The Rise of Wearable Healthcare Technology: Opportunities and Challenges for Pharma
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Opportunities and Challenges for Pharma

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Executive summary

Digital health and wearable technologies are booming. Wearables, sensors and remote monitoring technologies are revolutionising healthcare and creating new opportunities for clinical innovation. There is a convergence of trends that includes: wearable tech, smartphone adoption, ubiquitous mobility, real-time data and analytics, cloud solutions, smart homes and smart cities.

Wearable tech is an important segment of the rapidly growing Internet of Things, or IoT. Global retail sales of wearable tech are predicted to reach $53.2 billion by 2019, when an estimated 35 billion devices will be connected in the Internet of Things. Everything will be connected. While people track their bodies with devices, sensors integrated into the home and in cities will track the environment.

Healthcare will be transformed through new types of data collected via wearable tech and remote monitoring. These data elements will include passive data, real world data, real-time data, continuous data, accurate data, transparent data, contextual data and massive amounts of “Big Data,” or predictive analytics. Pharma’s biggest opportunity is to access this data through wearable tech and remote monitoring to transform clinical trials and research and speed up drug development.

Wearable tech has evolved, and the frontier between wellness and health is blurring. First generation activity trackers are being replaced with sophisticated wearables and smartwatches that collect multiple points of biometric and other data. The most anticipated device is the Apple Watch debuting in April 2015.

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Patient-Generated Data, or PGHD, is being collected from consumer, clinical and medical devices as patients tracks themselves and want to be “the CEOs of their own health.” The challenge for healthcare and pharma is not the collection, but the handling of massive amounts of data and subsequent analysis. Virtual coaches will help drive behaviour change, and prescriptions will include devices and apps with therapies.

The future includes more electronics for the human body. Pharma needs to ask critical questions to prepare for a future where wearables will become ingestibles, and technology becomes more passive, adaptable and intelligent.
Methodology and objectives

This FirstWord Dossier report provides insight into the Wearable Technology market, which is predicted to represent 35 billion devices and have global retail sales of $53.2 billion by 2019, and will become a significant segment of the Internet of Things. Wearable tech is at the convergence of trends including: smartphone adoption, ubiquitous mobility, real-time data and analytics, cloud solutions, smart homes, and smart cities.

Wearable tech devices in the healthcare space are focused on fitness and wellbeing (consumer) and healthcare and medical (healthcare). But lines between consumer and healthcare are now blurring, catalysing the need for clinical insight into the opportunities and challenges of these devices and the data they generate.

The information for this report was gathered from multiple sources, including primary research from in-depth telephone interviews with people leading wearable tech and remote monitoring initiatives, including physicians, pharma leaders in innovation, and technologists developing mHealth (mobile health) apps and health data solutions. Secondary research was sourced mainly from publically available sources of information to understand the scope of the wearables market, and to support decision-making within the pharma industry for the impact of Patient-Generated Health Data and the opportunities in clinical research and innovation.

The interviewees were selected on the basis of their expertise and include the following individuals:

- Dr. David Albert, Chief Medical Officer/Founder, AliveCor, US | twitter @drdave01
- Rafael J. Grossmann, MD, FACS, Trauma Surgeon, Eastern Maine Medical Center, US | twitter @ZGJR
- Tomasz Sablinski, Co-Founder and CEO, Transparency Life Sciences, US | twitter @TSablinski
- Lucien Engelen, Director, Radboud REshape & Innovation Center at Radboud University Medical Center, Netherlands | twitter @lucienengelen
Gillian Tachibana de Llull, Director, Global eMedia Communications at Merck Serono S.A., Switzerland | twitter @pharmaweb

Michael Greenberg, MD, MPH, Associate VP, Head of Epidemiology at Sanofi Pasteur, FR | twitter @greenbergepi

Paul Jacobs, Digital Marketing Manager, LEO Pharma A/S, UK and IE | twitter @pj_medigital

Wendy Blackburn, Executive Vice President, Intouch Solutions, US | twitter @wendyblackburn

Andrew Rangel, Developer, Intouch Solutions, US | twitter @andrewrangeliOS

David McNierney, Director, Product Marketing, Medidata Solutions, US | twitter @davidmcnierney

Kara Dennis, Chief of Staff, Medidata Solutions, US | twitter @KaraNDennis

Matt Noble, Senior Director, Product, Medidata Solutions, US | twitter @themattnoble

James, Driscoll, VP, Director of Creative Technology, Concentric HX, US | twitter @drlp038

Ángel González, Founder and CEO, Ideagoras, SP | twitter @angel189
Key questions answered in the report

1. What is the future for pharma in wearable technologies? Are there opportunities for wellness or chronic conditions?

2. Will pharma be partnering wearable and mobile devices with therapies?

3. What opportunities are there from Patient-Generated Health Data through wearable technology? What are the challenges?

4. How can wearable tech and remote patient monitoring facilitate clinical trials innovation?

5. How can pharma get involved with wearable tech for more personalised and patient-centred medicine?

6. How can pharma make wearable tech data more relevant? Is there an opportunity for pharma in the aggregate data?

7. Adherence is one of the biggest challenges in pharma. Can wearable tech facilitate behaviour change?

8. Will pharma be moved to greater data transparency in clinical trials as a result of wearable devices and home monitoring?

