts resulting from illness. Tapping into disease registries and online patient communities can also provide insights into illness and real-world demographics. The "true benefit" of a medicine can then be calculated and used in value-based reimbursement discussions. In addition to demonstrating value, real-world data is valuable for gaining marketing information on patient segments to use in targeted clinical trial recruitment, responding to changing expectations with patient and physician engagement, and personalized e-marketing content. Investing in real-world data and analytics will provide pharma, medtech and biotech companies a competitive edge over their peers, and provide valuable inside for regulatory and reimbursement discussions. Third party companies are now aggregating these datasets and providing the analyses as Data-as-a-Service with a consequence of increasing data transparency. This may open pharma up to the scrutiny of patient groups, payers and regulators. Pharma companies must be alert to data security arising from the capture and transfer of patient data, cybersecurity of digital therapeutics and mobile applications.



Pharma deal structures reflect their strategic ambitions

There are clear differences in business approaches between pharma and technology companies as they develop and commercialize digital technologies. Companies are choosing the deal structure that meets their digital objectives

- ▶ **Acquisitions/M&A** of digital solutions or digital health care platforms are largely executed when there is a need for greater control and ownership of intellectual property, sharing both risk, capital, and capabilities.
- ▶ Pharma is far more focused on building **partnerships or joint ventures** with technology companies. The maturity of the deal type is dependent on how close to commercialisation a product or service is i.e., non-equity collaboration or partnership maturing to equity joint venture and acquisition.
- ▶ The majority of pharma, like technology companies, are actively investing capital, and providing support via **accelerators or incubators** to small and start up digital health companies.

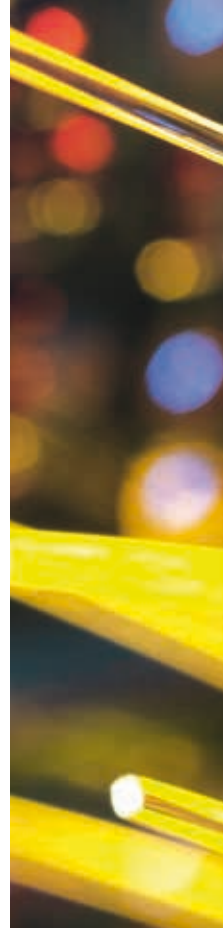
Digital acquisitions are principally executed by the technology companies as they build analytical capabilities or access vast patient and health care datasets. A good example are the sizable investments made by IBM during the creation of Watson Health, an artificial intelligence health care technology company, and clearly illustrates the potential market value of health care data insights offered by advanced analytics. As IBM Watson Health built the required capabilities it acquired Merge Health care (medical image handling and processing), plus the big data analytics companies Explorys (to detect patterns in diseases and treatments) and Phytel (care coordination and outcomes). Watson also acquired Truven Health Analytics (comprehensive datasets, plus methodologies and algorithms to analyze health care costs). Other technology companies have used major acquisitions to rapidly access the medical technology sector. For example, Panasonic Health recently set up Ascensia as stand alone digital life science company following the acquisition of Bayer Diabetes Care. Ascensia develops and produces glucose monitoring devices and diabetes management platforms.

Pharma is far more focused on building partnerships or joint ventures with these technology companies to gain access to their health care management platforms, their complex patient datasets, and supporting infrastructure (see Fig 4). Pharma partnerships have largely clustered around the technology giants of Verily-Google, Qualcomm, IBM Watson and companies with specialist technology platforms such as Propeller Health (connected inhalers for respiratory) and Proteus Health (smart pills technologies for improving treatment adherence). Many of these partnerships result in pilot studies that are designed to test the functionality, usability and insights into commercial benefits. Evidence from these studies may be used for regulatory discussion to establish the approval requirements. These alliances or early partnerships may begin as non-equity collaborations or low equity partnerships. As the partnerships mature and pilot studies move to full-scale commercialisation programmes, then we observe larger investments, joint ventures and acquisitions. This is often associated with pharma becoming increasingly comfortable with the technology, the digital processes and their integration, and their partners.

