

respiratory_care v2.0

Technology and Healthcare: a call for collaboration



_introduction

With aging populations and the rise in chronic conditions, the burden on global healthcare systems will become unbearable if innovative solutions for disease management are not found.

Drugs alone are not enough to manage disease. Increasingly, there is a place and a need for individuals to take on a more active role in managing their own health. But while the consumer mind-set prevails in most areas of our life, the provision of choice, engagement and involvement in treatment decisions in healthcare is still a relatively new concept.

Modern health technology may be the most promising way to empower patients when it comes to their own disease management. With plenty of new offerings, health technology is a rapidly growing sector, but what experience do the tech companies, who are driving this growth, have of the healthcare arena? While healthcare companies are also developing an interest in technology, and becoming braver in their approaches and offerings, both industries still have much more to learn.

Neither traditional healthcare nor tech approaches alone can solve the complex problems that exist. To make digital health solutions truly useful, healthcare and tech need to work together, taking the best from each industry and applying them to create wholly new approaches and ways of thinking.

At Teva, we are committed to driving this collaboration forward, particularly in the field of respiratory care. We want to understand how we can work better together to optimize care. For the last five years, and to an even greater extent moving forwards, we are listening to and collaborating with leading minds from both the health and tech arenas. This report presents a summary of what we have learned to date, and our recommendations for the road ahead. By working together, we can make a real positive impact for the future of patients, caregivers, healthcare professionals, and healthcare systems.



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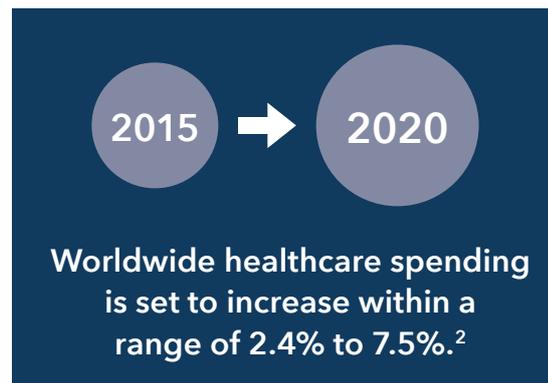
_the growing healthcare challenge



Managing chronic disease increasingly involves collaborative care and self-management.⁵

A need for innovation

In recent decades, global healthcare costs have risen dramatically.¹ This trend is only projected to continue, with healthcare spending worldwide expected to increase even further by 2020.²



This will be exacerbated by an increasingly aging population. Globally, people aged 65 or older are projected to significantly outnumber children under five by 2050 (growing from 524 million in 2010 to 1.5 billion in 2050).³ For global healthcare systems this relentlessly growing demand for treatment has severe implications: in particular it necessitates a shift in treatment focus from acute to chronic illnesses, and a paradigm shift in the delivery of healthcare itself.⁴ Managing chronic disease increasingly involves collaborative care and self-management. The oft-quoted ideal is 'empowering patients': enabling them to become more involved in and take more control over their own care.⁵ However, patients first need to become more knowledgeable about their own disease and personal treatment plans. Once knowledge increases, so does confidence and motivation, enabling honest and open communication with healthcare providers and encouraging people to become more involved in their treatment.⁶ But are all healthcare professionals (HCPs) encouraging their patients to become active participants in care?

Healthcare in the digital age

While new technology can make our life easier, some healthcare experts argue that the development of new medical technology leads to increased health spending out of line with overall economic growth, and may account for more than a half of long-term spending growth.⁷ The overwhelming challenge of 21st century healthcare is how to move from cost-increasing,

to cost-reducing technology.⁸ Moore's law suggests that every two years, the cost of computing will fall by half. If we are to apply the same rule to healthcare, as medicine becomes more digital, it should also become more productive and increasingly cost-effective.⁸

However, equating progress and improvement with the adoption of sophisticated technology is a trap that needs to be avoided.⁹ Before adopting a technology, we must weigh up the overall cost with the associated benefit and proven outcomes to ensure we are supporting cost-effective solutions that have a real benefit for patients.

