



Pharma and the connected patient

How digital technology is enabling patient centricity

Deloitte Centre *for*
Health Solutions

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Deloitte Centre for Health Solutions

The Deloitte Centre for Health Solutions is the research arm of Deloitte LLP's healthcare and life sciences practices. Our goal is to identify emerging trends, challenges, opportunities and examples of good practice, based on primary and secondary research and rigorous analysis.

The Centre's team of researchers seeks to be a trusted source of relevant, timely, and reliable insights that encourage collaboration across the health value chain, connecting the public and private sectors, health providers and purchasers, patients and suppliers. Our aim is to bring you unique perspectives to support you in the role you play in driving better health outcomes, sustaining a strong health economy and enhancing the reputation of our industry.

Foreword

Welcome to the Deloitte Centre for Health Solutions' report *Pharma and the connected patient: How digital technology is enabling patient centricity*.

Powerful forces are transforming healthcare from a provider-driven marketplace to a patient-centric health ecosystem. They include:

- an ageing population with an increase in chronic diseases, placing unrelenting pressures on the capacity and financial viability of healthcare systems
- policymakers and payers seeking to control costs by requiring evidence of value and comparative effectiveness
- health technology, genomics, connected devices, big data analytics and artificial intelligence generating vast amounts of health data and insights, enabling providers to make better and faster diagnoses and more informed treatment decisions
- the blurring of provider boundaries with new entrants, partnerships and collaborations forming part of the new health ecosystem
- more informed, *connected patients* with heightened expectations of more personalised services and of playing a more active role in their own health.

These forces require, providers and the life sciences industry to become more agile, acquire new capabilities and adopt new business models. In response, most pharma companies are taking steps to do more for patients than deliver safe and effective drugs – they are beginning to utilise advances in digital technology to engage with patients to become more patient-centric.

Genuine patient centricity means having a deep understanding of the patient's experience of their condition – what the individual patient values and needs, their attitudes and behaviours, and what is most likely to improve health outcomes. Listening to the voice of the patient provides insights that can inform every stage of a pharma company's business, from drug discovery to winning regulatory approval to post-market disease management. This can help the company bring drugs to market that reflect patient needs, align with the reward-for-outcomes that governments and payers require, and help patients and providers achieve better outcomes.

While patient centricity is important to all parts of the health ecosystem, our report focuses on how digital technology is enabling pharma companies to become more patient-centric and transform its business and operating models. Our findings are based on the results of extensive literature reviews, primary research into how health apps are being used to engage with patients and patient groups' views on the use of these apps. We identify the challenges facing the industry in adopting the technology in pharma's interface with patients, examine strategies being used to overcome these challenges and suggest future enablers of patient centricity.

We hope you find our assessment insightful and thought-provoking, and as always welcome your feedback on the findings and the implications for the pharma industry.

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Executive summary

The pharmaceutical (pharma) industry is undergoing dramatic changes in its operating environment due to globalisation, heightened transparency expectations and an increased exposure to innovative technologies. Challenges impacting the traditional business model include escalating cost and pricing pressures, increasing competition, shorter time in market, expiring patents, declining profitability and mounting regulatory scrutiny. These challenges are compounded by the social and economic pressures facing the wider health ecosystem.

Pharma's initial strategies to address these challenges and preserve their traditional product-driven approach have included acquiring or merging with other companies, or becoming more focused on a narrower range of therapy areas. Many companies are also looking to demonstrate value for money through a combination of new pricing models, improved benefit tracking, and the introduction of 'wraparound' services that go 'beyond the pill'.

There is a growing realisation that a new business model is needed that involves patients more effectively. By engaging directly with patients and partnering with them across the entire pharma value chain, pharma companies can re-invent their business and operating models. This transformation towards patient centricity has the potential to revitalise the industry so that it remains relevant and profitable.

A key enabler of this transformation is innovative digital technology. While pharma has been quick to respond to the increasing pace of scientific developments, it has been much slower in adapting to the technological revolution of the 21st century. This is now changing, with pharma seeing digital technology's potential for creating a new patient-centric business model that combines connected devices with big data analytics and artificial intelligence to develop new, more personalised, drugs for smaller groups of patients while monitoring and managing patient adherence and health outcomes.

Over the past few years there have been numerous patient engagement initiatives involving regulatory bodies, patient advocate groups, healthcare providers and payers, and the pharma industry. Despite the increased dialogue and discussion around patient engagement and the declared aim of becoming more patient-centric, the industry recognises that it still has much to do.

Our research involved extensive literature reviews, supplemented by primary research that explored how 12 top pharma companies are utilising health apps to engage with patients. We also surveyed 190 patient groups for their views on how health apps in general, and those developed by or for pharma companies, are being used. We found that while there has been a proliferation of health apps, with around 260,000 such apps available in major app stores, the pharma industry produces only a small percentage of these apps. Of the apps that have been produced by the top 12 pharma companies, five apps constitute over 50 per cent of downloads.

Meanwhile, patient groups told us that most of their members use at least one health app, with 29 per cent using them regularly and 26 per cent occasionally. Some 76 per cent of patient groups who responded stated that patients have 'high' or 'some' trust in health apps developed by patient groups, but only 32 per cent could say the same for apps produced by pharma. Moreover, 83 per cent of patient groups said that their members would be 'willing' or 'somewhat willing' to share the personal data from their health app with their own specialist/consultant or primary-care doctor, while only 30 per cent would be willing to share their data with a pharma company.

Overall, we identified six main challenges facing the pharma industry in its ambition to become more patient-centric. Specifically:

- **the traditional product-based pharma culture can be at odds with the move to a more agile and responsive patient-centric culture** – engaging differently with patients' needs collaboration and co-ordination among cross-functional teams
- **regulatory uncertainty with regard to digital technology and patient centricity** – despite some guidance the rapid pace of technological advancement is adding to the already complex regulatory landscape, creating uncertainty amongst pharma as to regulators' expectations and requirements

- **data safety and privacy in the face of the proliferation of medical apps and other digital technologies** – in moving from randomised controlled trials and anonymised data collection, to collecting identifiable data as part of a more patient-centric approach, pharma needs to ensure the highest levels of data safety, privacy and user consent are maintained
- **corporate reputation can undermine patient engagement with pharma** – largely due to past publicity about excessive pricing and a lack of transparency, public confidence has been eroded, reducing patients' willingness to engage with pharma
- **attracting talent with the skills to support a patient-centric ecosystem** – pharma's traditional risk averse corporate culture and perceived lack of agility and 'fail-forward mentality' that normally governs entrepreneurial endeavour can impact recruitment and retention of digital skills
- **low levels of health and digital literacy impacts patients' ability to engage effectively** – with between a third and a half of people having low health literacy, this can undermine patient engagement with mobile health technologies.

We identify five strategies that pharma are adopting to respond to the above challenges and help ensure that the vision of patient centricity becomes a reality. These are:

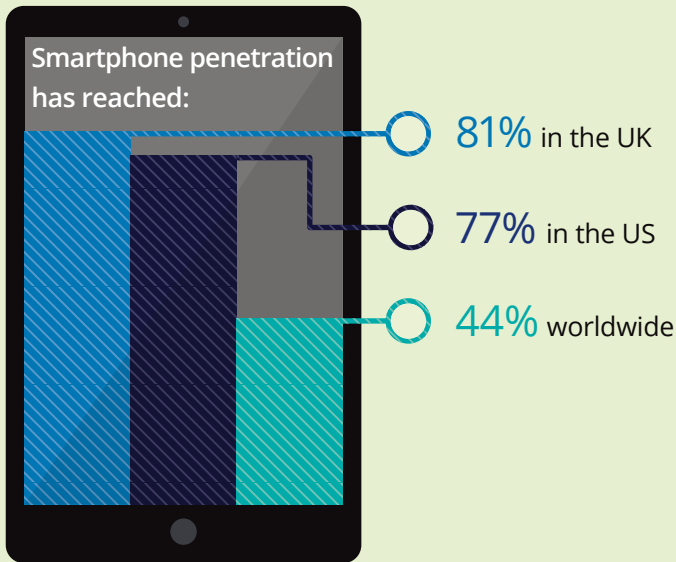
- **change corporate cultures and structures**, based on shared values and cross-functional working to promote agility, foster innovation and attract and retain appropriate talent
- **develop partnerships to support the deployment of digital technology**, including patient portals and engagement platforms, to help deliver a more patient-centric experience
- **automate processes supporting patient-facing activities and optimise the use of digital talent**, which can benefit clinical trial management, drug launch monitoring and marketing content approval. The use of digital hubs can optimise deployment of digital talent
- **create new contracting and pricing models**, underpinned by patient information and insights, and generated through the use of digital health technology and big data analytics
- **build collaborative relationships with patients, healthcare professionals and regulators** to improve health and digital literacy, and predict and manage new risks, including data security and privacy risks.

As pharma moves from simply engaging with patients to becoming more patient-centric, more needs to be made of the opportunities and challenges of connecting with patients and their carers via digital and social media. Despite being a natural source of information for patients and healthcare professionals alike, using digital and social tools is still difficult in pharma. While it has become easier to provide patient apps, certainty over the regulatory response still needs to be clarified. This would result in better opportunities for the pharmaceutical industry to have a valuable ongoing conversation with patients and the teams that care for them. However, if patient centricity is to reach its full potential, it must be measured as accurately and as honestly as any other activity or variable in drug development and delivery.

Looking to the future, pharma's adoption of patient engagement strategies is inextricably linked to its digital technology-enabled transition to 'wraparound' solutions and a focus on improved outcomes. While these 'beyond-the-pill' or 'around-the-pill' services have been talked about for some time, they are now starting to gain traction. New disruptive technologies, like blockchain, gamification and 3D printing will provide further opportunities to guarantee the sustainability and growth of a more patient-centric pharma industry.

As pharma moves from simply engaging with patients to becoming more patient-centric, more needs to be made of the opportunities and challenges of connecting with patients and their carers via digital and social media. Despite being a natural source of information for patients and healthcare professionals alike, using digital and social tools is still difficult in pharma.

The rise of the connected patient



Of 190 patient groups surveyed:



Over **65%** access health apps using a smartphone



Almost **70%** use at least one health app to manage their condition



Over **50%** use health apps 'regularly' or 'occasionally'

Big pharma's drive towards digital

Analysis of the top 12 pharma companies revealed:



Pharma apps generated **5.6 million** downloads out of **3.2 billion** downloads generated overall by mHealth apps in 2016



Year-on-year, the **growth rate of pharma app downloads** has slowed from **197%** between 2013 and 2014, to **5%** between 2015 and 2016

2013



2016

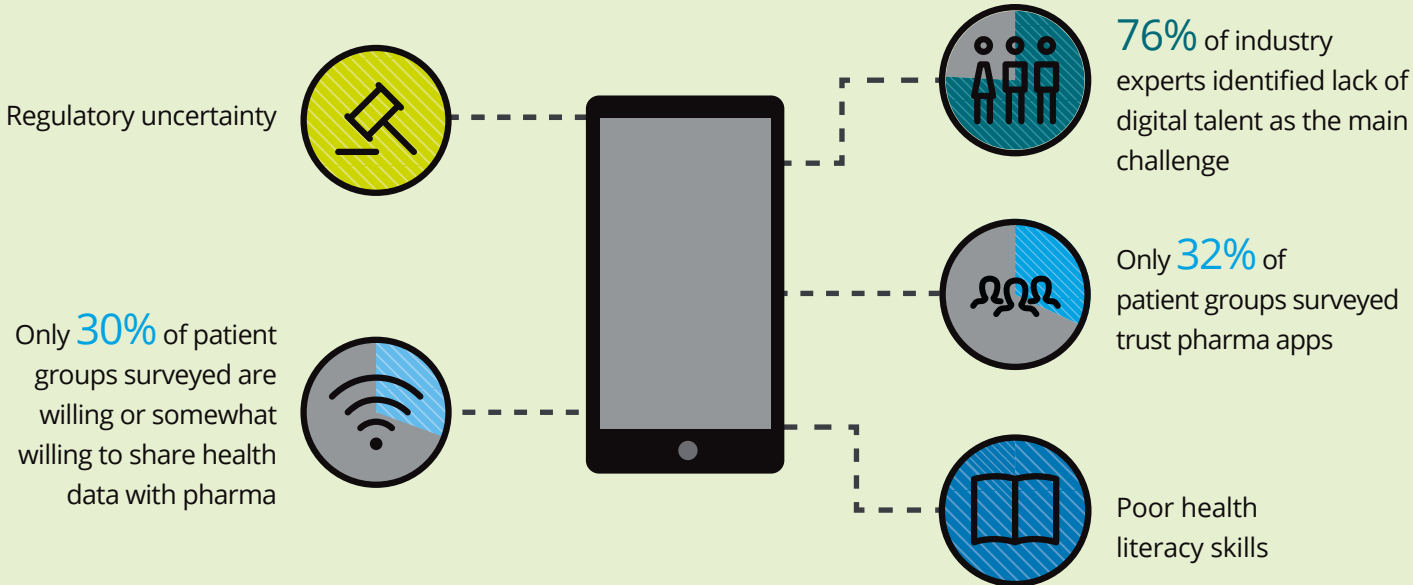


The **number of apps produced** by pharma companies has more than **tripled** from 305 in 2013 to 988 in 2016