9. What does pharma have to lose if they are not involved in wearable tech?
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Overview of Wearable Technology and the Internet of Things

Digital health technology investments set records around the world in 2014. The digital health boom is expected to continue in 2015, and one of the fastest growing segments is wearable technology. Part of the “Internet of Things,” wearable technology and sensors are driving rapid revolution in healthcare and new opportunities for clinical innovation.

What is the Internet of Things?

At its core, the “Internet of Things” (IoT) is all the connected devices and sensors in the world that will collect machine-generated data that can add value to the human experience. However, the term IoT is still very much misunderstood. When 400 C-suite executives were asked to define IoT, answers ran the gamut from types of devices to the challenges of a growing machine-to-machine (M2M) connected world.

The IoT is the “second generation of the Internet,” according to Cisco CEO John Chambers, speaking at the 2015 Goldman Sachs Technology Conference. “Every person, your home, your car, the way you do healthcare, your sporting activities will become connected. It’s disrupt or be disrupted,” he notes.

Tim O’Reilly, who popularised the terms “open source” and “Web 2.0,” says that the IoT is really about human augmentation. He explains that the applications are profoundly different when you have sensors and data driving the decision-making, “It’s a more context-oriented world, because there is better data… There is a complex interplay of humans, interfaces and machines. A big question is, ‘How do we create feedback loops from devices to humans?’”

According to George Kurvian, Executive Vice President of NetApp Data Storage and Cloud Computing, data scientists are key to finding value in the massive data devices will generate, “the data scientist is the human choreographer of the Internet of Things.”

IDC, a global market intelligence firm, predicts data streams from 19 billion objects with sensors will create a value of $9 trillion by 2020, while Cisco forecasts the market size of IoT will be $19 trillion by 2025. Almost 35 billion devices will be connected in an “Internet of Things” by 2019, according to BI Intelligence.

**BI Intelligence “Internet of Things”**

**Figure 1: Number of devices in the “internet of things”**
Why the sudden surge in the Internet of Things?

An almost unlimited number of devices are now able to connect to the Internet with the new version of the Internet Protocol, IPv6. The four major network providers—Cisco, IBM, GE and Amazon—are simplifying network connectivity, and the cloud offers easy and inexpensive storage. Add in the computing power of new wearables and sensors, connected through smartphones, and the IoT trend is now in hyper-drive. “This is the largest growth in the history of humans,” according to Janus Bryzek, who has been dubbed the “father of sensors.”

Currently, one in five developers are targeting the IoT for upcoming projects. Research by Evans Data shows connected device development grew 190 percent in 2014, and that developers are keen on wearables.

Adoption of IoT Technologies: Acquity Group

Figure 2: Projected new adoption of connected technology by consumers

Source: Acquity Group 2014 Internet of Things Study www.acquitygroup.com

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The IoT’s biggest challenge is compatibility. Products cannot yet all talk to each other, as there is not one universal language, but companies will need to collaborate to make connectivity work. Working towards interoperability for the IoT, the Industrial Internet Consortium (IIC) plans to release its Reference Architecture recommendations in March 2015. It will address the major components for IoT success, including connectivity, data processing and security. The IIC is looking to define requirements, but will rely on standards organisations to fill in the gaps.

Wearable tech, convergence and data explosion

Wearable technology is part of the IoT, and a convergence of trends that includes smartphone adoption, ubiquitous mobility, real-time data and analytics, cloud solutions, smart homes, and smart cities.

Global retail sales of wearable tech are predicted to reach $53.2 billion by 2019, with enterprise wearables accounting for $18 billion, according to Juniper Research.

Cisco says the number of wearables is expected to exceed a half billion by 2019, fuelling 18-fold growth in mobile traffic, with the majority channelled through smartphones. By 2019, global mobile Internet Protocol (IP) traffic is expected to reach an annual run rate of 292 exabytes, up from 30 exabytes in 2014.

With the massive amounts of data being generated, the growing challenge for wearables in health will be the integration of systems, making sense of the data that is produced and protecting the data. Standards for interoperability are still in development.

Evolution of wearable technology

Figure 3: Key insights

Wearable Technology evolved from consumer wellness to uses in healthcare and enterprise. The first wearable tech devices were targeted to consumers as a health and fitness accessory. The activity trackers had limited functionality, some not much better than old-fashioned pedometers. Many criticised the rubber tech designs as lacking a fashion sensibility, and a reason for lack of mass adoption.

Sunny Vu, the designer and founder of Misfit Wearables, including Shine, presented his view of the evolution of wearables at Web Summit 2014.¹⁹


Source: FirstWord research and analysis
**Wearables 1.0**

Sensing: brain waves, heart rate, sleep and activity tracking.

Medical: glucose levels and medicine reminders.

Smartwatch: GPS tracking and alerts.

**Wearables 2.0**

Safety: emergency response and monitoring.

Identification: lock, login and payments.

Controls: HVAC, music, lights and gestures.