A collaboration between Janssen, Havas Health, and a UK National Health Service (NHS) South-East Healthcare Trust led to the creation of Care4Today, a digital health manager application with specific mental health, orthopaedic, and cardiac rehabilitation solutions. In a study of 173 patients who used the mental health mobile app, there was a 58% decrease in hospital referrals.¹⁰ When the orthopaedic version of the app was trialled in Guy's and St Thomas' Hospital in London, it was found that the average length of a patient's hospital stay following a knee or hip surgery reduced from 5-7 days to 2-3 days. Applying this across the UK has the potential to substantially reduce the cost of knee and hip surgeries, saving the NHS an estimated £64 million.

The growing burden of respiratory disease

As in many other therapy areas, the costs of respiratory care are continuing to rise on a global scale.^{11,12} In 2007, the cost of asthma to society in the US was \$56 billion – a 6% increase from baseline since 2002¹¹ – while in 2011 the equivalent cost to the EU was €33.9 billion.¹³ Respiratory disease represents a significant drain on the economy,^{11,12} and as populations age and chronic conditions become more common,⁴ finding cost-effective ways of managing asthma and chronic obstructive pulmonary disease (COPD) is imperative.^{11,12}



In healthcare, technology has often increased costs and complexity rather than reducing them.⁷



Around 70% of self-defined 'well-controlled' asthma patients reported regularly experiencing limits to performing everyday activities, such as walking.¹⁵

Perceptions of disease control and communication

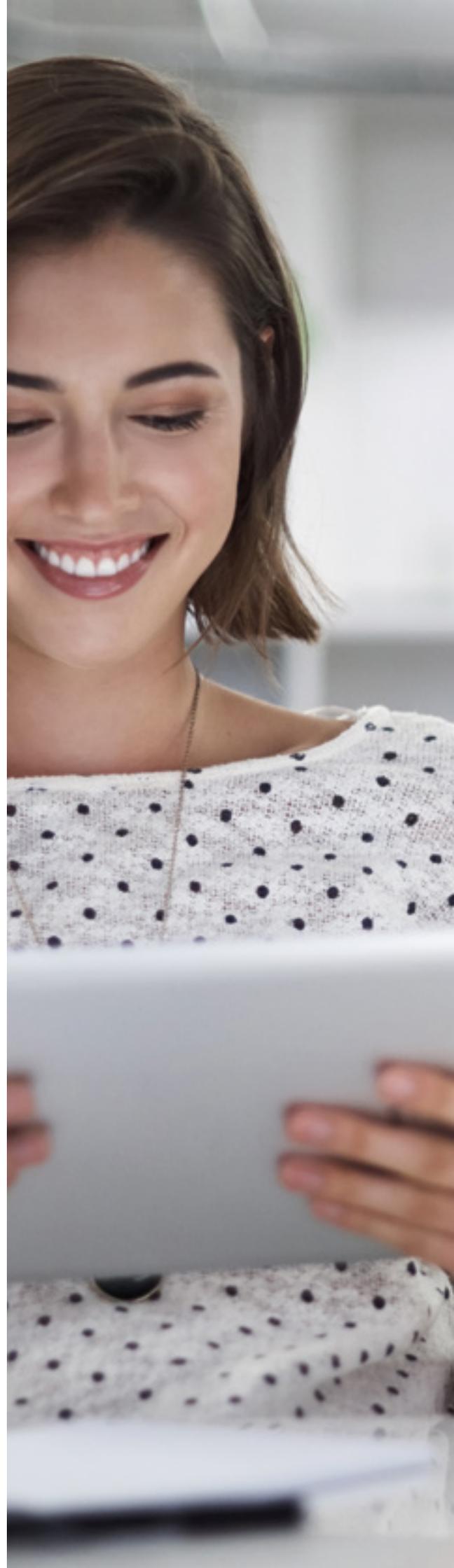
Nearly half of people with asthma in Europe and the US have uncontrolled disease as defined by guideline standards.¹⁴ However, when talking about disease control, patients and HCPs don't always mean the same thing. While the majority of HCPs perceive good control as no limitations to a patient's daily activities, patients understand the term differently.¹⁵ In fact, around 70% of self-defined 'well-controlled' asthma patients reported regularly experiencing limits to performing everyday activities, such as walking.¹⁵ The same contrast occurs in COPD, with over a third of patients who reported their symptoms as 'mild-to-moderate' often being too breathless to leave the house.¹⁶ This discrepancy in defining control suggests a lack of clear communication between patient and provider, or misunderstanding of the language being used.