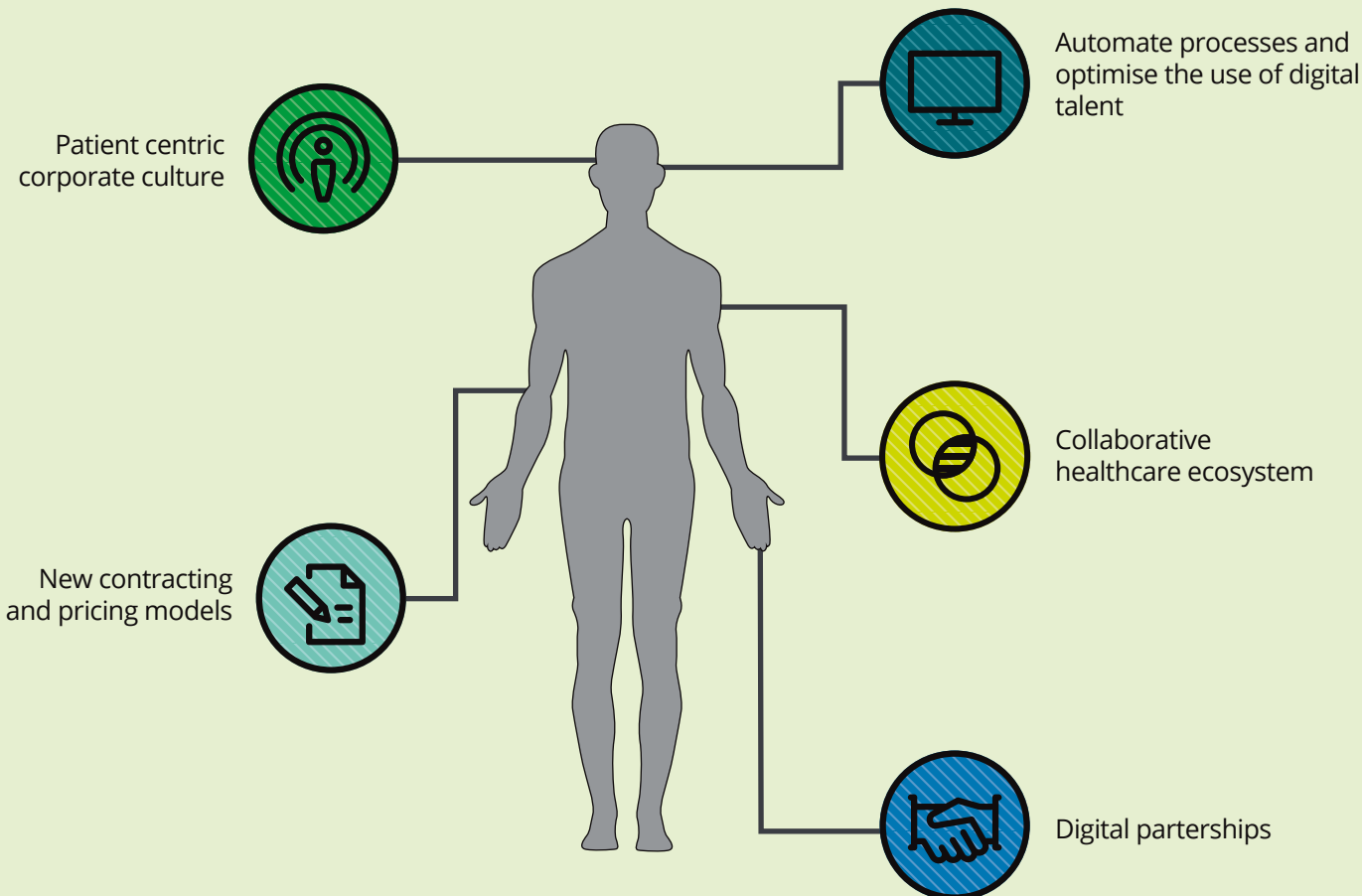


The **5 most popular apps** produced by pharma companies accounted for **51%** of downloads in 2016

Barriers to adoption of digital technology



Strategies to improve patient centricity



1. From patient engagement to patient centricity

“The patient vs. consumer conversation is a new one, as many are still adjusting to thinking of patients as consumers and the gatekeepers to their own health.”

Akanksha Jayanthi, Becker's Healthcare¹

Patients are becoming increasingly connected via mobile technology and social media. Nearly 90 per cent of the US and UK populations use the Internet regularly, and smartphone penetration has reached 77 per cent in the US and 81 per cent in the UK.^{2,3,4,5} In the rest of the world, 44 per cent of the population will own a smartphone in 2017.⁶ This increased connectivity will have a profound impact on how pharma and other stakeholders in the health ecosystem engage with patients.

The advent of the connected patient

In our 2014 report *Healthcare and Life Sciences Predictions 2020: A bold future?* we predicted that by 2020 patients would be more like consumers, able to understand their healthcare options and use information and data to get the most effective and convenient treatment.⁷

Although the consumerisation of care that we envisaged is well-established in North America and accelerating in Europe and emerging markets, there is still some way to go before patients become true consumers. However, the increased capacity and capability of digital technology are now transforming how patients interact with their own healthcare, whether through the use of smartphone apps, wearables or patient portals. Patients who utilise these technologies learn more about their conditions and treatment options than those who do not but are similarly affected. Moreover, the ‘quantified self’ movement – using wearable devices to allow consumers to track various physiological parameters – can enable patients and their doctors to measure and monitor health-relevant variables in real time.

These advances are driving a completely different level of engagement and expectation from patients and carers. People are increasingly seeing technology as a key enabler in empowering them to take a much more proactive role in their own health. They are researching their family history for disease risks, modifying their diet and lifestyle, and taking preventative treatments. Increasing numbers are embracing health screening, advanced diagnostics and genetic testing. These changes are leading people to evaluate where and how they spend their own resources and to have a more informed view on the types of healthcare and treatments they want to access and how healthcare systems should prioritise their spending.

This more proactive role that people are taking is creating de facto partnerships with healthcare providers, payers and life sciences companies, with clear evidence that a more engaged consumer is almost always a healthier consumer.⁸

Meanwhile, the healthcare ecosystem is facing a ‘tidal wave’ of complex age and behaviour related diseases, which are increasing healthcare costs and research risks, and challenging the pharma business model. Indeed, pharma is facing an increasing number of scientific, economic and delivery risks while having to manage an increasing number of contradictory demands and cost pressures, specifically:

- patients, providers and payers seeking better, more effective medicines at affordable prices
- expiring patents, increasing research and development (R&D) costs, slowing sales growth and declining profitability, while attempting to develop medicines that justify the risk and investment required to bring new drugs to market in an increasingly challenging regulatory environment.⁹

In response, pharma companies, payers and clinicians are turning to new transformational health technologies, including deploying wearables, personal devices, mobile apps and patient portals to engage more effectively with patients. These technologies enable pharma to monitor the R&D process and patients’ compliance with and response to treatments; they are also crucial to improving patient engagement, finding better medicines and achieving better patient outcomes.

Patient engagement empowers patients to get involved in their own health decision-making and treatments

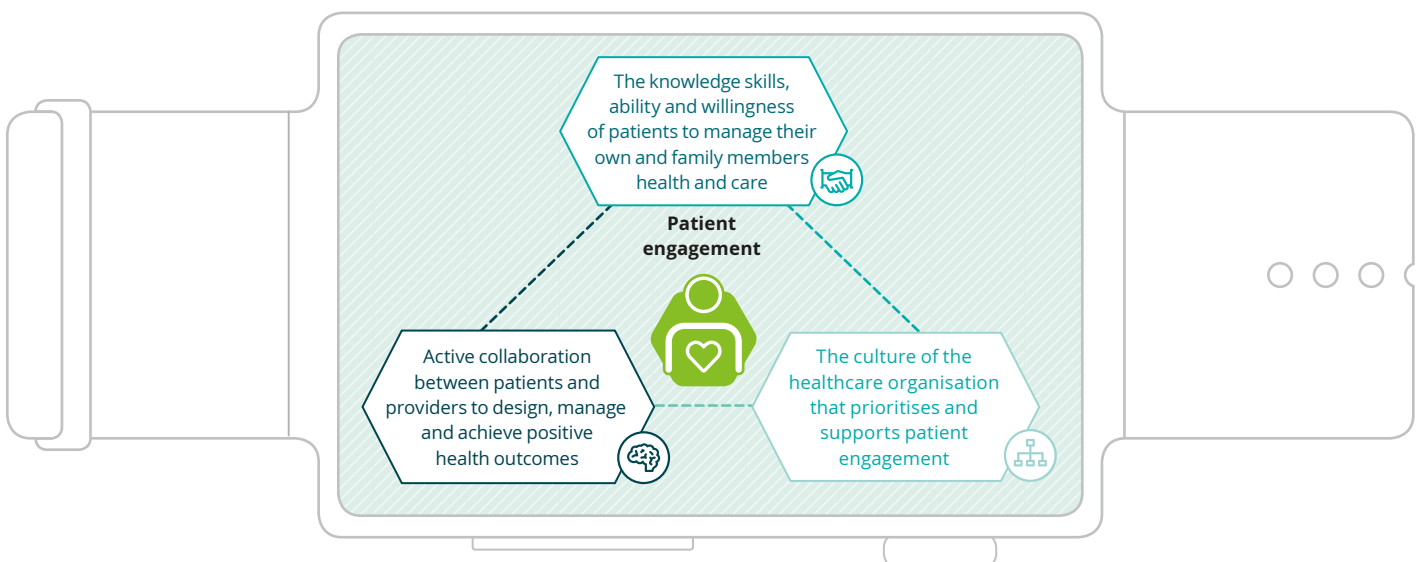
Patient engagement is not just patient communication or education – nor is it simply implementing online patient portals. While there are numerous definitions of patient engagement, all share a set of common characteristics (see Figure 1).

“If patient engagement were a drug, it would be the blockbuster drug of the century and malpractice not to use it.”

Leonard Kish, VivaPhi¹⁰

Our 2016 report *Vital Signs: How to deliver better healthcare across Europe* highlighted why no healthcare system can be sustainable without engagement with patients and carers. It also highlighted the importance of health literacy and how poor health literacy can prevent people from understanding the diagnosis they have been given and lead to misunderstandings and treatment errors. Engagement also enables patients to become more involved in decision-making, known as *patient activation*.

Figure 1. Characteristics of patient engagement



Source: 5 elements of a successful patient engagement strategy, athenahealth, 2014¹¹

Patient engagement and activation are essential strategies for achieving the quadruple aim of healthcare (see Figure 2).