In the past year, form factors have evolved, and more wearables are collecting biometric information, including heart rate and blood pressure. In 2015, the number of users of wearable devices is predicted to triple, especially with the highly anticipated April release of the Apple Watch.\(^\text{20}\) Wearable Technology dominated the Consumer Electronics Show (CES 2015), with one report covering 56 new and different devices.\(^\text{21}\)

**“Pro-sumer” clinical wearables**

Consumer wearables that generate clinically relevant biometric data are being called “pro-sumer wearables.” With FDA clearance and clinical backing, clinical consumer wearables collect multiple points of data. The recently released SleepImage measures heart rhythm (ECG), breathing volume and snoring (through tissue vibration), as well as body movement and body position. Its algorithms calculate the second-to-second relationship between heart rate variability and breathing variability known as cardio-pulmonary coupling. It can therefore map sleep stages and breathing disruptions that previously only a polysomnogram could measure.\(^\text{22}\)

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Enterprise wearables

The enterprise wearables market, where wearables are used for workforce efficiency in industry and the supply chain, is expected to reach $18 billion by 2019, according to ABI Research. Healthcare wearables, smart glasses and smartwatches are forecast to be the dominant form factors used by employees and purchased in this segment.23

Google Glass is no longer being sold to consumers, but will continue to be developed for enterprise, and in healthcare, as “Glass at Work.”24 Glass allows quick, hands-free access to patient records and vital signs, and is being employed by an entire department at Beth Israel Deaconess Medical Center in Boston, MA for daily use.25

Augmedix is a startup that recently received funding to develop Google Glass for use in medicine. “We have unimpeded access to Google Glass units and support,” says Ian Shakil, the CEO of Augmedix.com.26

Dr. Rafael Grossman says Glass will continue to make advances in healthcare, because it “humanises medicine,” allowing physicians to focus on the patient instead of a computer for entering data.27
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From tracking the Body to tracking the Environment

Wearables, data analytics and the IoT are integrating to provide intelligent sensing. Dan Ledger of Endeavor Partners was on the Wearable Tech panel at CES 2015. He says that although some devices have failed, it’s still very early days for wearable tech. “We’re going to see some absolutely mind-blowing stuff in the next three to five years,” he noted, adding that the next step is taking data and making it more prescriptive, not just descriptive. This will change in the next few years as companies build capabilities to model human bodies.28

Intel’s Alyse Ildeniz, who was also on the panel, says, “It’s not just what we wear, but it’s everything else around us. From smartwatches to smart homes, people are gaining more data and intelligence about not just themselves, but also the environment around them.”29

The Home-as-a-Platform: sensing and controlling

Smart home automation technologies have been growing steadily over the last few years, but smartphones, wearables and the IoT are collectively accelerating a “Home-as-a-Platform” movement. Early smart home technologies allowed for centrally controlling a home’s environment, but Barry Levine in VentureBeat says, Home-as-a-Platform (HaaP) is about both “sensing and controlling.”30

An example of sensing/controlling is Misfit Wearables, which enables its customers to connect its sleep tracking functionality and smart alarm with the Nest Learning Thermostat from Google’s Nest Labs to allow customers to wake up to their ideal temperature.31

Misfit is one of several wearables manufacturers working on integration with Google’s Nest Labs, a smart home automation company. Google acquired Nest Labs in January 2014, and Works with Nest\textsuperscript{32} was launched six months later. Nest only has two products, the learning thermostat and a carbon monoxide detector, but “Works with Nest” already has 16 partnerships with companies who will integrate their technology, including Misfit, LG, Withings, Jawbone and Philips.\textsuperscript{33} Two smart home automation integrators in the HaaP movement are Notion and Logitech.\textsuperscript{34}

According to Acquity Group, smart thermostats and wearable technology are each expected to have more than 40 percent adoption by 2019, and more than two-thirds of consumers plan to buy connected technology for their homes.\textsuperscript{35}

**Home-as-a-Platform for seniors aging in place**

Home-as-a-Platform will become increasingly important to healthcare as more baby boomers age. The current trend for seniors is already to remain in the home for as long as possible, a trend called “aging in place.” In the US, 80 percent of seniors have one chronic disease, and half have two chronic conditions. By the time seniors reach the age of 85, they may have three or four chronic conditions that may be able to be managed in the home via wearable devices and remote monitoring.\textsuperscript{36} “The home will be a major part of our health care,” according to Startup Health co-founder Unity Stokes.\textsuperscript{37}

\begin{itemize}
\item \textsuperscript{32} Nest Retrieved from: https://nest.com/works-with-nest/
\item \textsuperscript{36} CDC. (2011) Chronic disease prevention and health promotion Retrieved from: http://www.cdc.gov/chronicdisease/resources/publications/AAG/aging.htm
\item \textsuperscript{37} O’Connor, F. (September 18, 2014) As healthcare digitizes, consumer technologies will have the greatest impact Retrieved from: http://www.pcworld.com/article/2685932/as-health-care-digitizes-consumer-technologies-will-have-greatest-impact-says-panel.html
\end{itemize}
Smart cities: Connected and adaptive

From sensing and controlling smart homes, the IoT moves beyond the screen to our environments. Anthony Baker of R/GA London says, “The true disruption is when spaces become connected and adaptive, and allow us to interact with them through many different ways.” Connected city initiatives in Chicago, Rio de Janeiro, Helsinki and Singapore are working “to collect, manage and share data about the local environment, security, transport and finances.”