There are a number of joint ventures set up between pharma and the technology companies. These include Sanofi and Verily-Google who launched Onduo, a joint venture with 50% equity each partner, to develop a comprehensive diabetes management platform. Also GlaxoSmithKline (GSK) and Verily-Google formed Galvani Bioelectronics (55% GSK equity) to enable the R&D and commercialisation of bioelectronic medicines. GSK has previously disclosed an electroceuticals and a bioelectronics venture fund.

Pharma company's desire for this real-world data and analytic capabilities can be clearly observed from the partnerships and Data-as-a-Service agreements that have recently been reported e.g., Genentech with 23andMe in the area of Parkinson's disease which makes use of the database created by customers who have bought 23andMe's DNA test kits and donated their genetic and health data for research. Other life science companies have focused more onto the real-world data contained within patient online community sites, and these have often be the target for focus clinical trial recruitment e.g., patientslikeme and multiple pharma partners - UCB, Sanofi, Roche, AstraZeneca, and Pfizer.

Pharma, like technology companies, are actively investing capital, and providing support via accelerators or incubators, to smaller technology start-ups. This can be a flexible, cost effective and nimble route to digital innovation. Janssen/Johnson & Johnson (J&J), GSK, Merck, Pfizer and many more all have incubators set up near biotechnology hubs to help start-up companies. Technology companies also have large venture funds focused on digital innovation e.g., Google ventures is looking to invest 6% of its fund in medical technologies technology, and Google was pivotal in the development and launch of 23andme.



Which deal type suits your current, and future, business model?

Clearly pharma have different strategies for digitalization and the development of smart devices. For example, in recent deals in the Respiratory disease area, it is apparent that all the major asthma and chronic obstructive pulmonary disease (COPD) players are progressing smart (or connected) inhaler devices. However when one looks closer it is apparent that there are at least three broad strategies being pursued.

1. Partnership with an established "technology expert" to improve an existing product or service


e.g., development of a connect version of an existing inhaler. Novartis have partnered with Qualcomm, Boehringer Ingelheim, GSK, Vectura have all partnered with Propeller Health (who already have an FDA cleared device). Propeller Health is also developing the next generation of "integrated" connected inhalers with Aptar, and by partnering with a technology expert it is possible that access to future innovations in device technologies may be possible.

2. Partnership with "medical device start up" to develop a new product or service e.g., a connected device.

AstraZeneca formed a digital health partnership with the medical device company Adherium to collaborate on the use of "smart inhalers". After a commercialisation pilot program, AstraZeneca invested as part of the Adherium IPO.

3. Acquisition/M&A of the enabling medical device and platform.

Teva purchased Gecko Health Innovations rapidly gaining access to chronic respiratory disease platform including a sensor device that connects to most inhalers, a health care management platform, and behavioral triggers to help asthma and COPD patients manage their condition.



How do you define the aims, goals and the desirable outcomes of these partnerships?


Pivotal to successful development of a product, service or solution is setting a series of pre-defined goals and partnership objectives. Defining the objectives is simpler when you are partnering to develop a product, for example a digital therapeutics or an analytics platform. However the partnership outcomes are far less apparent if you are generating ideas or propagating highly innovative solutions where commercialization of a product is much further away, and the risks of failure are high. Many of these emerging technologies will be pre-revenue and pre-profit.

Partnerships that are pursuing development of medical technologies have clear goals around product development timelines and economic endpoints i.e., achieving positive proof of concept and proof of value. A good example is Novartis who have an exclusive worldwide agreement to license Proteus Health's smart pill and sensing technology. A recently disclosed Novartis study highlights that the objectives were being established in that the product has entered clinical development and from a value perspective that patient's treatment adherence had improved from 30% to 80% after six months. A small increase in adherence will not only drive an increase in "pill days" increasing pharma's revenue stream, but also have a significant benefit on patient health care outcomes thereby reducing health care costs and societal burden. Otsuka is also aiming to use the Proteus smart pill technology with ones of its blockbuster medicines to record ingestion and share information with health care providers.