Figure 2. The quadruple aim of healthcare across a health system



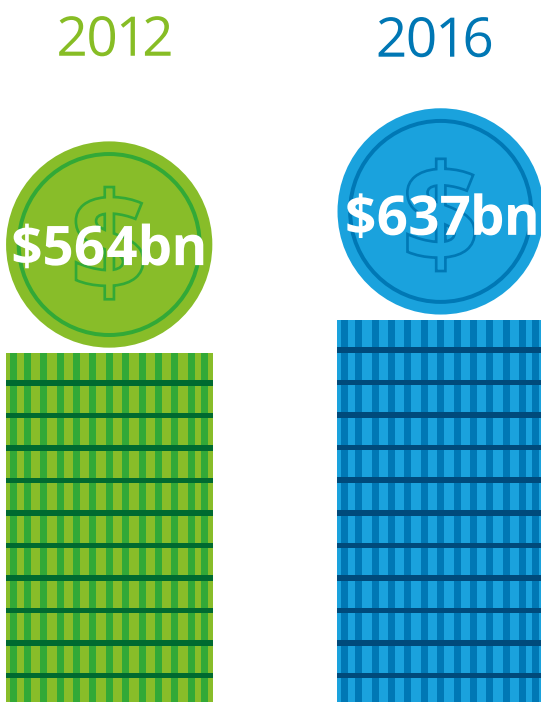
Source: *From triple to quadruple aim: Care of the patient requires care of the provider*, Annals of Family Medicine, 2014.¹²

What patient engagement means for pharma

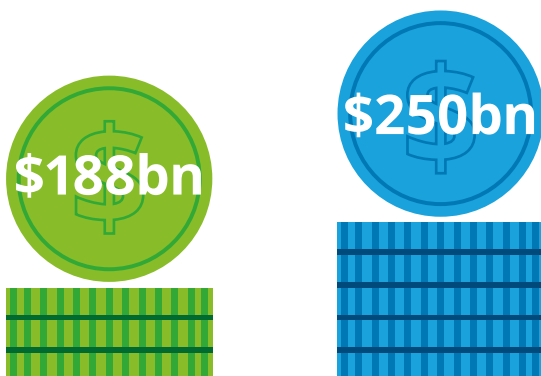
Companies need to engage with patients across the entire pharma value chain, from R&D through to product launch. This could be particularly effective in developing and optimising a new model for clinical trials that decreases costs by improving the efficiency of patient recruitment and increases patient retention throughout the course of the trial. These are critical cost points in clinical trials, as patient recruitment can account for nearly a third of clinical trial costs,¹³ and approximately a third of phase III clinical trial terminations are due to enrolment difficulties.¹⁴

Patient engagement strategies can also improve adherence and the patient experience post product launch, resulting in cost savings and improved patient outcomes. Research estimates that 20 to 30 per cent of patients do not adhere to medication regimens that are curative or relieve symptoms, and 30 to 40 per cent fail to follow regimens designed to prevent health problems. When long-term medication is prescribed, 50 per cent of patients fail to adhere to the prescribed regimen.¹⁵ This leads to extensive revenue loss (see Figure 3). To combat this, pharma are deploying patient engagement strategies to improve adherence and keep up with changing patient expectations.

Figure 3. Non-adherence leads to large losses in revenue for pharma



Lost revenue due to non-adherence globally



Lost revenue due to non-adherence in the US

Moving from patient engagement to patient centricity

Patient centricity is not the same as patient engagement. Genuine patient centricity means understanding the patient’s experience of his or her condition – what the individual patient values and needs, and what is most likely to result in a positive healthcare outcome. The insights gained by listening to the voice of the patient can be applied at every stage of a pharma company’s efforts, from drug discovery to winning regulatory approval to post-market disease management. This can enable a company to bring drugs to market that better reflect patient needs, better align with the reward-for-outcomes that governments and payers now expect, and help patients and providers achieve better outcomes.

“Patient centricity for pharma was a novel, futuristic concept three years ago, but today, it’s a pillar in every life science and healthcare company out there.”

Ido Hadari, CEO, Treato¹⁷

Most healthcare providers and payers have developed definitions of patient centricity, but these are not readily transferable to pharma. In 2016-17, AstraZeneca embarked on an initiative to develop a ‘consistent definition of patient centricity and its associated principles’ in partnership with patients and industry representatives. They defined patient centricity as:

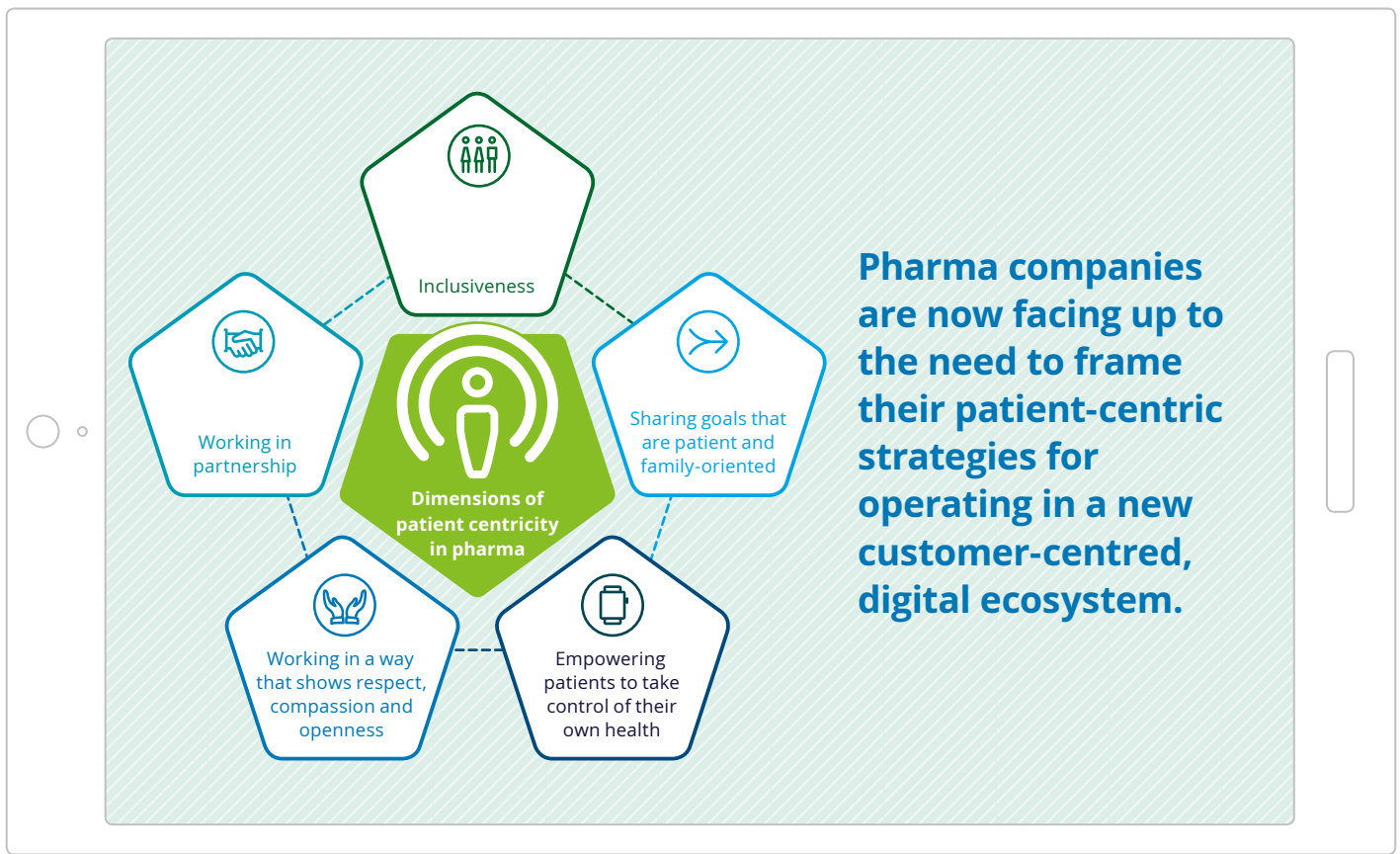
“Putting the patient first in an open and sustained engagement of the patient to respectfully and compassionately achieve the best experience and outcome for that person and their family.”¹⁸

Source: Estimated annual pharmaceutical revenue loss due to medication non-adherence, Capgemini Consulting and HealthPrize, 2016¹⁶

Their intention is that this definition will evolve as patient engagement evolves and, in view of the extensive consultation involved in developing the definition, we have adopted it for this report. The definition encompasses five clear points of importance to patients, identified and validated through the research (see Figure 4).

Pharma companies are now facing up to the need to frame their patient-centric strategies for operating in a new customer-centred, digital ecosystem. Breaking away from that model requires a new mind-set for companies accustomed to communicating with patients somewhat impersonally, for example through traditional media campaigns. But as new policies and technologies tilt the balance of power towards patients, all stakeholders in the health ecosystem will need to shift to a more direct, personal relationship.

Figure 4. The five dimensions of patient centricity



Source: *Defining patient centricity with patients for patients and caregivers: a collaborative endeavour*. BMJ Innovations, 2017¹⁹

2. Advances in technology are pivotal to improved engagement

The rapid advances in digital technology over the past decade are helping pharma companies put patient centricity at the heart of their new operating models. Pharma has recognised the opportunities that technological advances have brought and are looking to utilise their disease expertise and marketing capabilities to improve patient engagement and activation, improve outcomes and increase revenue.

“The mobile revolution placed powerful, general-purpose computing in our hands, enabling users to take actions in the digital world while moving about in the physical world.”

Tech Trends 2014, Deloitte University Press²⁰

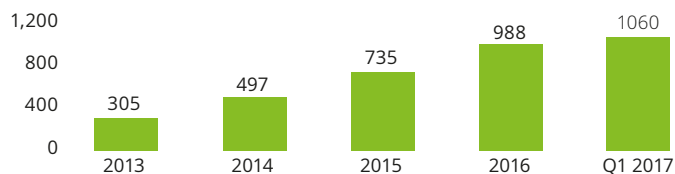
The age of the smartphone

The most ubiquitous healthcare technology is the smartphone app, which is a ready-made platform for patient engagement and coordinated care solutions. In 2016, it was estimated that there were 260,000 mHealth apps on the market, which collectively generated 3.2 billion downloads.²¹ Pharma companies have

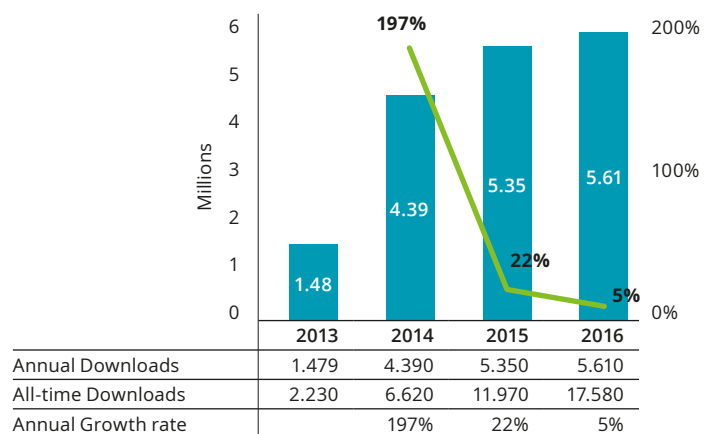
begun to capitalise on the rise of health apps to engage more with patients, but research we commissioned from Research2Guidance found that the number of apps and downloads lags behind those produced by other stakeholders. Indeed, the top 12 pharma companies produced just under a thousand apps in 2016 that accounted for only 5.6 million downloads (see Figure 5).

Figure 5. Pharma companies have lagged behind other stakeholders' development of health apps

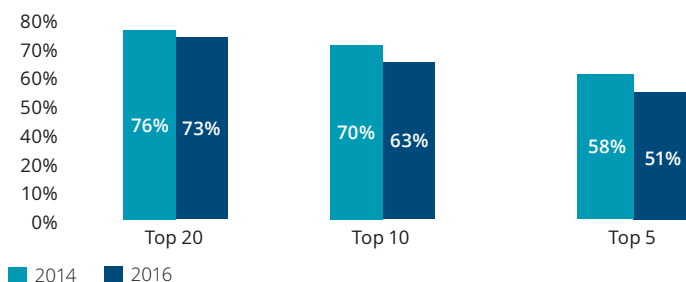
The 12 largest pharma companies are producing more apps each year



However, growth in the number of downloads of these apps has begun to stagnate



And the most popular apps dominate total downloads



Source: Deloitte research commissioned from Research2Guidance, 2017 (see Appendix)

Figure 6. Seven reasons why smartphone apps should matter to pharma



Source: Research2Guidance research, 2014²²

However, the move to a more patient-centric approach should result in much more engagement between pharma and patients, particularly through smartphone apps, with specialist research identifying seven main reasons why pharma companies should utilise smartphone apps (see Figure 6).

Until recently, the impact of the smartphone on patient care has been limited, but many of the barriers that have prevented the wide-scale adoption of connected health technologies are now being addressed. As a result, patients are increasingly downloading health apps. Consequently, pharma companies are now well-placed to capitalise on patients' familiarity and use of smartphone apps to engage more effectively with them, as part of their move to more patient-centric strategies.