The management of asthma and COPD bring its own specific challenges: firstly, a large proportion of people with asthma and COPD have issues with adherence to their medication,^{17,18} and secondly, only 30% demonstrate correct inhaler technique, numbers that likely contribute to the levels of poor disease control seen.^{19,20}

With over 200 drug-inhaler combinations available, correct medication use is made even more complicated. When prescribed three different inhalers, to be taken at different times and each in a different device that has to be used a certain way, how do you know if you're getting it right? Patients must master the specific technique required for each of their devices, yet often don't get the minimum necessary inhaler training they need – and HCPs do not always know or demonstrate correct inhaler technique themselves.²¹ Furthermore, without feedback, they don't always recognize when they are using their inhaler incorrectly.²²

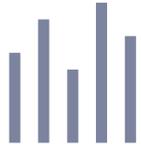
There is huge potential for digital innovations to help improve patient outcomes in this area, from improving adherence and quality of life through to reducing the risk of hospitalization for patients who improve their disease management. Mobile apps have already shown potential for improving medication adherence,²³ and reducing short-acting β -agonist (SABA) usage²⁴ with accurate information on inhaler usage. By integrating digital innovations into traditional asthma management, patients and providers can have more informed conversations, increasing the shift towards shared decision-making, empowering patients to actively manage their own conditions.²⁵

Patients have already expressed a desire to access personalized healthcare quickly and conveniently,²⁶ and have even been willing to pay premiums for such services,²⁷ suggesting an appetite for further digital innovation exists.



02

_tech can't solve the challenge alone, and neither can pharma



App evaluation strategies, or stricter regulations, are essential to distinguish between apps which are evidence-based and efficacious, and those which are not.³¹

Two contrasting approaches

Innovators in the pharma and healthcare industries are beginning to see the advantages of partnerships with digital technology companies to improve their patient offerings.²⁸ While skill sets and knowledge bases from the two sides offer great opportunities for mutual benefit, the industries have very different attitudes and processes around product development, measuring outcomes, and regulation.²⁸

Pharma and healthcare have as much potential as tech to create bold, imaginative solutions, yet traditionally have followed a more conservative approach, applying risk-averse, slow-paced strategies.²⁹ As a highly regulated industry, pharma may be deterred from digital healthcare – privacy and security are great concerns, and hold the potential to damage a long-built reputation.³⁰

A lack of regulation

Currently, despite the proliferation of apps and novel ways of using technology to impact health, the mHealth sector lacks regulation. There are few measures to ensure that mobile apps are user friendly, host accurate content, are evidence based, effective or have a real impact on health outcomes.³¹ The rigorous clinical efficacy and safety requirements that apply to new drugs, formulations, and medical devices are not yet being applied to technology that is promising to have an impact on health and disease.³² Therefore app evaluation strategies, or stricter regulations, are essential for physicians and patients to distinguish between mobile apps which are evidence based and efficacious, and those which are not to ensure that patients have access to those which will actually improve outcomes.³¹

