Executive Summary

Global healthcare is under increasing amounts of pressure, in no small part due to aging populations, the rising costs of chronic illness and health budgets under pressure. But there is hope that technology could provide an efficient and cost-effective solution to many of these challenges.

Medical-grade wearables is one area that shows promise, having the potential to relieve some of the most pressing issues facing healthcare systems worldwide, while also facilitating the shift toward patient empowerment and personalized medicine.

The transition from consumer to medical-grade wearables is far from seamless, with many stakeholders involved and many questions to be answered. Issues around development and funding costs, usability, data security and privacy, and patient engagement must be addressed if wearables are to become a mainstay in health systems around the world. Above all, wearables must offer all stakeholders a genuine value proposition that can improve health outcomes.

This white paper, the first in a two-part series, discusses the current environment for health wearables and some of the challenges involved, drawing on insights gleaned in a survey of life sciences companies, specially commissioned by SAP. The survey was also completed by related businesses such as IT-solutions providers and medical-communications agencies, and other stakeholders in health wearables including healthcare providers and researchers. The results were supplemented with in-depth interviews involving a pharmaceutical and healthcare consultant, a general practitioner active in digital health, and a diabetes patient with extensive personal experience of mobile-health technology (full details of contributors can be found in Appendix 1).

A second white paper will look at how we address the challenges discussed here and provide a roadmap for moving wearables beyond consumer ‘nice-to-haves’ to vital tools within the healthcare ecosystem.
Contents

Introduction 06
The market for health wearables 07
Development and uptake of wearables programs 08
The devil is in the data 09
Driving adoption and covering costs 10
The patient acceptance challenge 12
A new patient-physician paradigm leading to better outcomes 13
Conclusions 14
Appendix 1: Contributors 15
Appendix 2: Methodology 16
The hype and the hope: The journey from consumer to medical-grade wearables

We surveyed 143 members of the life sciences industry to better understand the future role of health wearables and the challenges involved.

32% of survey respondents said patients play the most critical role in driving health wearable adoption.

The TOP FIVE challenges to developing a health wearables program:
- Data safety and security considerations: 4.40
- Turning data into clinically actionable information: 4.29
- Integrating collected data into healthcare system: 4.13
- Integrating collected data into R&D process: 3.79
- Technology not available for managing the data: 3.72

The TOP THREE areas where health wearables may be used in the future:
- To assist with prevention of exacerbations and provide early warning signals: 31
- To improve treatments through better understanding of patient behavior and long-term medicine intake
- As part of an integrated telemedicine system to monitor patients and enable quick adjustments to treatments
Introduction

Just a few years ago hardly anybody had heard of ‘wearable’ technology. But today the leading brands in sports, fitness and consumer tech are household names thanks to products such as Fitbit, Android Wear, Jawbone and Xioami; filling out a market which grew 171.6% in 2015.¹ The meteoric rise of these health and wellness consumer wearables has raised expectations of a second growth wave – this time in medical-grade wearables.

The rise in popularity for wellness wearables has not been without controversy. Fitbit, for example, is currently facing a lawsuit over the accuracy of its heart rate monitor, calling into question the efficacy and safety of largely unregulated wearable technology.² Medical-grade wearables, meanwhile, which are used in a disease rather than a wellness setting are carefully regulated. In the US, the FDA grades wearables in the same manner as medical devices, from Class I (simple devices with no potential risk) to Class III (intricate in design with possible risk factors for patients).³

These new devices could have a significant impact on the outcomes and costs of long-term, high-burden conditions such as diabetes, cardiovascular disease, epilepsy, obesity, chronic obstructive pulmonary disease, depression or Parkinson’s disease. Health wearables in conjunction with mobile apps and other software offer predictive capabilities that allow patients and healthcare professionals to identify early disease signals or prevent exacerbations, shifting interventions toward personalized medicine. Moreover, by generating continuous data in real time, they enable timely therapeutic adjustments, tracking of outcomes to substantiate health policy or reimbursement decisions, and incentives for lifestyle changes to enhance overall effectiveness.