The Array of Things

The Array of Things project is installing hundreds of sensors across Chicago for a new breed of data-driven urban planning. The devices are located on street corners housed as public art to measure environmental factors in a city that normally don’t get measured with the granularity now available through technology, including temperature, humidity, precipitation, air quality, sound, vibration and light.

To fully understand the future role of wearables and sensors, it is important to view them in the whole context of the Internet of Things. The future of the sensors we have on our bodies will be interacting with the sensors that are in our environments.

Contextual data

In the context of health, everything that is connected could potentially be a source of data for consumers/patients to make decisions about their own health or quality of life.

According to Dr. Michael Greenberg of Sanofi Pasteur in France,

“Not all the data is necessarily going to come from wearables. You can get a lot of data about the environment people are in through other sources or contextual data. For example, we’ve got a Dengue vaccine that’s just completed Phase III trials, which we hope to licence soon. We’re very interested to see where people live, who is in risk areas for Dengue, and how you get that information.”


It’s one thing to pull up a map that would show you what your Dengue risk is, or where people have identified Dengue-carrying mosquitoes, or water pooling that would be mosquito breeding areas, or where cases of Dengue have been reported. Some of that can come from government reports. Some of it can come from self-reports. Some of it can come from predictive analytics. So I think, you need to think more broadly than wearables.”
Frontier between Wellness and Health will disappear

Speaking at LeWeb 2014, an international digital innovation conference, Withings co-founder and CEO Cédric Hutchings says there is a big difference between early trackers and the new smartwatches. He says that first-generation trackers were niche and easily abandoned once the novelty wore off. But smartwatches will integrate naturally into a person’s everyday life, and therefore have a better chance of being used regularly to truly change behaviour. “We believe that the frontier between wellness and health will disappear, and that people will begin placing themselves at the centre of their own health management,” according to Hutchings. 40

From ‘Quantified Self’ to the CEO of your own health

Quantified Self (QS), a term coined by Wired editors Gary Wolf and Kevin Kelly, is self-knowledge through numbers. Quantified Self has grown into a worldwide collaboration of individuals using self-tracking tools to monitor daily habits and behaviours, and to effect positive life change.41 Some people opt to share their data on social media platforms, on the QuantifiedSelf.com community site, or anonymously on data-collecting sites like CureTogether.com.

The evolution of wearable tech and mHealth apps simplified self-tracking, and more people started tracking behaviours related to health.42 Access to self-tracking data through wearable tech devices and mHealth apps, and the growth of an empowered patient movement, has more people practicing self-care – managing their own health, and looking for ways to prevent disease.

Case Study: Nike+ FuelBand

An early adopter of wearable tech, Ángel González is the founder of the healthcare social media agency, Ideagoras, in Madrid, SP. He started using the Nike+ FuelBand to self-track exercise to prevent a life with diabetes:

"I see the need for taking control of one’s own health, not just because I’m a geeky boomer, but because of my own experience. Last year, I went to the endocrinologist asking for help in losing weight. The doctor explained that my issue wasn’t just losing weight, but my triglycerides were sky high.

Before having to put me on Metformin, she advised a change in my diet and stressed the importance of exercise. I got a Nike+ FuelBand, and discovered the magic of quantifying myself on a daily basis, monitoring myself by tracking my level of activity. I am not an athlete – it’s not a question of being an athlete – it’s a question of being consistent with a routine for one’s own health.

Every three months now, I go to the doctor with a printout from my Nike+ FuelBand together with my blood analyses. It’s personal. I am the owner of my health. I know that my health is in my hands, controlled by my will and my behaviour. But I am addicted to this device. I always talk about this – not only from a professional perspective – but a personal perspective, that I believe in it 100 percent."

Exploring wearable tech for disease prevention

According to Paul Jacobs of LEO Pharma, his company is investigating how wearable tech can be used for disease management prevention by building aggregate data points of patient health parameters and measuring how parameters change ahead of a psoriasis flare-up. He says,

“With this information we can help patients signal that something needs to change to avoid some serious outbreak of psoriasis.

There are areas where it would have impact with regards to preventing progression to skin cancer, from actinic keratosis, for example, or preventing a flare-up and a serious outbreak of psoriasis.”
Apple bridging the consumer and healthcare markets

Watch, HealthKit and HomeKit

Apple is an example of one tech giant whose ambitions in health include wearables, healthcare technology integration and smart home technology. Apple is launching a wearable (Apple Watch), building a health platform (HealthKit) and controlling devices in the home (HomeKit), a smart home offering that uses voice recognition through Siri.

A smartwatch at the centre of health technology

Even before the Apple Watch ships in April, experts predict Apple’s market dominance and success for launching products will make the Apple Watch the winner in the smartwatch category. Forrester Research, an independent technology and research company, predicts 10 million Apple smartwatches will be sold in 2015.