An example of a dedicated digital technology company entering the healthcare space is the recently launched Apple CareKit: a software framework designed to help developers build apps that empower patients to manage their health.³³ It has also been reported that Apple wish to recruit expert lawyers who specialize in health privacy regulations, and can inform engineering teams throughout the development process.³⁴

Managing privacy and data protection requirements in pharma is a highly complicated affair. Privacy programs that are required for other industries similarly exist within healthcare;

however, additional ethics committee rules, pharmacovigilance, and safety requirements must be met. There are frequent concerns around the privacy of patient clinical trial data, and the risk of storing this in the cloud.³⁵ Pharma can learn from tech in this sense, as companies such as Apple will have years of experience in storing and managing masses of user data.

The potential for mHealth solutions

Despite these challenges, the mHealth future is bright.

In 2014, the European Commission funded several research and innovation projects related to mHealth, and in 2016, the US Food and Drug Administration (FDA) approved 36 mobile health apps and devices that provide medical advice to consumers, a trend which is likely to continue as healthcare becomes increasingly digital.^{36,37}

The UK's NHS has begun prescribing mHealth solutions that help patients monitor chronic health conditions from their homes. One such mobile app allows COPD patients to use a finger probe to measure their heart rate and blood oxygen saturation every day, and enter the results into the app. After three months of data, the app learns to detect the individual's 'normal' range of oxygen saturation levels, and sends an alert to physicians when the measurement is lower than this range. In a 12-month clinical trial, this intervention reduced hospital admissions by 17%, and GP visits by 40% – demonstrating the potential for remote patient monitoring to reduce healthcare costs.³⁸

Thanks to encouraging results such as these, HCPs are becoming more open to, and more familiar with digital health solutions – it has been found that a third of physicians now prescribe mHealth apps to their patients.³⁹

When prescribed mHealth solutions, patients' 30-day adherence rates were found to be 10% higher than those who downloaded the same apps on their own.³⁹



A third of physicians now prescribe mHealth apps to their patients.³⁹

This demonstrates the potential for mHealth apps – when simple tools are recommended by GPs, they may have the power to improve patient adherence and consequently health outcomes. Despite the gradual shift towards shared decision-making in healthcare, HCPs evidently still hold an authoritative role in a patient's mind, and therefore ought to consider this when recommending such mHealth apps.

At Teva, we have recognized the potential for collaborations with the tech industry to revolutionize the delivery of healthcare, and have subsequently made the somewhat unconventional move of investing in telemedicine start-up American Well. This service allows patients to have video-enabled consultations with their physician, with plans to incorporate home delivery of medications in the future.

At Teva, we are committed to attaining a renowned presence in the digital health field, and expanding our solutions to go 'beyond the pill'.^{40,41}

In 2015, we completed the acquisition of inhaler technology company Gecko Health Innovations. The collaboration aims to connect patients, HCPs and caregivers through remote monitoring and accurate, real-time information regarding inhaler usage. Our vision is to improve the management of asthma and COPD, harnessing the power of technology to shape the future of respiratory care and providing a roadmap for future digital pharma innovation.^{42,43}

Current barriers to mHealth

There are some major barriers to the adoption of mHealth on a larger scale. For instance, for wider adoption of digital and mHealth into healthcare systems, the issue of integration between device data and electronic health records (EHRs) will need to be addressed.³⁹ The current lack of compatibility and integration means that data cannot easily be incorporated into records and used to inform aspects of care, preventing mHealth from achieving its full capability in healthcare.³⁹ But with a collaborative approach, there is potential to tackle this problem. By partnering with tech companies, pharma could draw on a wealth of expertise regarding the collection

and processing of large amounts of health-related data, as well as processes and knowledge around integration of applications into multiple systems.²⁹ This, along with the collection of previously unavailable data on health and disease, would help to broaden pharma's research and development (R&D) horizon, facilitating preventative and personalized medicine through a deeper understanding of patient characteristics.²⁹