---

¹ IDC (2016). The Worldwide Wearables Market Leaps 126.9% in the Fourth Quarter and 171.6% in 2015, According to IDC. [Link](http://www.idc.com/getdoc.jsp?containerId=prUS41037416)

² The Telegraph (2016). Fitbit heart rate tracking is dangerously inaccurate, lawsuit claims. [Link](http://www.telegraph.co.uk/technology/news/12086337/Fitbit-heart-rate-tracking-is-dangerously-inaccurate-lawsuit-claims.html)

The market for health wearables

The potential implicit in consumer wearables and the dramatic growth of that market over recent years has led to bullish predictions for mainstream healthcare applications. These are tempered by doubts about the sustainability of current wearables usage and the ability of product developers to create a compelling value story while addressing crucial issues such as:

- regulatory gray areas
- data consistency, privacy, security and management
- legal liability for suboptimal performance
- interoperability and standardization
- the need for meaningful analytics and demonstrable outcomes
- affordability and responsibility for wearables coverage
- user education and compliance
- potential strain on doctor–patient relationships

As a result, market forecasts for the sector vary significantly. A report by Soreon Research estimated that the global healthcare market for smart wearables was worth US$2 billion in 2014 and would reach US$41 billion by 2020. 4 Mordor Intelligence puts global sales of wearable medical devices at US$3.2 billion in 2015, rising to a far more modest US$7.9 billion by 2020. 5

The market fundamentals for health wearables are compelling, underpinned by a number of social, demographic, epidemiological, economic and technical trends. At the heart of these are societal aging, a corresponding focus on healthy living, and the doors opened to the ‘quantified self’ by smart sensors, miniaturization and the digital revolution. Aging societies and changing lifestyles have brought a heavy burden of chronic disease that requires day-to-day-management and remote monitoring to address limited mobility and the high cost of inpatient care. According to a report issued by the US Census Bureau earlier this year, 8.5% of people worldwide (600 million) are now aged 65 or over, with that number set to rise to 1.6 billion by 2050. 6 Escalating cost pressures on health systems are set to continue, with a recent OECD report predicting that health expenditure could reach 14% of GDP in many countries by 2060. 7 This increasing cost pressure is driving a shift toward accountable care, underlining the need to track and measure the cost-effectiveness of health interventions in real time.

---

Development and uptake of wearables programs

The life sciences sector is certainly taking notice, even if development and uptake of medical-grade wearables remains selective to date. In a cross-sector survey of the life sciences industry (see Appendix 2 for details of the survey methodology), 43% of respondents didn’t know if their organization planned to include medical-grade wearables in future programs. But of those who answered ‘yes’ or ‘no’, 69% said their organization intended to work with wearables in the future. As Michael Edwards, partner at Eden McCallum, points out, interest today tends to be concentrated in the upper echelons of the industry, with nearly all of the major companies experimenting with wearables. Indeed, by late 2015 there were 299 clinical trials using wearables, according to the National Institutes of Health’s records. A number which grows almost daily.

Pharmaceutical companies are unlikely to seek to develop wearable technology in-house. To date, development of wearable technology has stemmed largely from established or startup tech brands specializing in data capture and analysis. Examples in varying stages of development include the medical-grade cardiac activity tracker by the life sciences team at Google X, and Biotricity’s wearable electrocardiogram (ECG) monitor.

Current interest from pharmaceutical companies therefore usually manifests in partnerships with such tech companies in which both parties can bring their focused expertise to the project. An early example of such partnerships is in the field of Parkinson’s disease research and treatment. UCB has been working with electronics company MC10 Inc. on trials of its Biostamp platform to monitor patients with the condition.

Respondents who participated in our industry survey envisage a range of future applications for wearables, including:

- improving treatments through better understanding of patient behavior (96%)
- monitoring and adjusting treatments as part of an integrated telemedicine system (92%)
- preventing exacerbations and providing early warning signals to healthcare professionals (96%)
- capturing real-world data to prove value of medicines and drug candidates (92%)
- clinical-trial monitoring for endpoint development (90%)

In addition to viewing information gathered through wearables as beneficial to healthcare providers and pharmaceutical R&D, respondents also saw a role in helping patients to self-manage their conditions and embrace healthy behavior, with associated savings in public-health expenditure. Suggested applications included educating patients about triggers for disease exacerbations and alerting them to side effects, so that health professionals, product manufacturers or patients could adjust therapy or behavior accordingly.