HealthKit will be available on the Apple Watch, and enable customers to share information with physicians from many different apps. However, the WSJ recently reported that many key health-monitoring features, such as biometric data, will not make it to the first release of the Watch in April because sensors failed to meet expectations.

According to Paul Jacobs, of LEO Pharma,

“Previously, apps for health tracking were often a waste of investment for pharma, no clear ROI. If HealthKit does become widely accepted by Apple users, then there’s a major opportunity to drive patient-led adherence and also disease management.

Data that is pulled through from this widespread uptake should also be robust enough to be used to inform business intelligence, as well as strategy, marketing and future investment. It could kick-start quite a large cycle of R&D with regards to patient-led software without consultations.”

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Apple HealthKit adoption by hospitals

*Reuters* reports that healthcare technology for remote monitoring is showing promise at US hospitals. Fourteen hospitals say they have implemented or have plans to implement pilots of Apple’s HealthKit service, which is ahead of Google and Samsung as a repository for Patient-Generated Health Data.⁴⁷

Initial HealthKit pilots at the University of Pennsylvania Health System show physicians are concerned about monitoring continuous notifications. The initial scope is relying on medical monitors that are familiar, as opposed to nonmedical tracking devices. Penn Chief Medical Officer, C. William Hanson III, says that context for data is important, and a challenge is information acquired outside the medical environment. Penn’s approach is getting data into their Epic Electronic Medical Record (EHR).⁴⁸

Jeff McGeath, VP of Software Solutions for Iatric Systems, says most development for HealthKit is focused on getting data from the device to the Electronic Medical Record (EMR). His firm is taking a patient-centred approach.

The HealthPulse app by Iatric is working on giving patients secure access to histories and lab results via their iPhone. So, instead of going to the Web to log on to a patient portal, patients are able to gain access to notifications for any documentation from a hospital that works with HealthKit. McGeath says, “We’re trying to take data collected by physicians and push it to your handheld device.” Patients can then share their data with HealthKit.

In designing these apps, McGeath says healthcare needs to follow the workflow for how consumers and patients already use technology.

“Most people are willing to integrate digital, whether it is an app or a wearable, that will actually help them make their life easier. You are more likely to gain and sustain new users when you are able to weave technology into their lifestyle.”

— James Driscoll, Concentric HX, US


The role of design in the adoption of consumer and healthcare wearables

Low early adoption of wearables was attributed to unattractive, geeky or uncomfortable designs. Google Glass failed with consumers because of its conspicuous design and privacy concerns.

When you put a device on the body, it becomes personal, and an extension of who you are. Making these devices aesthetically pleasing, especially to women, is a trend shift.

The past year has seen the redesign of wearable tech, and partnerships with major fashion brands. Ralph Lauren became the first luxury brand to incorporate wearable technology with the debut of the Polo Tech shirt. Polo Tech features sensors knitted into the core of the product to read biological and physiological information. The goal of the tech line is “to promote general wellness and quality of life.”

Clinical wearables may face some of the same adoption challenges as consumer wearables, and design will be a factor. Peta Bush is a UK designer working on PhD research for “people-centric” health devices. She says, “We wear objects as adornment, to feel good. How can we change these objects [medical devices] to fit in with all the other objects we wear?”

Empatica founder Matteo Lai says he became obsessed with solving this problem. He asks, “Why do people who are sick have to have ugly devices, while the people who are healthy get beautiful devices that aren’t very useful? Are people living with a chronic condition not worthy of the same design, quality and sophistication that we’re all used to? We wanted to have a device that could be sold at the Apple Store, but that was designed to save lives.” The company’s recently released an epilepsy tracker, which is designed to help epileptics track and manage their seizures without feeling stigmatised.55

“Companies, like Samsung, LG, and even traditional brands such as Mont Blanc, think that wearables are going to be the fashion choice for the future. There’s some truth to that. But it really is about having the technology, so that you don’t have to think about it. As a patient, you won’t have to continuously think about your disease management. In the end, we’re all people, and we’re not defined by our conditions.”

– Paul Jacobs, LEO Pharma, UK and IE


www/fwreports.com
Wearable technology and sensors in medicine

Access to data is key

Julie Papanek, an investor at Canaan Partners, says the value of mobile and wearable technologies for pharma, device companies and hospitals is getting access to data quickly and efficiently.\(^{56}\)

All experts agree that if pharma does not get involved with wearable technologies, it will lose tremendous access to data, and its potential for insights into therapeutic conditions.

“You get access to Big Data, but you need insights from that data. This is what pharmaceutical [companies] are looking for when they call themselves innovative. They’re looking for that key data that would make their product or service just that much better than the competition.”

– Gillian Tachibana de Llull, Pharma, EU

Patient-Generated Health Data (PGHD)

Figure 4: Key insights

<table>
<thead>
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<th>PGHD present a challenge &amp; opportunity for physicians</th>
<th>Virtual Coaches will drive behaviour change</th>
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<tbody>
<tr>
<td>More partnering of devices with therapies</td>
<td>Remote patient monitoring reduces hospital readmissions</td>
</tr>
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</table>

Source: FirstWord research and analysis

\(^{56}\) Timmerman, L. (February 10, 2015) BIO Buzz Center with Julie Papanek, Healthcare Investor at Canaan Partners Retrieved from: https://www.youtube.com/watch?v=j5WcQBuY3kE
Wearable technology and remote monitoring are creating a category of data referred to as Patient-Generated Health Data (PGHD). PGHD may include information from consumer wearables that are increasingly collecting biometric information, and perhaps medical data, such as the glucose monitoring application from DexCom that will debut with the Apple Watch.