For other pharma-technology partnerships the end point is less commercially defined especially in the case of accelerators. For example Leo Pharma has invested in the Leo Innovation Lab, a site at which the drug maker will research how smartphone apps, health care platforms, wearables, virtual reality, artificial intelligence and telemedicine can improve the lives of patients with psoriasis. Interestingly there is no project revenue target, but instead the partnership aims to develop and build a series of solutions around the psoriasis therapeutic area. The goal is to achieve idea generation to beta testing in <100 days. Pharma sponsorship of hackathons maybe a relatively cost effective way to speed up innovation and support development of digital technologies however the successful outcomes are relatively sparse at the moment. There are signs that the incubator approach of supporting digital start-ups may have some degrees of success with the recent announcement that the J&J Innovation Centre in London facilitated the licensing of a series of novel clinical stage drug candidates from Janssen to BenevolentAI.

What happens when delivery is delayed or project attrition occurs? Two examples illustrate this, and ultimately this leads us to ask a number of questions around navigating your digital strategy and **how you quantify your return on digital investments.**

The first example is IBM who has made significant investments during the creation of Watson Health. These investments are paying off with a rapidly growing number of projects across the life science and health care sectors, however Watson Health is performing less brilliantly for the company's bottom line (at least so far). The second example is the "delay" to high profile digital innovation in the area of diabetes and continuous glucose monitoring. Novartis and Verily-Google are working in partnership on the development of a smart contact lens that has an embedded glucose sensor to help monitor diabetes. Novartis has recently abandoned its commitment to start clinical trials of the contact lenses in 2016. Novartis told Reuters "it is too early to say when exactly human clinical trials for these lenses will begin." An announcement like this clearly has financial implications and sets the project back. We can speculate about the reasons but regardless of cause, delays like this may bring a sense of realism around technology companies entering the medical device sector and highlights the development and manufacturing challenges these devices will face. It is likely that adoption of new technologies may face challenges from users too i.e., patients.



Are you prepared to execute an inorganic digital strategy?

Digital therapeutics and the benefits derived from collecting, aggregating and analyzing this patient-centric data will provide important customer insights into health, diseases, appropriate care and effective therapy. Improved disease awareness will result from this real-world evidence and can be used to accurately inform patients and health care professionals (HCPs) with quality information. Treatment adherence will increase as pharma develop medicines that are safe and effective, convenient to take and address patients' needs. This improved adherence is a win-win situation for the health care ecosystem. As for patients, it results in improved health outcomes and wellbeing, for life science companies, it means increased revenues, for providers it means less medication wastage, cost effectiveness with improved health care outcomes and reduced burden on the health care system.

Understanding your digital ecosystem, selecting the right partners and structuring deals to protect intellectual property and extract maximum value are keys to success in navigating the digital economy.

Questions you should be asking about the performance and value of your company's digital strategy

1. How is digital affecting your business?
2. How well developed is your current digital strategy to future proof your business?
3. Do you understand where the gaps are in your digital portfolio? Should you "Build or Buy" solutions, services or capabilities?
4. How will you identify and then triage the high number of digital opportunities? Some of which will be emerging technologies and are pre-customer, pre-revenue and pre-profit.
5. How will you define the aims, goals and the desirable outcomes of these product or platform partnerships?
6. Do you know who you want to partner with? Which deal type suits your current, and future business model?
7. How do you value, and decide on ownership, of the intellectual property generated from these business models (e.g., discoveries from patient datasets, new indications arising from AI)?
8. How do you plan to integrate digital solutions into your organization and be confident of delivering the business benefits as well as the adoption of a digital culture?
9. How will you measure the success of your digital strategy? What is the payback period for your digital and big data technology investments?
10. Are you prepared to continually validate and improve your digital strategy?

How EY can help you navigate the digital health care ecosystem

The digital capital agenda

Evidence from the life science sector clearly shows that companies should no longer only pursue organic R&D growth activities to meet their digital ambition. With limited capital and time, life science companies should look to create balance using M&As, joint ventures and alliances. These partnerships with health care providers coupled with technology and data-management companies will facilitate the sector's digital transformation driving opportunities, business benefits and overcoming the challenges faced by digital disruption.

Your capital strategy in a digital world should look to gain competitive advantage through organic and inorganic routes (i.e., partnerships, M&As, joint ventures, etc.,) to growth. Acquisitions are a potential route to growth as acquired technology platforms, start-up businesses and innovation could all transform your business. Divestments offer the change to reshape your business and enable you to reinvest in digital capabilities.