---


The devil is in the data

For GP and digital-health entrepreneur Dr. Anu Patel, wearables are enjoying a “honeymoon period” with consumers in which “the novelty is the connection.” The next step will be combining data generated by wearables with other available sources, such as social media, and applying analytics to deliver meaningful health insights. “There is some really exciting stuff out there in terms of user wearability and acceptance,” Patel comments. “But the user is left with the quandary of, what do these data mean, what do I do?” With the explosion of data-aggregation platforms, “you can start tying in data points on what it takes to keep people well”, he notes.

Melissa Lee, who publishes a blog called Sweetly Voiced on her journey as a person with diabetes, is a strong advocate of mobile health technology and has used a variety of wearables and associated apps, both commercial and customized, to track fitness levels and monitor her diabetes. “For individuals already comfortable with devices that are on-body and generating data, a wearable is a logical next step,” Lee says.

With the rise of these new data sources comes questions that need answers. One of the highest rated challenges in the survey was turning the data generated by wearables into clinically actionable information (94%). For example, healthcare professionals may fear that patients (rather than gaining education and autonomy) will seek more support from health systems as they become hypersensitive to fluctuations in bodily function.

Lee acknowledges the concerns around continuous glucose monitoring: that patients would have too much data to process, or the devices would encourage them to focus too intensely on their disease. “But having worn devices that help me maintain my health, I believe these predictions aren’t borne out over time,” Lee adds. “I feel empowered by access to my health data via a wearable. I feel spurred to engage with my health and do better.”

One form of wearable already available in the healthcare market is glucose monitoring. Called Accu-Chek View, Roche’s package combines a blood glucose monitor, a wearable fitness tracker, and an app developed by SAP that are integrated together. Specifically targeted to meet the individual needs of patients and doctors, a patient’s vital signs and blood sugar level can be watched in relation to their physical activity level, in real-time. The doctor can monitor the patient remotely, and the patient can communicate with the doctor’s office.11

Driving adoption and covering costs

Given the range of potential stakeholders in health wearables, it is unsurprising that some respondents in the pharmaphorum survey saw uptake being driven by a combination of commercial and non-commercial interests. As one participant pointed out, wearables champions are likely to vary according to the nature and goals of the offering: “If a pharma company develops a program, it will not succeed unless the healthcare professionals endorse it and the patients buy into the value of it”.

Most survey respondents (32.2%) felt patients would play the leading role in driving wearables adoption, closely followed by healthcare professionals and providers (25.2%). Among commercial interests, big data companies such as Google, IMS and SAP (15.4%) were seen as key drivers, followed by pharma/biotech/medical device companies (8.4%), and health insurers (5.6%).

Michael Edwards suggests that a key driver to that adoption will be the availability of cost-effective, scalable technology, and so the driving influence on uptake will be “bodies who fund the development of the technologies, which will be pharma companies and other technology investors.”

While Lee is a prime example of a patient driving health-wearables adoption on her own initiative, she believes physicians “should be aware of the benefits of wearables and be able to suggest their use to patients, especially in circumstances where patients already wear a device to which a wearable might connect”. As the technology evolves, with potential for patients to manage both monitoring and delivery of therapy centrally through smartphone apps, “we’re going to have new models to explore as the lines between optional wearable and prescription accessory blur”, Lee says, adding that today, health wearables are “a luxury item.”
This highlights what could ultimately be the primary determining factor in adoption – who foots the bill. The stark truth is that pharmaceutical companies, insurers, or healthcare systems may have to meet the cost of wearables if they want patients to engage with them.