Wearables are poised to enable patient centricity

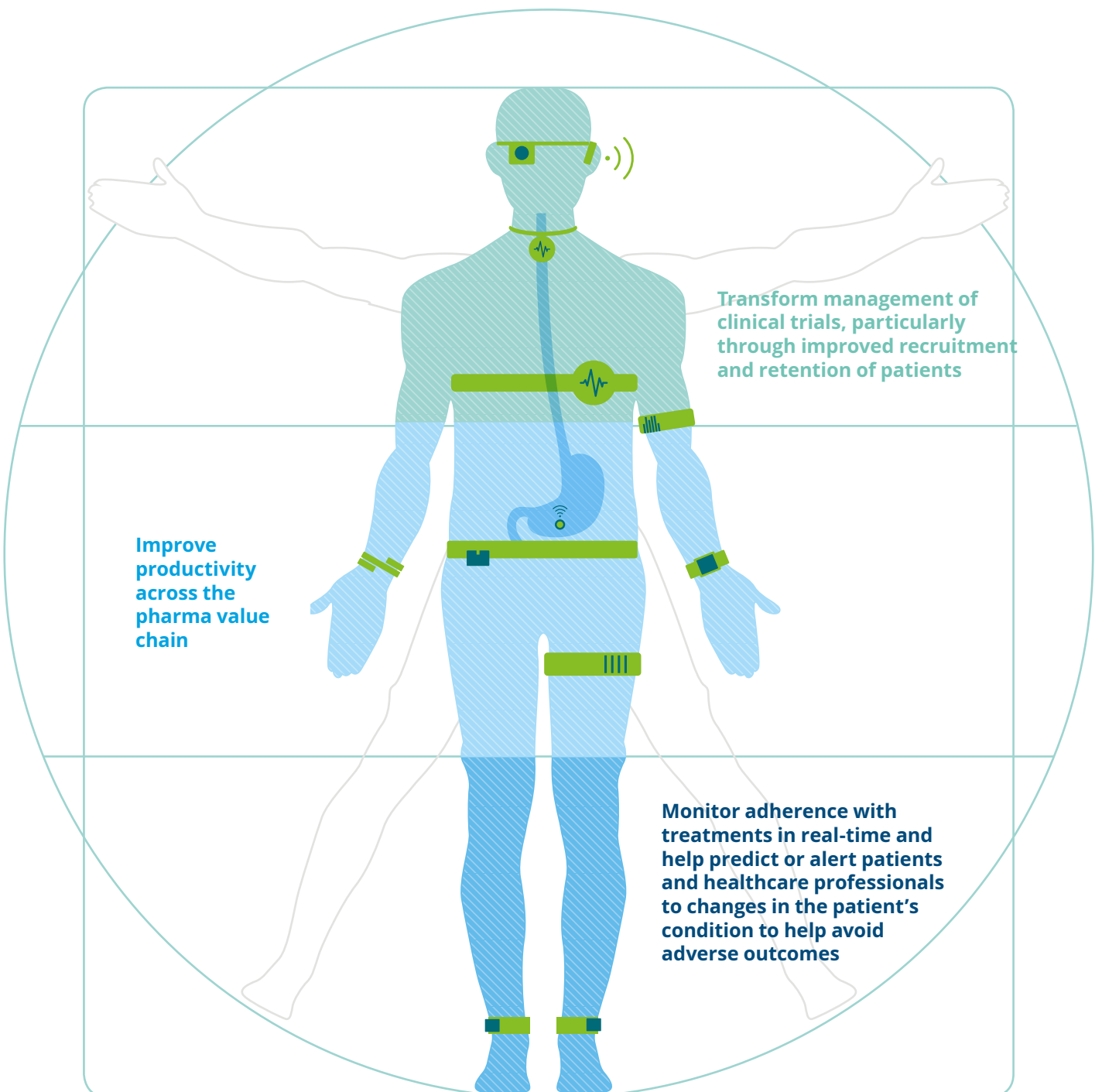
“Wearable technology surrounds us with devices that primarily enable other devices with digital information, which in turn support us in taking real-world actions.”

Tech Trends 2014, Deloitte University Press²³

Clinical-grade wearable technology (wearables) is similarly poised to contribute to pharma's ability to engage with patients to create a more patient-centric ecosystem, often in tandem with smartphone apps. Wearables are smart electronic devices worn on, or implanted in, the body. They incorporate practical functions and features that can be used to identify changes in vital signs at an early stage. They include smartwatches and other wrist-worn vital sign trackers, smart clothing, sensing tattoos, eyewear and medical patches. Examples include the glucose sensor contact lens developed by Google,²⁴ the glucose sensor temporary tattoo developed by UCSD,²⁵ and the electronic chip-in-a-pill from Proteus.²⁶

Wearables offer real-time data collection and continuous monitoring that can increase self-awareness and be used to increase personal safety or as a motivational tool to eat healthier, lose weight or simply track general health and fitness. If used regularly, the data generated from a wearable device can show trends in a consumer's eating and exercising habits, which in turn can be used to set goals, reminders and incentives for living a healthier lifestyle.

Figure 7. Pharma could utilise wearables to transform their patient-centric business practices



Source: Deloitte research, 2017

The total value of the wearables market is expected to reach \$40 billion in 2018.²⁷ The market is currently dominated by the smartwatch and fitness band, which is not expected to change in the next few years, but other devices, particularly eyewear, are expected to grow significantly in the short term. Pharma could benefit from incorporating wearables into their business practices, as shown in Figure 7 (previous page).

Patient portals are a key digital platform for patient engagement

Historically, pharma companies have controlled both the generation and dissemination of information about their products. However, patients are using apps, wearables and online patient communities to learn and share information about their health, weakening that control. Patient portals (or patient engagement platforms) are secure online websites that give patients convenient 24-hour access to personal health information from anywhere via an internet connection, helping to drive patient engagement and activation. Research shows that patients are increasingly comfortable using patient portals as a way of accessing their medical records and communicating with their clinicians.

An important pillar in any pharma company's patient centricity strategy is patient support, utilising a variety of tools and resources. A pharma-branded patient portal could help patients, providers and payers understand the benefits of the particular therapy, raise the profile of the sponsoring pharma company and create opportunities to reform the pharma business model.

Current research has demonstrated that patients' interest and ability to use patient portals is influenced by age, ethnicity, education level, health literacy, health status and role as a caregiver. Healthcare provider endorsement and patient portal usability also contribute to patients' ability to engage through and with the patient portal. Ultimately, adoption by patients and endorsement by providers will require the patient portal to align with patients' and providers' information needs and be intuitive and easy to use.

Big data analytics is an important tool in developing a more patient-centric approach

The rapid proliferation of digital channels, apps, wearables and other health technology, together with the shift towards patient engagement, has generated an unprecedented amount of clinical and commercial data. Applying advanced analytics and artificial intelligence to these data can help pharma companies generate meaningful, actionable insights, and in turn, help pharma identify patient preferences and determine future engagement strategies.

Pharma marketers and patient engagement managers can use these data and multi-channel marketing channels to provide services more attuned to patient needs as part of their patient support programmes, and ultimately gain greater success in providing products that improve outcomes. In addition, big data analytics and machine learning can help improve the cost and efficiency of pharma R&D, including improving the chances of success of clinical trials (see Part 4).

3. Challenges in adopting digital technology

Consensus is growing around the benefits of a digitally-enabled patient-centric ecosystem. A 2015 survey of 1,600 pharma executives found that 86 per cent of respondents agreed that patient centricity is the best route to profitability.²⁸ Similarly, a 2016 study of key industry stakeholders found that 68 per cent of participants believe patient centricity is a key business driver for using digital health.²⁹ However, there are several key challenges impeding pharma's move to becoming more patient-centric.

The traditional product-based pharma culture can be at odds with the move to a more agile and responsive patient-centric culture

In order for pharma to become patient-centric, it will have to tackle its entrenched culture. For example, the margins achieved by a digital health business are small compared to pharma's margins from a blockbuster drug, making it harder to build a commercial case for investment. Also, the requirement for upgrades that digital device producers constantly face is at odds with the culture of an industry that traditionally takes more than a decade to get a drug from 'bench to bedside' and then expects to make no further changes once it has secured regulatory approval.³⁰ This cultural shift is arguably pharma's biggest challenge to becoming patient-centric.

An analysis of the 2016 RepTrak survey by the Reputation Institute, which surveyed over 23,000 participants across 15 countries, found that patient-centric initiatives were often seen as part of a corporate communication programme rather than an engrained step for culture change.^{31,32} Interviews conducted in 2016 with 21 pharma industry professionals concluded that many were unsure on about when, how and which patients to involve in engagement strategies; the study also identified concerns about the risks in moving from randomised control trials and anonymised information on patients to a real-world evidence model that involves patients more fully in R&D.³³

Regulatory uncertainty in relation to digital technology and patient centricity

Pharma operates in one of the most regulated industries in the world. Global pharma and medical device regulations are currently undergoing profound changes.³⁴ The rapid pace of technological advancement is adding to the already complex regulatory landscape as interoperable mobile apps, Health IT, telemedicine and wireless medical devices become more widely adopted.³⁵ Interviews with clinical leads in large life sciences companies stress the need for more collaboration between industry and regulators when it comes to digital integration strategies, especially those digital technologies that

aim to improve treatment, adherence, retention and health outcomes for patients participating in clinical trials.³⁶ Ongoing regulatory change will impact the use of digital technology and the ability of pharma to engage with or monitor adherence of patients who have been prescribed a drug or want to understand treatment options.

In a recent industry survey, 97 per cent of pharma participants indicated that they plan to use digital health technologies in clinical trials³⁷ over the next five years, with 64 per cent having already used digital technologies in clinical trials. However, regulatory bodies are striving to keep up with these market trends, and although they have developed some guidance and initiatives to help support innovation, there remains a lack of clear guidance, which pharma executives suggest can undermine their confidence to deliver innovative patient-centric initiatives quickly, despite their enthusiasm to do so.³⁸

Regulators have found the pace and rate of change challenging and continue to modify their policies and regulatory procedures to keep pace with the widening use of software products in healthcare.³⁹ For example, the FDA only classifies apps as devices if they are used in the diagnosis, treatment or prevention of a disease, or if they affect the structure or function of the body. In 2016 the FDA published guidance covering the use of mobile technology, among others, in clinical trials.⁴⁰ It is developing a new Digital Health Innovation Plan to clarify the regulations around the adoption of health apps and other digital technologies aimed at encouraging safe and effective innovation. It also intends to pilot a new risk-based regulatory framework for overseeing medical technologies.⁴¹

In the EU, the new Medical Devices Regulation (EU MDR), finalised in May 2017, will come into force over the next few years. It classifies all medical software apps as medical devices, under Annex VIII of the regulation. Most standalone medical apps will fall under Class I, unless they are used for diagnosis or influence diagnosis decisions, in which case it will be upgraded. Software that is used to control or influence a medical device would fall under the same class as the

device itself. While the safety of Class I devices will need to be self-assured by manufacturers, higher risk Class II and III devices will have to go through a process of certification by Notified Bodies.^{42,43} Currently, however, there is still uncertainty as to how regulators will respond to the growing use of innovative digital technology in running clinical trials, improving patient engagement and activation, and in monitoring treatment adherence. Consequently, pharma, alongside other health app developers, will need to engage directly with key regulatory bodies to clarify compliance requirements, given that the legal and financial ramifications of non-compliance could be significant.⁴⁴

Data safety and privacy in the face of a proliferation of medical apps and other digital technology

If pharma is to become more digitally-enabled and patient-centric, data safety and the way personal health data are acquired, analysed and stored, are crucial considerations. Generally, apps that fall within the remit of large healthcare organisations and life science regulators are more likely to be deemed safe for consumer use, due to the added layers of regulatory procedure required to gain approval. However, even these apps may not have adequate measures in place to ensure data safety. In 2015, a six-month review of 79 apps certified as clinically safe and trustworthy by the UK NHS Health Apps Library, found systemic gaps in compliance with UK data protection principles concerning information safety.⁴⁵ The security concerns raised by this review resulted in the NHS Health Apps Library closing in 2015, due to gaps in compliance with data protection principles. It has since reopened (March 2017) but with far fewer apps.⁴⁶