EY Transaction Advisory Services Digital Capital Agenda can help businesses respond to digital disruption and realize strategic options by focusing on raising, preserving, investing and improvising capital.

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EY Transaction Advisory Services Digital Capital Agenda helps businesses respond to digital disruption and realize strategic options by focusing on raising, preserving, investing and optimizing capital.

Raising

- ▶ Identify funding options
- ▶ Assist in fundraising (equity and debt) and address capital markets requirements
- ▶ Advise on how to optimize funding/financing structures
- ▶ Identify assets and operations to divest
- ▶ Advise on tax-efficient structures, including challenges arising from new digital products

Preserving

- ▶ Assist with digital improvement analyzes - enterprise-wide or product
- ▶ Perform valuations to model the impact of digital align on company economics
- ▶ Analyze customers and suppliers via social media monitoring
- ▶ Help preserve tax assets and reduce costs
- ▶ Analyze customer journey (mobile, website, call center, email, social)

Investing

- ▶ Advise on acquiring digital operations and service, including financial and tax-related matters
- ▶ Provide digital commerce due diligence and growth strategy analyzes
- ▶ Evaluate the infrastructure and digital capabilities underlying investment decisions
- ▶ Perform transaction diligence, including digital analyzes aimed at revenues and costs
- ▶ Advise regarding tax structuring, including consideration of digital models

Optimizing

- ▶ Develop strategy and business models to improve a company's digital positioning
- ▶ Assist with digital scenario planning and assess impact to shareholder value
- ▶ Identify and evaluate assets
- ▶ Support operational reorganization through modeling, planning and implementation to improve a company's digital value

How the capital agenda can support your digital ambitions

The EY Transaction Advisory Services (TAS) Digital Capital Agenda can help businesses respond to digital disruption and realize value from strategic options by:

- ✓ Identifying digital investments and strategic partnership
- ✓ Reviewing competitor digital maturity and ecosystem
- ✓ Optimizing funding options
- ✓ Performing digital and commercial due diligence and growth strategy analyzes
- ✓ Valuing digital assets and IP
- ✓ Integrating digital businesses and capabilities
- ✓ Assisting with digital scenario planning and assessing impact to shareholder value



Case studies

Inorganic approaches to digital strategy execution



Recent digital innovations

Digital disruption is transforming the Respiratory disease area with regulatory approval of smart inhaler devices and smartphone apps.

The most “digitally mature” therapeutic areas are associated with chronic disease indications that already contain blockbuster therapies, where there is significant competition or treatments are nearing loss of exclusivity. The respiratory areas of asthma and chronic obstructive pulmonary disease (COPD) are rapidly evolving into a digital health care ecosystem where smart and connected inhaler devices will supply approved medicines to patients, and their usage and disease symptomatology will be monitored by treatment and disease-managed platforms respectively. This patient centric information can then either be monitored by patients themselves, by care-givers, or securely transmitted directly to the patients’ health care providers. Smart inhalers are being used in late stage clinical trials to provide an understanding of real-world treatment effectiveness. This evidence will be part of regulatory filings and provide valuable cost-effectiveness data for pricing negotiations. All pharma with significant respiratory franchises are developing smart connected inhalers (i.e., GSK, Novartis, AstraZeneca, Boehringer Ingelheim, Vectura, and Teva). To achieve this objective

pharma are either jointly developing smart inhaler devices with two of major technology companies (i.e., Propeller Health or Qualcomm) or alternatively by investing in, or acquiring, medical device companies that have developed their own connected inhalers (i.e., Adherium or Geko Health Innovations). The most advanced and first to market is likely to be GSK and Propeller Health who secured FDA clearance in November 2016 for the use of its digital respiratory disease management system with GSK’s Ellipta dry powder inhaler. The sensor attaches to GSK’s inhaler (and to inhalers developed by other manufacturers) and has the ability to track when patients take their COPD medication. The next generation of connected inhalers with an integrated sensor and electronic dose counting is being jointly developed by Propeller Health and the drug delivery systems provider Aptar. Asthma UK recently urged health services to increase the use of digital technology in delivering asthma care. They highlighted the use of smart inhalers to monitor inhaler technique, making action plans accessible online and allowing patients with mild asthma to complete their assessments remotely.