Asked who should bear the majority of the costs for making health-wearables programs a success, most survey participants (30.1%) favored pharmaceutical/biotech/medical-device companies, followed by health insurers (26.6%) and government or healthcare authorities (21%) (figure 2). Among those who chose the ‘other’ option, most said the cost of wearables should be split between all or combinations of stakeholders.

In Edwards’ view, there is “no one answer” to who should cover wearables costs. “If it is a clinical trial, then the sponsoring company will probably be funding it. Similarly, if it is a company trying to gather real-world evidence post-launch, then the company should be funding it.” Companies supplying wearables “may choose to fund programs that are helping the health systems gather information, or co-fund them with health systems”, he adds. “But they will only do that in situations where they think that is going to deliver a benefit to the patient consistent with what their product is delivering.”
The patient acceptance challenge

For the majority of patients, Lee believes that the safety and accuracy of wearables is more important than data security or funding concerns. “A device should do no harm,” she comments. “I should be able to trust that the data I get are reliable and timely, so that they are meaningful for my decision-making.”

While patients seem content to use consumer-driven solutions, they might hesitate at giving pharmaceutical or insurance companies access to disease-specific data that could risk identification, stigmatization, or compromise treatment coverage. The data Lee collects via wearables on diabetes and general health are “solely for me, and used for real-time decision-making”, she notes. “I don’t want to have to submit my fitness tracking information to a health insurer and be judged on that data.”

For Stephan Schindewolf, VP of Product Management at SAP, the biggest issue lies within awareness and the patient being in control. “We have a patient-centric view, so it’s always the patient that is in charge. The patient decides which data is stored, and of course what kind of data they would like to submit and share. They can opt-out and decide to discontinue the program, ensuring any stored data is also removed.”

For Edwards, a larger issue than data-sharing is patient adherence with wearables, so that the right volume and quality of data are coming through consistently. One suggestion in the survey was that insurers could drive device uptake by reimbursing associated therapies only if the patient demonstrated compliance using a wearable. Part of the equation, Edwards notes, is ensuring healthcare providers support wearables usage and train patients appropriately, just as they would be bound by a study protocol or registry when conducting clinical or observational research.

User-friendliness was seen as crucial to uptake, with patient experience feeding back into device designs. As Lee emphasizes, wearables should be above all “human-centered. If a device collects critical data but presents hurdles to its usability, I will not use the device”. Too often, she says, product developers “design something because it can be done, without starting first with the patient experience of it”.


A new patient–physician paradigm leading to better outcomes

Health wearables have the potential to disrupt the traditional dynamic between physicians and patients around health and disease. Traditionally, physicians and healthcare providers have been the custodians of patient health data, but as Gayatri Gopal, Product Manager at SAP observes, the advent of the Internet of Things is tipping the balance. “Patients now have increased accessibility to their own data. This enables greater transparency, thus empowering patients and improving overall patient engagement. A data-driven conversation generates meaningful insights about the patients’ condition, thereby truly enhancing patient–physician interaction and health outcomes.”

The question is whether this disruption can be mutually beneficial, or whether it will drive a wedge between the two parties. In the survey, respondents hoped to see wearables empowering patients to take charge of their health, while also facilitating communication between patients and healthcare professionals.

In Edwards’ view, the true value of wearables is changing “the ability for someone to not physically be with a healthcare professional, but for their status to be fully monitored by a healthcare professional”. That enables patients to operate more independently and health systems to manage risks and outcomes more carefully. It also means physicians spending more time reviewing patient information generated by wearables. Physicians must also be able to recognize when those data are a signal to bring the patient in for a review. “That is something most physicians currently would not have the infrastructural support to do,” Edwards warns.

At current levels of exposure, the data flow is both manageable and productive, Patel suggests. While the medical profession may be worried about a “huge data influx”, he adds, “this is not currently emergency data. Rather than asking somebody how much exercise they have done, it is easier to see it in front of you. It facilitates meaningful recommendations”.

Lee suggests that the degree of physician interest in wearables data could also depend on how easily the information can be integrated with software already used for patient assessments. “Until the data from these other devices and trackers can be integrated seamlessly into the glucose and insulin-dosage data my doctor is reviewing, there is not enough time in any one visit to overlay another platform's data on top of already complicated print-outs.” In this way, health wearables can be seen as an extension of care, but one that very much puts the patient in control.