In the past, pharma companies relied on 'blockbuster' drugs, focusing on large scale diseases, investing in a development process which takes on average 12.5 years, incorporating preclinical testing, clinical trials, regulatory review and post-marketing surveillance.^{29,44} These days, stakeholders are coming to expect pharma to bring new value to the healthcare system, and to focus on patients' individual needs. Marginal improvements in clinical endpoints are no longer adequate for treatment success.²⁹ Pharma need to learn rapidly to streamline launch processes; it has already been demonstrated that technology-enabled clinical trials will speed up trials, lower costs, and improve data quality and compliance. By harnessing the latest digital advancements, pharma have the potential to streamline the drug development process, saving significant time and costs.⁴⁵

With future mHealth solutions, both healthcare and tech must exercise caution in terms of data protection. Artificial intelligence (AI) startup DeepMind has been working with leading British physicians to create the Streams app, which uses blood test results to detect patients at greatest risk of acute kidney injury. However, DeepMind were recently found to be in possession of 1.6 million identifiable personal medical records on an 'inappropriate legal basis'. The data was used for initial testing of the Streams app, however explicit consent was not given by patients, so both DeepMind and the NHS hospital that supplied the records failed to comply with data protection laws. Moving forward, we must ensure we learn from critical oversights such as these.^{46,47}

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_pharma must listen, learn and embrace change



The top ten highest-grossing drugs in the US only help between 1 in 25 and 1 in 4 of the people who take them.⁴⁹

A new perspective on pharma's heritage

Speed is vital in launching technology products, with the aim to be the first to market in any given niche. This necessitates launches with a minimum viable product (MVP), followed by refinement and evolution over time as the product is tested in the field.

In contrast, the process of launching pharmaceuticals is extensive and time consuming, during which meticulous regulations must be met. However, even pharma's rigorous development process does not mean that every drug works for every patient.⁴⁸ The process caters for the population as a whole, and aims to ensure the product is considered 'acceptable' by long-established standards in terms of risk and demographic based on currently available treatments and standard of care.⁴⁸ The top ten highest-grossing drugs in the US only help between 1 in 25 and 1 in 4 of the people who take them. Statins, for instance, may benefit as few as 1 in 50.⁴⁹ Therefore, some would argue that payers have been investing in drugs which were essentially the pharma equivalent of MVPs all along.

With this in mind, integrating or adding digital technology into treatments which are already established and approved with proven efficacy, would therefore be an improvement on the typical pharma MVP. Because of this, pharma need to avoid becoming unduly concerned about the shift to software and the differences in the development processes. The initial offering does not need to work for every patient, in every scenario – it simply needs to be clear who will benefit at launch and the magnitude of that benefit, before future iterations are launched and the target demographic is extended.

A holistic approach

It is important to recognize that people have needs and influences beyond, and in conjunction with, their health needs.

Consumer health apps have much more success in this area compared to healthcare, by embracing the person holistically, beyond the central business plan and aims of any single mobile app.⁵⁰

Tech giants such as Google and Facebook successfully cater to individual users' socio-economic and cultural backgrounds based on their internet data and search history. A profile is built around each user, and this forms the basis of the adverts they will see when browsing, meaning the content is targeted and specific.⁵⁰

In mHealth, convenience is key

Walgreens made full use of this requirement through their health app – along with offering medication reminders and goal-setting features, the convenience of the app was extended even further. A 'refill-by-scan' feature was launched, enabling users to refill their prescriptions via their smartphone camera by scanning the barcode on their medication bottle. Additionally, the app now offers a 'transfer-by-scan' feature, where users can effortlessly transfer their prescription from another pharmacy to Walgreens.⁵¹

Walgreens successfully identified and answered an existing patient need, while simultaneously capturing useful data.

As we move towards a patient-centric healthcare system, pharma and tech companies must identify the distinct convenience or benefit to patients, ensuring the question of 'what's in it for me?' is answered.