Of particular concern to patients and regulators, considering the sensitive types of data that are inputted and transmitted via these apps, is the handling of health data by apps that fall outside the approval remit of large healthcare organisations or life science regulators. Research by the Future of Privacy Forum found that only 76 per cent of mobile health apps had a privacy policy that was readily accessible to users.⁴⁷ This lack of adequate privacy policies could have legal ramifications downstream. For example, in March 2017, the New York State Attorney General announced settlements with three mobile health app developers after an investigation revealed that users had been misled regarding the marketing and privacy practices of the apps; the developers agreed to change their labelling and privacy policy implementation and paid a combined \$30,000 in penalties.⁴⁸

Also relevant for pharma is the implementation of the EU General Data Protection Regulation (GDPR) in 2018, which will add further regulatory, compliance and data protection obligations for all companies collecting data from EU residents, with significant financial penalties for non-compliance.⁴⁹

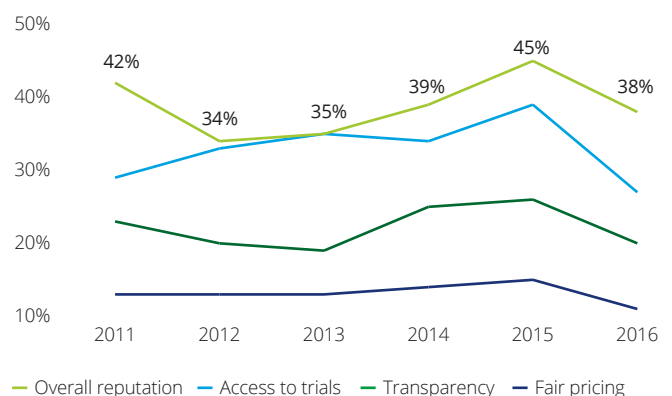
The potential for retrospective legal action in the general health apps market is therefore significant. Pharma needs to ensure that for even the most basic of health apps the highest levels of data safety, privacy and user consent are maintained. In addition to financial consequences, the potential damage caused to the industry's reputation from a data breach could further deter patients from wanting to engage with a pharma industry striving to be digitally enabled and patient-centric.

Corporate reputation can undermine patient engagement with pharma

Large pharma companies have often struggled with a negative reputation, which can undermine attempts to improve patient engagement. This perception is often the result of past stakeholder experiences with the industry, including factors such as failing to serve the needs of neglected patient groups, excessive pricing and a lack of transparency, which have eroded public confidence in the practices pharma has used to develop its products.⁵⁰

For the past six years, PatientView, a UK-based research company specialising in obtaining perspectives from patient groups, has evaluated the corporate reputation of pharma companies based on the perceptions of patient groups from across the world. Its 2016 report, published in March 2017, evaluates the corporate reputation of 47 pharma companies, based on responses from some 1,500 patient groups across 46 medical specialties in 105 countries. Its findings show that patient groups' perception of the pharma industry's corporate reputation fell in 2016, after reaching a high in 2015. Figure 8 shows the trend in overall reputation and the changing perception in relation to transparency, access to clinical trials and fair pricing.

Figure 8. Patient-groups' perceptions of the pharma industry (2011-2016) that stated the pharma industry was 'Excellent' or 'Good'



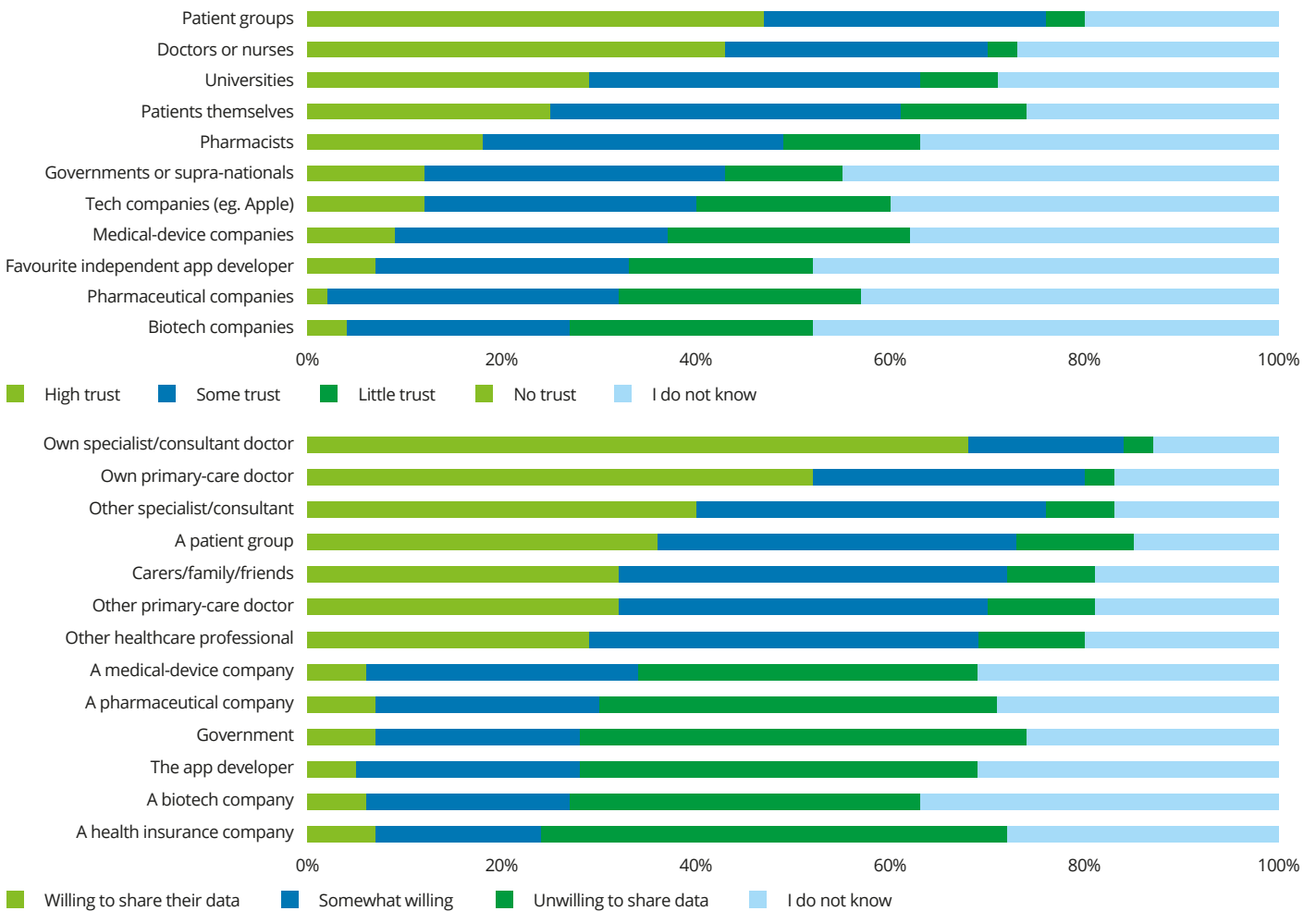
Corporate reputation of Pharma in 2016, PatientView⁵¹

Our own research, commissioned from PatientView, included questions on the degree of trust patient groups afforded developers and producers of health apps. It found that for patient group respondents, 76 per cent stated their members have 'high' or 'some' trust in health apps developed by patient groups, but only 32 per cent could say the same for apps produced by pharma. Similarly, 83 per cent of patient groups said their members would be 'willing' or 'somewhat willing' to share the personal data from their health app with their own specialist/consultant or primary doctor, but only 30 per cent would be willing to share the data with a pharma company (Figure 9). Our research indicated that this lack of trust among

patient groups, especially surrounding data sharing, stems from a fear of negative personal consequences (e.g. loss of insurance), a lack of trust in data gatherers, the need to protect privacy protection and a lack of confidence in the ability to guarantee the security of personal data.

Despite these concerns, patient groups highlighted a willingness to collaborate in the creation of apps with pharma. However, only 15.1 per cent of the patient groups surveyed had been involved in co-creating a pharma health app.

Figure 9. Patient groups' views of their members trust in health apps (top) and willingness to share data with pharma and other groups (bottom)



Source: Deloitte research commissioned from PatientView, 2017 (see Appendix)

Attracting talent with the skills to support a patient-centric ecosystem

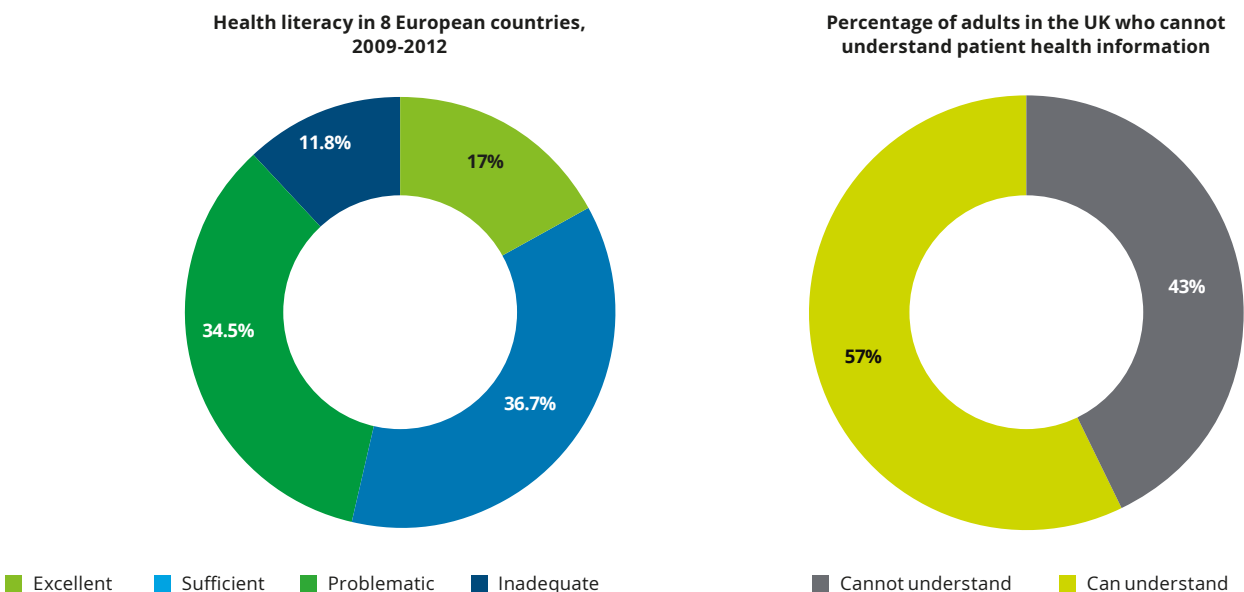
Attracting the right talent is crucial to the development of patient-centric initiatives and a wider digital agenda. However, as discussed above, the public’s negative perception of pharma could deter digital talent from joining the sector, thus slowing pharma’s progress in developing digital initiatives.