Physicians can be proactive about raising awareness of wearables or other digital tools where patients are likely to benefit and are receptive to new technology, Patel suggests. They can also spread the message among their colleagues. He is confident about the future of health wearables, even if “the technology hasn’t quite got there yet”. With expanded use, awareness and validation, wearables will find a place in the mainstream of healthcare.
Conclusions

If health wearables are to realize the considerable potential they hold to facilitate cost-effective treatment and prevention of high-burden diseases, as well as helping to steer R&D processes and therapeutic interventions towards truly personalized medicine, they will have to negotiate a range of barriers, be they legal, regulatory, technical, practical, or cultural.

This speaks to the need for a broadly collaborative approach to integrating wearables into the mainstream of healthcare provision, one that involves trust, understanding, and innovative thinking on all sides.

By engaging the full spectrum of stakeholders in health-wearables development and uptake, life sciences companies can build a compelling value proposition that translates patient independence and awareness into better outcomes with reverberations across healthcare and society.

In a follow-up to this white paper, we will examine more closely industry’s current and potential role in health wearables, including the associated regulatory and legal challenges, the applications of real-world data from wearables, and how life sciences companies can add value to the technology. Industry experts will provide recommendations on taking the sector forward.
Appendix 1: Contributors

Michael Edwards, Eden McCallum

Michael is a Partner with Eden McCallum, a consulting business credited with innovating how consulting is delivered. He has more than 20 years’ experience working in and consulting to the pharmaceutical industry. Michael started his working life at GlaxoSmithKline, working in brand teams, sales and strategy roles. He then joined Andersen Consulting (later Accenture), with a particular focus on the interfaces between commercial, R&D, and external stakeholders. Michael was then a Partner at McKinsey in London, where he built their European market access practice.

Gayatri Gopal, SAP

Gayatri Gopal is a product manager in SAP’s Connected Health group responsible for next-generation applications for the biopharmaceutical industry. Her focus areas include solutions to improve clinical R&D productivity and patient engagement. She has over 9 years of broad consulting experience having worked with top US and EU based biopharma companies. Gayatri has undergraduate degrees in pharmacy and biological sciences as well as a masters in pharmaceutical marketing from the University of Mississippi.

Melissa Lee, patient advocate

Melissa Lee is a patient advocate, blogger, and diabetes thought leader. Diagnosed with type 1 diabetes at the age of ten, she writes as Tech Editor for A Sweet Life Online Magazine, and in 2015, led Diabetes Hands Foundation as its interim Executive Director. She and her husband Kevin, a software engineer who pioneered work in diabetes remote monitoring wearables, currently work for Bigfoot Biomedical, a Silicon Valley startup pursuing automated insulin delivery, where she serves as Director of Community Relations.

Anu Patel, GP and digital health entrepreneur

Anu is both a trained surgeon and GP, and has gained commercial experience through years spent in big pharma. He sat on the board of the National Telehealth Forum, and has held advisory positions at several digital health companies. With primary care, secondary care and industry experience, Anu is uniquely placed to grasp the digital health disruption that is changing the industry. As a digital health entrepreneur, Anu is also heavily involved in realizing these changes to the health sector.

Stephan Schindewolf, SAP

Stephan Schindewolf is responsible for product management for new healthcare products such as SAP Health Engagement at SAP. Before starting to work for SAP in January 1998, he worked in various positions at Hewlett-Packard on product data management and computer-aided design solutions. He holds an MS in mechanical engineering from the University of Karlsruhe, Germany.
Appendix 2: Methodology

A survey was conducted with 143 professionals within the pharmaceutical industry, technology and healthcare landscapes to ascertain the current attitudes, trends and adoption rates of medical-grade wearable technology. In addition, respondents were questions about future development, usage potential and the role that wearables might play in healthcare in the years to come. This data was analyzed and the findings were discussed with our interviewees.

A breakdown of the industries included in the survey results can be seen below.