Concerns around PGHD include the amount of data that is created, how much of the data is actually relevant, and if physicians can interpret and use the data generated from patients. Currently, most healthcare providers do not have the necessary workflows in place to capture this data.

“Physicians are absolutely overwhelmed by all this data. No physician wants you to bring in six months of Fitbit data. It’s useless. Physicians want insights. They don’t want to see all the raw data. They want to see the trend. Is your weight going up or down? Is it staying the same? Is your activity level going up or down or staying the same? Is your heart rate going up, down or staying the same? That’s going to tell them whether or not they need to change something, whether or not they need to get you to do something differently.”

– Dr. Dave Albert, AliveCor, US

In a Webinar on PGHD, Dr. Danny Sands, Chief Medical Officer for Conversa Health and a physician at Beth Israel Deaconess Medical Center in Boston, MA, reports that PGHD actually saves him time as a physician and improves the value of care for his patients. By minimising in-office visits for activities patients can monitor and report from home, he says there are reduced costs to the patient, as well as the healthcare payer. While there may be reduced revenues to the physician (in fee-for-service), there is more time to treat more patients more efficiently, and patients are more satisfied.  

Virtual coaches and behaviour change

The success of health tech wearables and sensors is tied to making data actionable and delivering insights to affect real behaviour change. Another solution for managing the amount of PGHD will be the use of virtual coaches.

Sean Duffy of tech health start-up, Omada Health, says behavioural medicine works. “When you use digital to do that, and you can very accurately monitor your outcomes, and charge for those outcomes, it actually enables you to commercialise that clinical outcome in the same way as any other medical intervention. Through the host of human history, clinical outcomes have usually been created with a molecule, with a device, or a procedure. Technology can now get a clinical outcome.”

The IoT and Artificial Intelligence (AI) in Health

Sensors, devices and whole IoT systems will be talking to each other, providing insights and making decisions without human intervention, according to IBM, who is already advancing medicine with IBM Watson.

Dr. Michael Greenberg from Sanofi Pasteur FR, says his company already has pilot projects working with Watson,

“We’re looking at what some of the potential use cases are, whether it’s to accelerate drug development, or something like drug safety. Big Data, in general, is an approach – where do we need to be investing and adapting both our current business models, and preparing for the future.”

In healthcare and life sciences, the IoT is changing healthcare delivery, home and remote monitoring, and clinical research and diagnosis. IoT solutions are seen as opportunities to increase operating efficiencies, improve customer experiences and drive innovation.

Dr. Rafael Grossmann, the first surgeon to utilise Google Glass in the operating room, believes the intelligence afforded by connected technologies can fix the current problems in healthcare, while also helping physicians provide more patient-centred medicine,

https://www.youtube.com/watch?v=VhLJw79NKA8

60 Chamberlain, B. (January 27, 2015) Twenty Internet of Things trends to watch in 2015 Retrieved from: 
“It is almost a paradox that this technology—these AI-Deep Learning systems—in the end, could indeed free us to be more human, better healers.”61

Wearable tech and remote patient monitoring

Remote monitoring for chronic disease

Remote monitoring for medical care is still in its infancy, but is already proving valuable for chronic disease to avoid costly hospital readmissions. Wearable medical devices can track multiple types of data at once, as opposed to the current one-point solutions. This is useful for chronic conditions because deeper insight can be garnered from multiple data captures.62

Vidant is one US healthcare system that piloted a programme as early as February 2012. At any one time under the programme, 600 to 700 patients with congestive heart failure, diabetes and high blood pressure are being monitored remotely.63

Patients receive devices to measure blood pressure and other vital signs, along with a transmitting device to send the data via cellular service to Vidant. Currently, providers are absorbing costs for equipment and monitoring as most insurers are not yet covering the expenses. However, hospital readmissions are down. In the congestive heart failure group, those being monitored had a readmission rate of 12.9 percent compared to 20 percent who did not participate.64

Medical device makers Medtronic, Philips and St. Jude Medical are leading manufacturers of remote monitoring equipment. According to Kalorama Information, a medical markets research firm, sales are expected to be $32 billion this year, and grow 9.2 percent compounding annually to 2019.65

Wearable tech and clinical trials data

Figure 5: Key insights

Real-time data an innovation driver for clinical trials

Data science must work alongside life science to discover “digital biomarkers”

Continuous data collection enables passive clinical trial approach, eliminates middlemen

Real world data accuracy revolutionises clinical trials, eliminates “snapshot” and “white coat” effect of episodic data

Monitoring allows patients to connect the dots to behaviour and improve compliance

Data from tech improves speed & lowers cost of clinical trials

Source: FirstWord research and analysis
Real-time data

Data collection and management has always been a critical part of clinical trials for new drug development. Wearable tech, mHealth, remote monitoring and machine-to-machine (M2M) technologies are changing the way clinical trials are being conducted.66

“The most obvious place for digital health and wearable technology is clinical trials, giving pharma better insights into the performance of their medications on a real-time basis instead of on an episodic basis as they do today.”