One of the key hurdles in attracting talent is transforming pharma’s traditional business model to one that embraces the agile nature of digital technology innovation and development.⁵² Certainly, digital strategies need to be prioritised if the pharma industry is to be successful in achieving its agenda on patient centricity. A 2015 survey of 106 pharma industry experts found that 76 per cent of respondents identified the lack of digital talent as the main challenge to the transformation of pharma.⁵³

Low levels of health and digital literacy impact patients’ ability to engage effectively

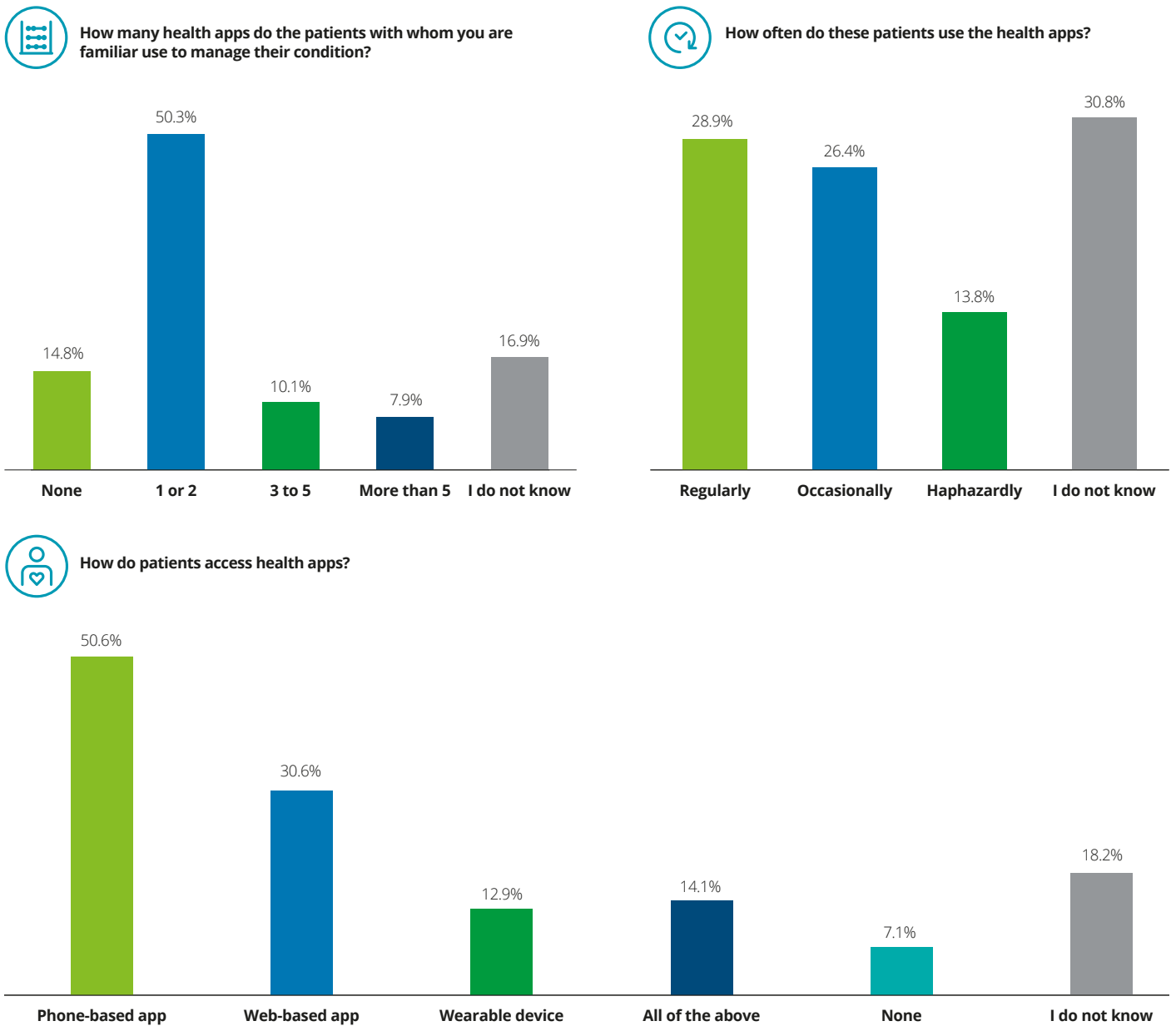
Crucial to the success of digital patient-centric initiatives is a patient population that is literate in both the medical terminology surrounding their condition and the technology used to help manage that condition. However, health literacy, and the ability for patients to act on health information, is quite low (see Figure 10). Low health literacy has been associated with higher use of medical services, less preventive care, greater difficulty managing long-term illnesses, poorer health, and higher mortality in older people. Moreover, low health literacy can also correlate with low levels of engagement with mobile health technologies. For example, a US study of 4,974 American adults, published in 2016, showed that only 25.7 per cent of patients with low health literacy had used a patient portal, compared with 42 per cent of those with adequate levels of health literacy.⁵⁶ High usage of smart devices across the world means that many patients now have a wealth of health information at their fingertips. One in twenty Google searches in 2015 was health related,⁵⁷ and our research found that among patient groups, most patients use at least one or two apps to manage their condition, over 50 per cent use them ‘regularly’ or ‘occasionally’, and 65 per cent of the apps are accessed via mobile phones (see Figure 11).

Figure 10. Health literacy in Europe and the UK



Source: The European Health Literacy Project, 2015⁵⁴ (left) and The British Journal of General Practice, 2016⁵⁵ (right)

Figure 11. Patient groups views on health apps used by their members to help manage their condition



Source: Deloitte research, 2017, commissioned from PatientView (see Appendix)

As a result, patients are more conscious of the options available to them to treat or manage their condition, even before they have consulted a healthcare professional. However, pharma has been slow to adapt to changing consumer behaviour.

Addressing these challenges will allow pharma to understand better the behaviour of its consumers at an earlier stage, build better relationships with patients and develop products that better fit the needs of its consumers.

4. Strategies to improve patient centricity

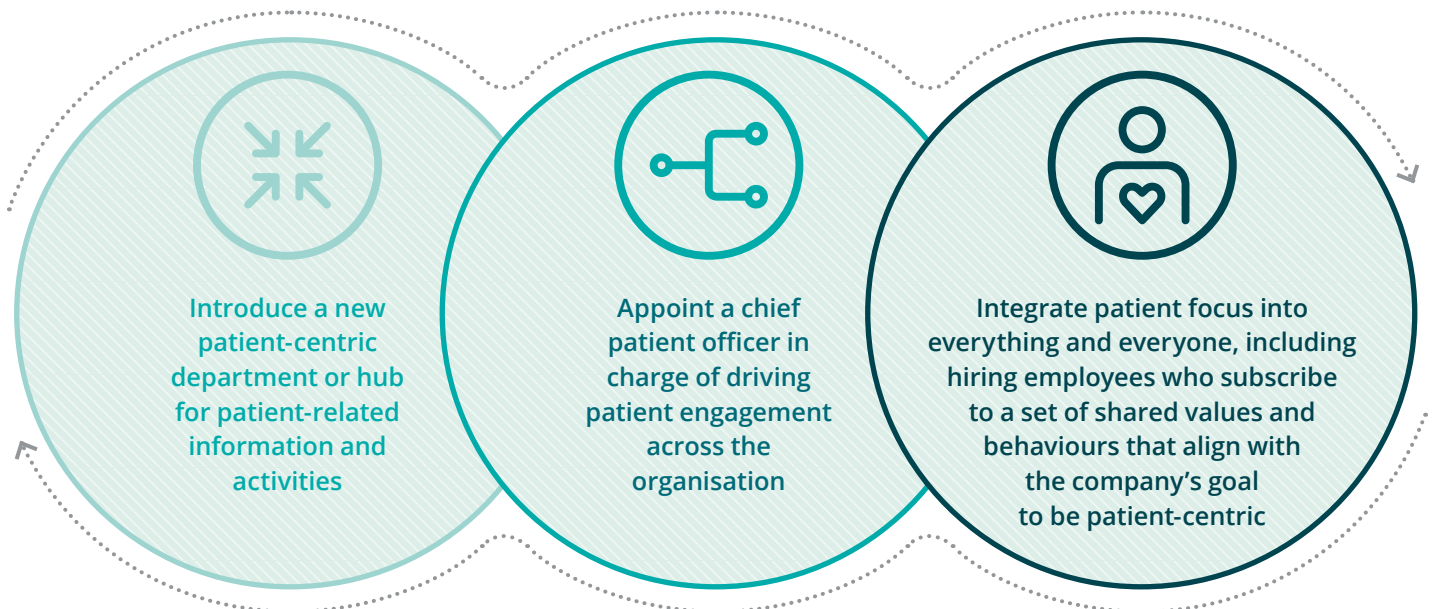
Developing a digitally-enabled, patient-centric business model will take time and resources to achieve. However, despite the challenges involved, there are already a number of initiatives and partnerships developing across the pharma value chain. Pharma companies are using a number of key strategies to achieve their ambition of becoming more digitally-enabled and patient-centric.

Change corporate cultures and structures

The shift from the traditional product-driven model to one geared towards patient centricity will require major changes in the habits, attitudes, beliefs and values of pharma across its business.

Adopting a patient focus requires a top-down approach that puts the patient agenda at the heart of everything a pharma company does, which means allocating the necessary resources and talents to drive patient-centric performance within the industry. Some strategic changes to organisational models that pharma companies are using are shown in Figure 12.⁵⁸ Specific examples are highlighted in case example 1.

Figure 12. Pharma's strategies to change corporate cultures and structures



Source: Adapted from Eye for Pharma⁵⁹



Case example 1. Strategies to change corporate cultures and structures

Restructuring marketing around Patient Value Units – UCB

UCB has put patient centricity at the heart of its values and has introduced several restructuring initiatives to bring the organisation closer to patients and made some adjustments to the executive committee, adding what they refer to as 'Patient Value Units,' which are teams located in all major UCB therapeutic areas who facilitate the growth of cross-functional

teams that are responsible for 'patient value practices, patient value operations, and patient value functions'. In driving employees to understand the holistic experience of the patient, the organisation aims to reframe the problems that must be solved around the patients' needs and imbed a culture which understands that success is only possible through cross-functional cooperation.⁶⁰

However, patient centricity strategies also need to be accompanied by the adoption of an agreed set of patient-focused metrics and departmental KPIs. The success of digitally-enabled patient-focused activities can be measured via appropriate, locally agreed, performance indicators. For example, surveys can be conducted to capture improvements of quality-of-life in programme participants and confirm the value of engagement activity.⁶¹

Pharma acknowledges the importance of patient education programmes, but measuring the outcomes as well as the return on investment for these programmes can be difficult.⁶²

Learning outcomes need to be linked with commercial goals. Data analytics and big data, generated through digital technologies, can help provide a better view of the return on investment for such interventions. The same general movement within the industry towards utilising real-world evidence (RWE) for clinical trials could also help determine, at relatively low cost, investment opportunities to improve patient centricity more widely. This is especially applicable in the US market, where data is rich and available and pharma is allowed to have a more direct relationship with patients.⁶³

The way companies reward their employees is also a key reflection of their culture. Currently, there is a continuum of incentive practices across big pharma's commercial activities. At one end there is a non-financial oriented model that adopts individual and team targets linked to specific objectives such as service quality, technical knowledge and patient interaction. At the other, the more traditional model that assess financial performance against (say) quarterly revenue targets. Most companies fall somewhere between these approaches. While there is no 'silver bullet' solution, the incentive approaches that are most successful are those that adopt a holistic approach and look at incentives, training and recognition, while reinforcing employees' engagement with the product and patients. If pharma is to truly embrace patient centricity they will need to build measures of it into their plans, either alongside or replacing financial performance measures.

Develop partnerships that utilise digital technology

Developing partnerships with technology companies is another key initiative that pharma has been utilising to be more patient-centric and digitally-enabled across both their commercial and clinical spaces. Partnerships allow for innovative solutions to be tested, trialled and implemented faster and at reduced risk for both parties, especially when key digital skills are lacking in larger

pharma organisations.

Such collaborations provide pharma with developed or highly tailorable platforms that bring them closer to how patients want to interact and have their healthcare managed. The success of these partnerships highlights the willingness of patients to engage with pharma and clinical research if the tools for collaboration are right (see case example 2).



Case example 2. Partnerships between pharma and technology companies

PatientsLikeMe – an online portal and mobile application that allows people with health conditions to share information and data relating to health and clinical trials with other patients and researchers with the aim to improve patient outcomes and involvement in research.⁶⁴ Currently, the platform has a network of over 500,000+ patients who have collectively contributed 40 million points of data about disease.⁶⁵ PatientsLikeMe has collaborated on a number of projects with pharma companies in an endeavour to be closer to what concerns patients most, including with UCB to create a patient community around epilepsy,⁶⁶ and Shire Pharmaceuticals to track and share experiences for patients and their caregivers living with rare diseases.⁶⁷

u-Motif – a collection of tools, including an easy to use mobile app and an online platform that has been validated for use in clinical trials, which enables patients, healthcare providers and life science companies to capture and analyse data surrounding health conditions.⁶⁸ Its patient-centric approach was honed through working with IDEO, experts in embedding human-centred design processes. In the past year, the tools have captured 64 million data points from over 18,000 patients who have chosen to take part in research studies.⁶⁹ The company has worked with several large organisation within healthcare and life sciences. In 2016, the mobile application was used in a clinical trial to assess the impact of using a smartphone-based Parkinson's tracker app to promote patient self-management, enhance treatment adherence and the quality of clinical consultation.