Real-time monitoring is revolutionising the treatment and management of chronic diseases.

Therapeutic areas where the population demographics and chronic conditions will drive significant market growth are also early adopters of digital innovations. Diabetes is most advanced when it comes to digital therapeutics and requires a multifaceted approach merging medical devices technologies, with medicines and disease management platforms. This scope is far broader than discussed for the respiratory disease area. To deliver a holistic disease monitoring and treatment paradigm requires firstly a device to measure the body’s glucose levels e.g., disposable continuous blood glucose monitoring or using smart contact lens measuring glucose in the patient’s tears. The output of this device needs to be coupled with an analytics platform, a miniaturized electronic device that is capable of adjusting insulin infusion rates from implanted pumps in response to

changes in glucose levels. A patient mobile app will capture and provide a real-time visualization of their glucose levels and health management. Sanofi, Novartis, Novo Nordisk are all deeply involved in developing digital therapeutics in partnerships with technology companies such as Verily-Google and IBM Watson Health, along with medical device companies such as Dexcom and Medtronic and disease organisations such as American Diabetes Association. There are currently two digital products that have received FDA clearance, both from Ascensia Diabetes Care (Bayer Diabetes Care Division prior to acquisition by Panasonic), where smart glucose monitoring systems connects either to a Medtronic insulin pump, or to a smartphone app to help patients better understand and manage their diabetes.

Innovative digital technologies increase medication adherence and compliance.

A major issue with the treatment of chronic diseases is poor medication adherence. This results in both a lack of patient therapeutic benefit and also drug product wastage, both of which lead to avoidable costs to health care providers. It is estimated that up to 25% of all health care spending is wasted on avoidable costs and hospitalisations. A study from the New England Health care Institute estimated that this cost could be \$290 billion per year to US health care providers. Follow on studies (IMS, HealthPrize/Capgemini) have estimated the revenue loss to the US pharmaceutical industry could be \$188 billion i.e., 59% of their total US revenue, and that increasing adherence by 10% would increase US revenues by \$41 billion. There are three examples where digital technologies are improving medication adherence. Firstly in the UK, the National Institute for Health and Care Excellence has recognised the Smartinhaler digital platform (Adherium) as the most effective means of improving asthma medication adherence and reducing hospitalizations. The Smartinhaler clips onto existing inhalers to monitor treatment usage and provide audio and visual medication reminders. Clinical trials have shown a significant improvement in medication adherence, with one trial reporting 84% of patients using the Smartinhaler followed their asthma treatment plans

compared to 30% in the control group. Secondly Novartis and Otsuka are both developing Proteus Health's digital "chip in the pill" technology to overcome poor adherence. A receiver sensor on the patient's shoulder records when the medication has been ingested and information is shared with health care providers. In a Novartis study this technology improved compliance from 30% to 80% after six months. Proteus's ingestible sensor technology has received an expanded FDA Indications for Use statement on the back of adherence claims. The third example is a mobile app that focuses on patient engagement as a methodology to promote adherence. This ensures that treatment action plans are developed avoiding unnecessary and costly hospital visits. It is the first app from a pharma to be approved as a Class 1 medical device and CE marked. The MyAsthma app allows patients to track their asthma attacks, medication use and monitor their disease by capturing their peak flow and spirometry readings. The information can be downloaded and shared with HCPs thus improving the dialogue between patients and their HCPs. Feedback, collected by GSK, demonstrates that doctors could potentially save 20 minutes per consultation ultimately freeing up more time for patient care. The MyAsthma app is also applicable to other disease areas, and GSK plans to use the app as a methodology to promote adherence.

Remote monitoring provides deep understanding of disease symptomology.