This approach means patients will gradually become familiar with digital health solutions, while companies can continually add more complex, high-value services to ensure patient attention, and build value – a strategy which has been applied by digital companies such as Google and Netflix. Companies such as these constantly add non-core products to their offering, with the goal to enhance the user experience as a whole. Healthcare can learn from these examples.⁵²

Finding the right users

Unlike customers who seek premium products, value customers are willing to sacrifice a certain level of innovation, quality and service, in return for a lower price. This means that not every patient wants to, or is open to the newest most high-technology product, and



A recent study found that 62% of 152 GPs and 29% of 350 hospital doctors feared that giving patients access to their records would increase their workload.⁵⁵

so would be the wrong target audience for an approach focused on technology innovation and new data. This highlights the need for careful patient segmentation and understanding to inform positioning and strategy when launching with mHealth products.⁵³

Arguably one of the principal factors influencing long-term adoption of mobile technology in healthcare will be how seamlessly the product integrates with existing processes and systems. HCPs are already concerned that the volume of health data generated by new technologies may shift more workload onto them, and are particularly worried about the time and ability needed to effectively analyze the data.⁵⁴ A recent study found that 62% of 152 GPs and 29% of 350 hospital doctors feared that giving patients access to their records would increase their workload.⁵⁵ Additionally, HCPs are concerned about their liability if data is not actioned correctly and immediately, leading to their reluctance to gain access to such data.⁵⁶

Apps must not simply provide physicians or patients with streams of data that need to be interpreted.

Any data supplied must be simple and immediately actionable, and HCPs and pharma companies must work together to ensure that new health apps abide by this. Alongside this, mHealth solutions must consider which, out of the hundreds available, EHR and payer systems to integrate with, and if the product stands alone, there must be an accompanying strategy to sell in the benefit of this.

The expectations of changing prescribing and paying behaviors must be measured against willingness to reduce friction, and seamlessly integrate into existing systems. The strategy should therefore focus on not creating unwarranted additional cost pressures, until the concept is proven. Pharma must explore creative, consumer-inspired distribution methods beyond the payer; the typical pricing strategy must be revisited to ensure early adoption, and value of concept.

Getting more from data

The potential of big data is immense. In healthcare, big data comes from a multitude of sources, such as web and social media data, and human-generated data. Big data analytics have the potential to transform the way HCPs use high-end technologies to gain insight from their clinic data, and make informed decisions. Specifically in respiratory care, in the future, apps can be developed which utilize big data to develop preventative medicine – for instance allowing patients to avoid asthma triggers, and acting as a

knowledge base for physicians and patients to enable more informed treatment decisions.⁵⁷

Another important consideration is that data can be intimidating for HCPs. With the increasing consumer mind-set in healthcare, HCPs may be wary of data that could be perceived as monitoring or measuring their performance in treating their patients. However, this may be beneficial for healthcare systems as a whole; there may be the potential to identify techniques and methods used by the most efficient physicians. These metrics would need to be used with caution, and it must be considered that viewing such measurements may be a barrier to entry of new products without a mind-set shift.

A positive, supportive partnership between pharma and HCPs is crucial. The technology needs to be easy to use and understand, facilitated by intuitive functionalities and simplified dashboards. Technology can never replace physicians, but if they were to embrace it, it would only serve to support them, and benefit their patients in the long-run.⁵⁸ In addition, modern tech should not be limited to the monitoring and recording of behavior, as patients do not have constant access to their doctors. To provide extra value, data should be used to inform recommendations and calls to action, so that patients' decision-making process is guided.

At Teva, we already see the potential of big data, and are expanding our existing partnership with IBM to embark on an exciting research collaboration that integrates with the Watson Health Cloud.