After 16 weeks 72 per cent of participants continued to use the application, elucidating that smart-phone apps may be an effective way for patients to manage complex chronic conditions.⁷⁰ In 2017, uMotif announced a partnership with AstraZeneca, which will use the companies' technology in order to develop a more patient-centric, real world evaluation based approach for future clinical trials.⁷¹

Voluntis – a technology developer that has created a range of Conformité Européenne (CE) and FDA-approved mobile apps in collaboration with big pharma.⁷² These include:

- **Sanofi:** Diabeo, a mobile application which aims to better treat patients suffering with type 1 and type 2 diabetes. The application provides patients with decision-making support through algorithms that help calculate personalised doses of insulin and remote management of a patients conditions through connections via telemedicine with healthcare providers.⁷³ Clinical evidence has shown that the technology significantly improves HbA1c in poorly controlled type 1 diabetic patients.⁷⁴ As a result of further clinical evaluation the application was approved CE certification in 2013.⁷⁵
- **Roche:** this is a partnership that aims to develop an application for women afflicted with breast cancer. The application will require the patient to manually enter their symptoms into the application which then analyses the data and relay it back to the patients' medical team to encourage personalised follow-up. The application will then facilitate tailored notifications and treatments to be pushed to the patient's smartphone in order to facilitate better care.⁷⁶

Automate processes supporting patient facing activities (and optimise use of digital talent)

Clinical-trial management, from recruitment to submission, is being transformed as a result of advanced automation. Targeted online recruitment and remote-monitoring technology are increasingly enabling clinical trials to take place in 'real world' settings, so that patients participating in a trial can go about their lives with only minor changes to their habits.⁷⁷ Increased connectivity and automation in trial-management processes will also enable advanced trial design and monitoring approaches. For example, sites and sponsors can be connected to support the data management and analytics required for adaptive trial designs. Adaptive trials provide information on outcomes (and other measures such as side-effects) at prescribed intervals; this enables the parameters of the trial protocol to be modified in response to the observations, making clinical trials more flexible, efficient and fast (see case example 3).

Other activities, such as employee on-boarding, sales and operations planning, launch monitoring, and marketing-content approval, would also benefit from streamlined, automated work flows and increased transparency. This requires pharma companies to set up a collaborative environment to bring together the right people from IT, business compliance, and external partners (including patients), to run quick test-and-learn cycles. Positive results can then be scaled up and new ways of working formalised and integrated into business processes. While the availability of sufficient digital talent can be a barrier, solutions include adopting open innovation and other collaborative models to fill in-house capability gaps. Some companies are also developing hubs or digital centres of excellence, bringing together scarce capabilities and concentrating them into a critical mass. Such hubs can also be responsible for managing the portfolio of digital partnerships, managing ring-fenced funding for digital initiatives, and evaluating and disseminating lessons from internally and externally run digital initiatives across markets.⁷⁸



Case example 3. QuintilesIMS and the move towards the digital CRO

Contract research organisations (CROs) such as QuintilesIMS are currently working to digitally enable clinical trials. For example, in 2012, QuintilesIMS formed a digital patient unit, a database which has over three million patients, to provide patients with information to better manage their personal health and to provide them with opportunities to participate in clinical research, observational studies and programs to better manage their conditions.⁷⁹

This large repository of patients can then be reached through digital mediums (such as smart phones)⁸⁰ and save pharma significant time and money in the clinical trial recruitment process.⁸¹ In 2016, QuintilesIMS unveiled its Solution Design Studio, which creates technology solutions that tackle some of healthcare's biggest challenges,⁸² including integrating digital technology within clinical trials.⁸³

Create new contracting and pricing models

Value-based contracts between pharmaceutical manufacturers are growing in number, with at least a dozen 'value-based' or 'at-risk' arrangements with manufacturers reached in the US since 2014.⁸⁴ These contracts bring higher payment rates for improving patient outcomes, supplanting traditional contracts in which payment is based on volume of sales and obtaining a place on the prescribing formulary. However, if pharma is to be paid on the outcome of a patient's health, it needs to be able to control patient adherence.

For example, diabetes treatments are based on over 90 years of refining treatment molecules, yet less than 10 per cent of patients have a level of control that would eliminate the risk of late-stage complications. Advances in technology such as machine learning and cloud computing are starting to solve this problem. A programme run by Livongo Health, a California-based start-up, measures a patient's blood sugar levels and uses technology to determine the best course of treatment. Using the latest advances in cloud computing, a drop of blood is instantly analysed, and a text is sent suggesting a course of action.

At the press of a button, patients can also access further help over the telephone from a 'coach,' often a qualified dietitian. These emerging digital technologies are reshaping the treatment landscape.⁸⁵

Oncology offers opportunities for new outcomes-based contracting. However, a survey of 45 payers indicated that only 5 per cent of respondents reported they currently have outcomes-based contracts in place for oncology drugs. In contrast, 55 per cent of respondents have contracts for diabetes drugs, 45 per cent for hepatitis C drugs and 42 per cent and 41 per cent, respectively, have contracts underway for cardiovascular and respiratory agents.⁸⁶ While outcomes for these latter diseases are easier to measure using digital technology, the benefits of developing such contracts for cancer to provide RWE of the value to patients could deliver real business benefits.

A new generation of companies is also using big data, sensors and artificial intelligence to provide precise real-time monitoring of patients, especially those suffering from conditions such as diabetes and chronic obstructive pulmonary disease, which impose a heavy burden on overstretched health budgets. The products and services these companies are developing mean that a patient's primary point of contact with the health system can be a remote monitoring centre or telephone advice line instead of a doctor's office. Investors are starting to bet heavily on the potential of technological innovation to transform the way healthcare is delivered. A total of \$4.2 billion was invested in the sector last year, with companies in the analytics and big data category attracting \$341 million over 22 deals, more than double the amount in 2015.⁸⁷

Build collaborative relationships with patients, payers, healthcare professionals and regulators

Good digital and health literacy are key determinants of patient centricity. Pharma is well-placed to help improve patients' digital and health literacy by ensuring that the information provided is written in clear, simple language and readily understandable at basic levels. Pharma also needs to continue to foster meaningful relationships with patients and healthcare professionals to provide a consistent customer experience to improve health outcomes (see Figure 13).

Figure 13. The benefits of engaging with pharma



Source: Deloitte research , 2017

In addition to partnering with online communities, crowdsourcing is another emerging engagement strategy. Crowdsourcing is an internet-enabled business model that harnesses creative input from external agencies.^{88,89} Crowdsourcing can help the full drug development process, from discovery to early development and even late-stage manufacturing and marketing (see case example 4).

Collaborative relationships can also help improve patient recruitment and retention in clinical trials, where delays can affect both study costs and sales. A key solution is to improve communication and public education about clinical trials. While greater communication between doctors and pharma is critical to improving recruitment and reducing delays, so too is improving communication with patients. Trials require a significant commitment from patients, and reasons for dropping out include forgetting visits, financial constraints, fear, anxiety and misunderstood expectations. Improving communication with patients through developing online information resources and optimising the use of digital channels, apps and mobile devices can help address this problem.

Examples include Apple's ResearchKit, which in the first few days following its launch in 2015, 60,000 patients signed up to clinical trials. Since then it has supported studies such as tracking Parkinson's symptoms and a screening protocol for autism. Likewise, partnerships with Google and its AdWords service has been used to provide easier access to and management of potential trial participants. The evidence suggests that a digital strategy can dramatically improve recruitment and retention over traditional methods.⁹¹

Building a more balanced, collaborative relationship with regulators is also essential to ensure that digital technologies, whether used in clinical trials or in patient support initiatives, are not detrimental to patients, as highlighted in our recent report, *Unravelling complexity: The challenge of compliance in the life sciences supply chain*.⁹² While the fast pace of innovation in this area is challenging (see part 3), regulators are opening more formal channels of communication and major regulators, such as the FDA, are in the process of forming digitally focused units.⁹³



Case example 4. How the crowdsourced innovation platform InnoCentive is helping pharma become more patient centric

InnoCentive provides an open innovation marketplace or platform linking the buyers ('Seekers'), who are looking for an idea or a solution to problems they face within their organisation, with the sellers ('Solvers'), who are providing the ideas and solutions. Following InnoCentive's framework of Challenge Driven Innovation™, problems are decomposed and formulated as 'Challenges' that are broadcast via their platform to their large and diverse global network, which can include patient groups. Under the terms of the 'Challenge' agreement, which covers IP treatment and restrictions on information disclosure, Solvers submit new insights and solutions.

Challenges can request deliverables at various stages of development, from early-stage ideas to theoretical proposals and experimentally validated solutions. While there is a 'bounty award' for the winner(s), the reasons for participation are numerous and diverse. Examples of applications can be found throughout the drug development pipeline, such as identifying new biological targets, seeking novel compounds and developing risk assessment tools. Examples can also be found post-launch, such as seeking new product uses. Challenges have been used to help organisations become more patient-centric and specifically engage patient groups.⁹⁰

5. Future enablers of patient centricity

“The biggest innovations of the 21st century will be at the intersection of biology and technology.”

Steve Jobs⁹⁴

Innovation and new technologies are developing at an unprecedented pace and are transforming the art of the possible. While there are still barriers to wide-scale adoption, the utilisation of these technologies could enable a successful, digitally-enabled, patient-centric pharma industry. Most big pharma companies are now moving towards a digital technology-enabled transition to ‘beyond-the-pill’ or ‘around-the-pill’ services. This final section of this report looks at enablers, based on emerging technologies, which could help pharma deliver a truly patient-centric model of care.

Embed blockchain technology to improve efficiency, safety and traceability

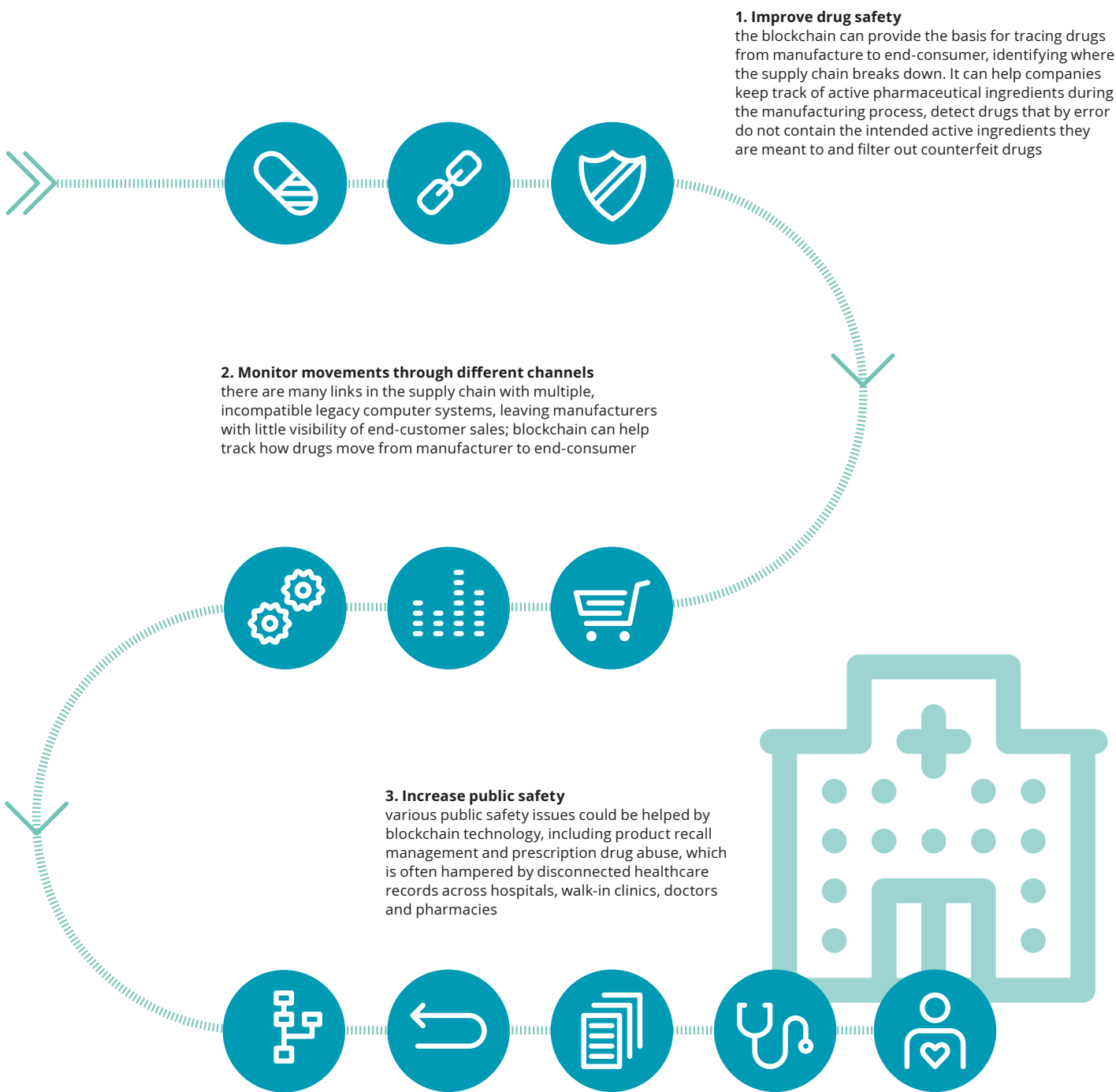
Blockchain technology is a shared, immutable record of peer-to-peer transactions built from linked transaction blocks and stored in a digital ledger. This allows each separate patient data source to be a ‘block’ part of a complete, unalterable patient data profile which can then be shared securely with healthcare providers or research organisations. Using blockchain technology can help organisations bridge traditional data silos, dramatically increase IT and operational efficiencies, keep business and medical data secure, and streamline patients’ access to medical data.