Pharma and their technology partners are experimenting with wearable devices and remote monitoring to determine if they can be reliably utilized for quantifying symptoms and tracking disease progression. Many of these disease areas have recently approved medicines or are indications where existing medicines are struggling to halt disease progression or then dose titration is required to maintain effectiveness. Chronic diseases testing these technologies include multiple sclerosis (Novartis-Microsoft; Biogen-Google Verily) and also psychiatric disorders including Parkinson's disease, schizophrenia and bi-polar disorders (Pfizer, Otsuka & Teva all with IBM Watson Health). One of these projects aims to gain a better understanding of a patient's Parkinson's disease progression and medication response by using a

system of sensors, mobile devices, and artificial intelligence to provide real-time, around-the-clock disease symptom information to clinicians and researchers. Ultimately this will inform treatment decisions and clinical trial design, while also speeding the development of new therapeutic options. GSK became the first pharma to run a clinical study using Apple's ResearchKit framework with an aim of gathering real-world data on the day-to-day lives of people with rheumatoid arthritis. The smartphone app gathers data using a mix of surveys and sensor-enabled tests using iPhone in-built sensors to record motion during wrist exercises. The trial was valuable in educating GSK on how the ResearchKit could be effectively used in future clinical trials.

EY thought leadership

Digital deal economy



The business world is being transformed. Advances in technology and digital communications have not only empowered customers but also enabled companies to collect, collate and analyze data in new ways that better inform strategic decisions and change how they operate.

Executives recognize that digital transformation is impacting all aspects of their business – from the front - end to the back. They also

know that the competitive landscape is changing rapidly as barriers to entry are eroded. Digital is a continuous form of disruption to existing (or new) business models, products, services or experiences, enabled by data and technology across the enterprise. The key challenge for many companies will be a lack of sufficient capital to meet their digital ambition.

Enabling a digital future requires smart capital allocation. Selecting the right strategic investments – organic or inorganic – offers routes to growth. The key question is can companies build the capabilities required to succeed in the brave new world – or do they need to buy?

Capitalizing on the digital challenge



Two of the biggest drivers of deal and investment activity in the market today are globalization and digital disruption.

With only modest increases in global GDP, cross-border M&A has been accelerated by divergent global economic conditions. Businesses are seeking higher growth in a low growth environment and are looking to boost their prospects overseas.

At the same time digital disruption is changing the whole business landscape and reshaping investment strategies. Technology is transforming business models, changing consumer preferences and blurring sector boundaries.

That rapid digital transformation is creating major opportunities for businesses in this fast-evolving economy. Executives are now focusing on digital-related investments to manage costs and secure innovation, competitive advantage and market share for the foreseeable future. Capitalizing on the digital challenge explores the changing business landscape and the opportunities available to companies which move faster than the competition. It also considers the complexity and risks related to developing a robust digital strategy.

EY M&A Outlook and Firepower Report 2017

Will payer leverage and post-election optimism shift dealmaking into a higher gear?



Payer pressure is growing across a wide spectrum of the health care sector. Price increases have been blunted by election-year rhetoric and competition in key global pharmaceutical markets. Continued portfolio rationalization, a professed preference for bolt-on deals, and lower target company valuations continue to sharpen global appetites for acquisitions into 2017. A distinct firepower advantage combined with suddenly

friendly political and tax climates in the US should allow big pharma to seize the M&A agenda.

ey.com/firepowerindex

The new innovation imperative

Reshaping biopharma business models



New technologies, customers and competition are forcing – and enabling – biopharmaceutical companies to find novel ways to create and capture value. Technological, economic, competitive and consumer-driven pressures are forcing fundamental changes in how pharmaceutical and biotechnology (“biopharma”) firms do business.

ey.com/businessmodels

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How EY's Global Life Sciences Sector can help your business

As populations age and chronic diseases become commonplace, health care will take an ever larger share of GDP. Scientific progress, augmented intelligence and a more empowered patient are driving changes in the delivery of health care to a personalized experience that demands health outcomes as the core metric. This is causing a power shift among traditional stakeholder groups, with new entrants (often not driven by profit) disrupting incumbents. Innovation, productivity and access to patients remain the industry's biggest challenges. These trends challenge the capital strategy of every link in the life sciences value chain, from R&D and product supply to product launch and patient-centric operating models.

Our Global Life Sciences Sector brings together a worldwide network of 11,000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. We can help you navigate your way forward and achieve sustainable success in the new health-outcomes-driven ecosystem.

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EYG No. 00905-174Gbl
EY-000025643-01.indd (UK) 03/17. Artwork by Creative Services
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