– Dr. Dave Albert, AliveCor, US

Tomasz Sablinski is the co-founder and CEO of Transparency Life Sciences, a drug development company based on open innovation. The company’s novel approach is to recruit patients through crowdsourcing, and involve patients in the co-design of trials. He says, “Having real-time data allows us to do infinitely more innovative clinical trial designs than the current snapshot system.”

Sablinski explains that the current clinical trials system “is very old,” established in the 1960s. He says, “We are moving execution into the digital space, which means that the majority of data is being collected from patients’ homes and from patients directly without the employment of middlemen, which are investigative sites and [contract research organisations.] The scalability of crowdsourcing and asking patients for feedback is enormous, both in terms of going wider with more indications and more diseases, and also in terms of increasing the number of patients and physicians who are contributing to these protocols. We are working on analytical models and software that will allow us to more easily analyse feedback from hundreds of patients.”

Sablinski explains that continuous monitoring of clinical parameters enables real-time detection of undesirable trends and enhanced safety of study participants.

Big Data and real world data
Wearable technology allows for the capture of real world data, or data that is collected during the ordinary course of daily activities.

Medidata tested the impact of wearables, mHealth and cloud-based technologies for collecting real world data in clinical trials with GlaxoSmithKline. Program participants were provided with two wearable devices – Vital Connect’s HealthPatch MD and ActiGraph’s wGT3X-BT Monitor – to continuously measure patients’ vital signs, electrocardiogram (ECG) data and physical activity levels.

In addition, participants carried smartphones that captured data from mHealth devices and used a mobile app for patient-reported outcomes. Data from the wearable devices and the apps was then pulled into the Medidata Clinical Cloud. Participants were asked to go about their standard daily routine, and checked in with the performance lab only at the start and end of the effort.67

Medidata and GlaxoSmithKline are working to turn the data into actionable insights that can be used to conduct faster and more patient-centric clinical research.68 In a separate initiative, Medidata is testing the Garmin vívofit activity tracker for use in clinical trials.

“Over the history of clinical trials, the subject has typically come to an investigator’s site. The data captured is only a snapshot, a point in time, and it’s captured in the clinic. There is the effect of white coat hypertension, which means that the results, the biometrics, might not be what they would be if the patient was living their normal life. With technology, we can now capture real-world data remotely while trial participants are going about their normal daily lives. This really opens the door to rethinking clinical trials and clinical research in a pretty fundamental way.”

– David McNierney, Medidata


"If we trust wearables enough so trial participants can go about living their life, and only check in at the beginning and at the end, we will see a much different type of data – data that’s more accurate.

– Andrew Rangel, Intouch Solutions, US

Massive amounts of data can present a Big Data challenge for study sponsors and contract research organisation (CRO) partners. To transform clinical trials, organisations must be able to rapidly analyse and act on the vital information gathered in real time.69

“it’s really down to making sure that the right data is being drawn through wearables. If a pharma company has a vested interest in a specific therapeutic area, and a specific measurement, then that is what they have to lead.”

– Paul Jacobs, LEO Pharma, UK and IE

According to Medidata’s President, Glen DeVries, the ability to monitor trial participants continuously is changing the way study sponsors think about endpoints and measurements. According to DeVries, “There used to be a physical limitation to how and when we could measure things about a patient. Every procedure costs. But if you use mHealth measurements, it changes everything. You can put a device on a patient and it doesn’t matter how often you take the measurements - the cost is the same.” 70

Equipping all patients in clinical trials with wearables would generate many petabytes of data, says McNierney, “The real challenge is similar to that of the human genome – how do we derive actionable insights from this ‘more complete dataset’? By applying data science alongside life science, we will be able to determine the scientific value of the data, including identification of ‘digital biomarkers.’”71

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Medical adherence and patient compliance in clinical trials

Adherence rates in clinical trials are an ongoing challenge among patients receiving treatment for chronic conditions. Experts see wearable and ingestible technologies, along with the data from real-time and continuous monitoring, as having a key role in improving adherence. Continuous monitoring utilising M2M technologies enables researchers to confirm adherence with near absolute certainty, which was not possible in the past.

“A first step we can tackle is to make sure we’re seeing better adherence and compliance with drug medications. One of the great things about mHealth data is it provides ‘look back’ potential. You can look at data over time, at different points in time, and correlate. It’s such a rich set of data.”

– Matt Noble, Medidata, US

“From a clinical perspective, advanced sensors within wearable tech can automate what was previously a manual process to input and measure health data. This reduces a massive barrier to tracking health-related issues, especially symptoms. It will really help to increase adherence because it reduces that barrier of having to type in what your symptom was, or taking a specific action, if it’s completely automated. However, if sensor technology is not ready for mainstream consumer use, this could be a barrier.”

– Paul Jacobs, LEO Pharma, UK and IE

However, industry experts acknowledge that there are limitations in the degree to which technology alone can improve medication or treatment adherence.