It provides a highly secure, decentralised framework for data sharing and has the potential to overcome the limitations of large-scale sharing of health data, namely data security and patient privacy concerns.⁹⁵

For pharma, the blockchain can record irrefutable evidence on the performance of a medicine and demonstrate adherence to the prescribed regimen, issues that are becoming increasingly important. Figure 14 and case example 5 (overleaf) explore ways blockchain technology could be used in the pharma supply chain.

For pharma, the blockchain can record irrefutable evidence on the performance of a medicine and demonstrate adherence to the prescribed regimen, issues that are becoming increasingly important.

Figure 14. Blockchain can benefit the pharma supply chain





Case example 5. How two California start-ups are using blockchain technology to build an electronic, interoperable pilot system to track the movement of prescription drugs

Blockchain startup Chronicled, which links the physical and digital worlds with cryptographic identity chips and blockchain technology, has partnered with the LinkLab, a life sciences supply chain consultancy, and launched a serialised 'track and trace' pilot for the pharmaceutical industry. The pilot launched at a one-day event, gathered feedback on the launch of a blockchain-based compliance protocol that will satisfy the Drug Supply Chain Security Act (DSCSA) which passed into law in 2013.

It requires that by 2023 pharma companies should be able to track the production of drugs from raw materials all the way to dispensing to ensure safety and legitimacy, and that they should be able to do so in an interoperable, electronic way. Blockchain technology, allows for the posting of such serial number data unidirectionally, creating an unbroken chain where the many players of the drug supply line can verify the drugs they are receiving are arriving from the correct source.⁹⁷

Adopt gamification to enhance patient engagement, health literacy and medication adherence

Gamification is a way of engaging patients by providing a built in reward mechanism, stimulating further play and greater understanding of health conditions. There is an increasing body of evidence that demonstrates how gamification can have a positive impact on patient engagement, health literacy and adherence.^{98,99} One example is the use of gamification in paediatric clinical research trials. Elements of incentivisation, challenge and reward can now be applied using digital technologies, allowing pharma to educate and engage paediatric patients in trials with greater success. This is transforming the scope for children to engage in trials rather than be bypassed by passing comprehensive study information through their parents/caretakers. Digital games provide a platform for communication directly to paediatric patients that is accessible, familiar, motivating, and can help educate future generations about the significance of clinical research in their overall healthcare.¹⁰⁰

Use 3D printing to transform all stages of the pharma value chain

3D printing technology has the potential to transform product development, manufacturing and distribution for pharmaceutical companies and improve drug discovery, dosing and delivery. Benefits include not only the customisation and personalisation of drugs, but also cost-effectiveness, increased productivity and enhanced collaboration.¹⁰¹ It's now two years since the first 3D printed prescription drug received FDA approval, with the technology enabling companies to make fast dissolving, easily ingested formulations of high dose medications in a single pill.

This technology is seen as the key to creating more personalised medicine, a concept that is growing in popularity, but which also introduces a set of new risks including cyber risks, including the safety and efficacy of 3D Printers, and product liability risk.¹⁰²

Optimise the potential of the connected patient to develop new outcome-based propositions

Pharma companies have acknowledged the need to move to outcome or value-based propositions, but to do this they need to understand what value means to each of their customer stakeholders. Pharma companies could become a central player in a learning healthcare system by leading the integration of clinical research into healthcare delivery and working with providers to embed continuous learning, including clinical trial results, into IT systems and next-generation electronic medical records.

Pharma companies could also be more effective in adopting 'beyond-the-pill' and 'around-the-pill' care services. This includes embracing approaches that improve the patient experience in using pharma products, support compliance and personalise the dose/dosing regimen for patients.

At the same time, high-tech companies are poised to become increasingly pivotal in the biomedical arena, through digitally enabled innovations, such as high-resolution imaging, unobtrusive monitoring devices, near patient testing and big data integration.

Drugs will increasingly be tailored to a patient's clinical and lifestyle needs, while health professionals monitor a patient's condition and adherence to treatment remotely, all as part of a digital ecosystem that constantly monitors a patient's condition and provides feedback to the patient and other stakeholders. There is already a plethora of wireless sensors on the market measuring biophysical signals, and combining these with smart scales, glucometers, blood pressure cuffs, refrigerators, exercise equipment and others will lead to patients becoming ever more connected, linked through middleware like Apple HealthKit.¹⁰³ Real-time alerts to caregivers will enable clinicians to respond quickly with targeted interventions.

One example is the role of electronic patient reported outcomes (ePRO) in which health apps are extending the lives of people with metastatic cancer (see case example 6).¹⁰⁴

Drugs will increasingly be seen as part of a digital ecosystem that constantly monitors a patient's condition and provides feedback to the patient and other stakeholders.



Case example 6. Electronic patient reported outcomes improve survival times in cancer patients

National studies have shown that doctors and nurses miss many of the symptoms that people experience during chemotherapy. Patients were therefore asked to report 12 symptoms such as breathing and sleeping difficulties using an ePRO app. The system proactively monitored symptoms, so that the care team was able to intervene earlier and identify problems before they became more severe. The results, published in June 2017, found that patients using the app were able to stay on chemotherapy for substantially longer than others because they were less likely to deteriorate to the point where they could not handle more chemotherapy.

The ePRO patients were also less likely to be admitted to hospital, reducing the risk of becoming bed-bound or acquiring a healthcare-associated infection. Patients who used the purpose-built app typically survived for 31 months versus 26 months for those who did not.¹⁰⁵ Although the ePRO system used in the research was purpose-built for the hospital, an Israeli start-up has developed a commercial version known as Moovcare, a medical device Classe I (CE mark in July 2017), which has had an independent evaluation of its effectiveness in improving outcomes for lung cancer patients; use of the app helped extend average life expectancy to 19 months compared to 12 months in the control group and improve quality of life.¹⁰⁶

Make patients true partners in managing their own healthcare

People will continue to expand their use of social media and other avenues to review symptoms, disease states, and potential treatments. Patients will also have increasing control of their data, enabled by trusted data-collection frameworks, such as Apple's ResearchKit¹⁰⁷ and platforms like PatientsKnowBest,¹⁰⁸ which let patients decide who can access their data.

The increasing connectivity of digital social networks will enable patients to own, operate and drive their own healthcare and, as a result, also become partners in clinical trials. Treatment management will also be revolutionised by biosensors, with connected patients using this information to gauge how effective their treatments are. This feedback will affect whether patients switch to a different therapy or remain on the prescribed one.

Utilise non-traditional players' experience of disruptive technologies and customer engagement

We are already seeing massive disruption to healthcare in many different areas, with technology giants like Google, Apple, Microsoft and IBM Watson already active in the patient-centric health ecosystem. Every year new start-ups are also entering this space, with innovative and consumer-focused products and new business models. These partnerships will also lead to massive advances in R&D using artificial intelligence in genomics and precision medicine to develop a deep understanding of the root causes of cancer, heart disease and neurodegenerative diseases and what can be done about them.¹⁰⁹ New arrivals also include big players from other industries, including McLaren Applied Technologies, which has formed a long-standing partnership with GSK (see case example 7).

Adopt distributed research networks and web-enabled virtual trials

Distributed research networks linking alternative clinical settings or web-enabled 'virtual' trials have introduced innovation into clinical research, with new clinical trial models that are less costly and more efficient and convenient for patients. Decentralising clinical trials has the potential to transform the conduct of clinical trials and dramatically reduce the infrastructure costs associated with drug development. This more patient-centric view, which uses digital technologies, helps eliminate central research sites and enables patients to become the 'site of data acquisition'. Lowering the cost of research should also make it cheaper to innovate, leading to an increase in the supply of new, more affordable drugs. Diversity, rather than scale, will become the new hallmark of the industry and will be the focus of new business and research models based on closer collaboration, data sharing and pre-competitive agreements. Consortia, public-private partnerships, and crowdsourcing platforms will expand and become key drivers of a transformed clinical trial ecosystem.¹¹⁰



Case example 7. How McLaren is helping GSK to improve monitoring of patients with neurological conditions during clinical trials

McLaren Applied Technologies was established to apply technologies, design and techniques developed in motorsport to other, highly regulated, data rich and safety critical, industries. Sensing, analytics, modelling and simulation technology and experience is being used to embed patients directly into the heart of pharma and healthcare industries. This is helping to drive a new level of connection, understanding and interaction with patients, resulting in digitally enabled programmes of care – 'Digital Therapeutics'.

Biotelemetry involves real time data being processed using F1-derived modelling and simulation software, and decisions being made by patients and clinicians across three time frames – real time (decisions made by machines), right time (data informed human decisions/interventions) and design time (long term interventions/process changes). This approach has led to multiple programmes and products across the end-to-end pharma process, ranging from development optimisation in R&D, to continuous monitoring of patients recovering from surgery to help deliver the best outcomes.

Applying advanced sensing and clinically sound algorithms can deliver clear and meaningful insights to clinicians and clinical trial study teams. McLaren has worked with GSK to apply biotelemetry technology to form the basis of important clinical trials and studies. Most notably, it has been used to provide new levels of objective and timely insight into patients recovering from strokes or managing neurological disorders such as motor neurone disease. By accurately charting an individual's reaction to treatment and quality of life in the home, researchers, clinicians and patients themselves are able to gain greater depth of knowledge about therapy efficacy and disease progression, while doctors can develop a personalised plan to make the right interventions and best improve medical outcomes.

Having shown how the F1-derived methodology can be applied to clinical trials, McLaren is helping pharma to overcome many of the non-technical process and regulatory challenges associated with the technology. The opportunity which McLaren is now focussed on is industrialising the approach into platform-based solutions so that these techniques can be applied appropriately on a systemic, business as usual basis.

6. Appendix: Deloitte research methodology

Research2Guidance

We commissioned Research2Guidance, a digital health advisory and market research company, to provide a Q1 2017 update of the app portfolios for the top 12 pharma companies. This review in May 2017 updated and refined the figures included in the Research2Guidance Pharma App Benchmarking report, released in 2014. The review focused on examining the number and types of health apps produced by the top 12 pharma companies from 2013 to the first quarter of 2017. The companies included in the research were: Abbvie/Abbott, AstraZeneca, Bayer, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Merck, MSD, Novartis, Pfizer, Roche and Sanofi. The project reviewed apps available on the Apple App Store (iOS) and Google Play Store (Android).

PatientView

PatientView is a UK-based research company specialising in obtaining perspectives from patient groups across the world. For the past six years it has undertaken an annual evaluation of patient groups' perspectives of the corporate reputation of six health care industries, including providing a long-term overview of changes in the corporate reputation of the pharma industry, based on what patient groups see as important over that timeframe (Ref 107). We commissioned PatientView to survey patient groups on their views regarding the use of health apps, including those produced or developed by pharma companies. The primary objective of the survey was to map the patient usage of health apps and determine patient group views of the usefulness of pharma health apps. 190 patient groups responded to the survey, representing 56 therapy areas from 38 countries. A mix of 10 multiple-choice and open-ended questions were asked, along with a number of profiling questions that were used to identify where the patient group was based and its disease specialty.

The Connected Patient

Insight for the report was also derived from working with Deloitte digital and other Deloitte teams working across the life science and healthcare industry teams in their development of the Connected Patient initiative. This is an immersive experience which looks at the various ways in which digital technology can be integrated into a patient's life and the benefits it can bring to patients living with complex and chronic conditions. This initiative also explores how these digital technologies and be integrated into pharma's business.

For more information on the Connected Patient initiative, please see: www.deloitte.co.uk/connectedpatient

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