With our therapeutic technologies such as CareTRx, and Watson's cognitive processing and algorithmic functional capabilities, we aim to provide actionable insights for doctors and patients, enabling predictive and preventative medicine. While the smart inhaler market may be becoming increasingly competitive, we stand out from the crowd with our additional potential to leverage the Watson Health Cloud on a massive scale, to combine human insight, machine learning and real-world evidence.^{59,60}

Aside from chronic respiratory disease management, the collaboration will also be focusing on developing a systematic approach to discovering new uses for existing drugs. The aim is for Watson to unleash its cognitive computing capabilities on decades of cumulative research data, in search of correlations that may allow for drug repurposing. Through harnessing the power of big data, we hope to streamline this normally time consuming and costly process, opening up new and exciting treatment possibilities.^{59,60}



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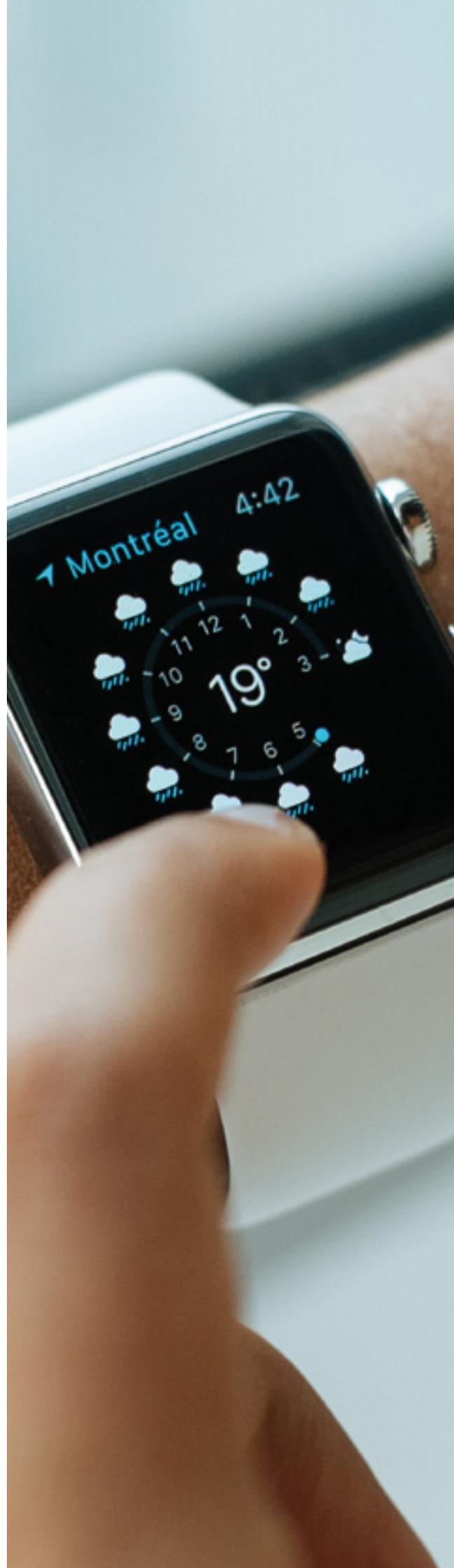
Connection beyond the company

Making health tech truly successful also involves some sober appreciations of limitations and potentials. Some combinations of apps and products might be generally more efficient than others, while some might work best for a specific set of patients. With multiple apps and products designed for the same therapy areas, there will be a need to prioritize and evaluate, to ensure that the most effective, and cost-efficient options are provided. Careful definitions of outcomes and effectiveness are required for such trials.

Since tech is evolving so rapidly, the traditional design of clinical trials may not be the best approach.

When drugs are compared, the trials are time-consuming, involving several stages and large numbers of people. In contrast, an app that was put into testing a few months ago may have already been through several upgrades, so the results of classic clinical trials would be outdated by the time the trial finishes. Instead, modern trials comparing health apps need to be much more rapid. Instead of comparing one drug against another, it is likely that clinical efficacy data is lacking from the treatment area and hundreds of apps might exist.

As a possible answer to this problem, researchers at Ryerson University, Toronto have come up with an innovative trial design to compare the effectiveness of diabetes management apps. In the first stage, medical experts and patients screen a large number of apps and decide which ones should be put into testing. Apps that lack crucial features would therefore already be screened out. The selected mHealth apps are then put into testing, but data is constantly analyzed and the testing runs in cycles. If an app is clearly not working for patients, they could be allocated to another treatment arm. This design has some shortcomings, such as the lack of insight about long-term effects, but also has significant advantages compared to classic trial designs.⁶¹





04

_a call for collaboration



Pharma and healthcare must work outside their comfort zone, embracing experimentation and risk.^{29,62}

Moving into the digital world brings a new perspective to pharma's heritage of drugs and devices, yet the move into software is not such a leap forward as it might seem. To optimize benefits and ensure efficacy can be demonstrated, the focus should be on creating an initial offering which caters to and demonstrates value for a specific patient subtype, before future iterations are launched, and the target demographic is broadened. Pharma must work outside their comfort zone, embracing experimentation and risk to meet the higher expectations and different perspectives generated from experiences with other industries.

The technology is ready, but both physicians and pharma companies must evolve if they are going to truly harness it.^{29,62}

Understanding a patient beyond their disease is essential for mHealth solutions to resonate. Pharma must learn from tech in this sense, and embrace the individual beyond the core agenda of the app, just as consumer health apps have succeeded in doing.⁶³ In order to be integrated into a patient's lifestyle, the offering must be convenient, and provide a distinct and immediate benefit to the user.⁶⁴

For both patients and physicians, mHealth products will need to seamlessly integrate into their lifestyles in order for them to engage. Collaboration between HCPs, pharma and tech companies is therefore essential, and each party must step up to create the most effective digital solutions for patients. Tech companies may not consider the complexity of the existing processes in the healthcare system, therefore tech must learn from healthcare and pharma's decades of experience to understand these intricacies in order to create a successful mHealth solution.^{29,65} To change prescribing and paying behaviors, the aim should be to reduce friction as much as possible, and in terms of pricing, additional cost pressures must be avoided until the concept is proven.

While mHealth represents a great opportunity in terms of capturing data, such data can be extremely powerful, and comes with greater responsibility and greater risk. Pharma must navigate their role in the context of data provision and management, and must be open to wider access of connected data, to promote

centralization and integration. A surge of data may threaten physicians' clinical autonomy, and while the value of the extended support services is understood, they wish to ensure their responsibility for the information remains the same. Many fear their workload will increase, and have concerns over duty of care implications.⁵⁵ To overcome this, strategies must empower and on-board HCPs, easing them into the digital world with a simple, easy to use service.

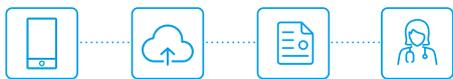
The healthcare industry is ever changing. Patients, physicians and payers expect companies to bring new value, and a more personalized approach to medicine. Through collaborating with HCPs and tech companies, established pharma companies with decades of healthcare experience can share their expertise, and bring innovative therapies to market, while moving towards a patient-centric healthcare system.²⁹ The digitization of healthcare is still in its early stages, but is having a significant impact on how all key stakeholders operate. Looking forward, we must be bold and adopt an act-now mentality; learning from tech companies to create innovative solutions, which can ultimately benefit the entire healthcare system.^{29,62}

Teva Pharmaceuticals is keen to keep learning from patients, HCPs, payers, and tech companies. All parties are needed to gain invaluable insights into the huge potential of technology in health – what tech can and should do for promoting health, the main obstacles in creating truly impactful solutions, and how they can be overcome. If you would like to learn more about our keen interest in connected solutions or would like to contribute to future innovations, please visit www.respiratorycarev2.com.

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