“Compliance is a human – a multifactorial issue. A lot of noncompliance is economic. People can’t afford their medicines, so they don’t refill their prescriptions. It’s not, simply, I don’t want to take my pills. Some of it is side effect based. There are all kinds of issues that are difficult ones to address with a technology solution, because - by the way, the technology solutions think it’s simply a matter of, oh, you forgot. No, that’s only one reason people don’t take medicine.”

– Dr. Dave Albert, AliveCor, US

Personalised, patient-centred and transparent

Data from wearables and sensors will be valuable for personalised and patient-centred medicine, and provide more data transparency in clinical trials.

“In the old media world, they used to target a few markets made up of millions. We’ve moved to personalised entertainment, where there are now millions of very small markets. There’s the potential for the same thing in life science. Instead of building a treatment or therapy for the masses, the treatment becomes much more tailored and personalised to individuals, whatever their biology, whatever their lifestyle. Data will help facilitate that.”

– Matt Noble, Medidata, US

Meanwhile, Transparency Life Sciences conducts trials using telemedicine and remote monitoring. Founder Tomasz Sablinski says it is more convenient for patients and physicians, and the challenges are few.

“In clinical trials, there are many factors that can make the experience more patient-centred. But one that is key is…transparency, being open. Here is the trial that we want to do. Here is what we want to accomplish. You, the patient, will tell us how you would do it differently. That builds trust and co-operation that is very strong.

We simply give patients and physicians all data that exists about certain compounds, and it’s for everybody to see. Contributors can see their feedback and the feedback of others as they go.

A patient-centred approach requires honesty. If we have a certain design in mind, or certain endpoint in mind, and we hear over and over again from patients that this doesn’t matter, we need to abandon it. Patients are much smarter than even pharma marketing realises.”

– Tomasz Sablinski, Transparency Life Sciences, US
Patients connecting the dots

With real-time and continuous data, patients are able to connect the dots and see more immediate correlations to their own behaviour. Sensors and wearables are more accurate than pen-and-paper, and there is less of an opportunity to ‘eFudge’ results.

“I think the data would make the patient more aware of just how serious their condition is, and maybe motivate them to better care for themselves.”

– Gillian Tachibana de Llull, Pharma, EU

“One obvious application for mHealth data is finding correlations with existing data sources - take patient reported outcomes, for example. If the patient says they’re not feeling well on a Tuesday, and they feel run down, we can we look at their mHealth data to figure out maybe their blood sugar was low last Tuesday, or maybe there are some other clues as to why that was the case. We’re at the very early stages, but the value that we’ll see this data generate is virtually unlimited.”

– David McNierney, Medidata, US

Improved speed and lower cost of clinical trials

Comprehensively collecting large volumes of objective data generated by mHealth and wearable technologies can speed up clinical trials, therefore lowering costs. Data is reliable, secure and analysis-ready, providing real-time, continuous insight into the wellbeing of patients.73

“The availability of data, and the ability to move it around easier, will help improve the speed of clinical trials. We know it’s important for pharma to fill and complete trials quickly. It saves money, in the long term, if they can speed up the whole process.”

– Wendy Blackburn, Intouch Solutions, US

“R&D is the most challenging side of our business model. The cost of trials is rising, as well as the benchmark products. If you look at the area that we focus on, which is dermatology, the risk of choosing to invest in specific molecules really skyrocketed in recent decades. If tech companies can make an efficiency gain for us with regards to the cost, then I think pharma companies will definitely adopt these kinds of solutions.”

– Paul Jacobs, LEO Pharma, UK and IE

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www.fwreports.com
The potential value of computing solutions will be challenged by privacy concerns. The prevailing question is: Who does, and who should, control the data that our smart devices collect and produce?

“I don’t really believe that pharma companies should own the data. The patients should always own their own data, and have the ultimate say about how it is used. But pharma definitely has a role to play in terms of facilitating the use of the aggregate data. I think the outcome of that will be improvements in services, improvements in products and improved usability of those devices.”

– Paul Jacobs, LEO Pharma, UK and IE


“There’s a growing concern around data protection, which is why consumers are being a little bit more hesitant about adopting these technologies.”

– Gillian Tachibana de Llull, Pharma, EU

“Data ownership is a big open question. Today, if you’ve got your supermarket frequent shopper card, you are willing to give access to your personal data in exchange for something of value, for example, a discount on your groceries. It’s a choice. Some people decide they don’t want to do that.

Obviously, there will be a personal choice on whether they want pharma companies to have a role to play, and obviously, there are going to be regulatory implications as well, in terms of what society more broadly is willing to accept. I don’t see pharma playing a big role in managing that data today, but certainly interacting more and more in the relationship with patients. We’ll definitely see.”

– Michael Greenberg, MD, MPH, Sanofi Pasteur, FR

Regulatory guidance in the US

HIPAA working on new guidance

In the US, data from wearable technologies is generally not considered personal health information (PHI) until it is shared with a healthcare provider or other covered entity under the US Health Information Portability and Accountability Act (HIPAA).^76

HIPAA only regulates data when it is in the hands of, within the control of, or within the purview of a medical provider, a health plan or other covered entity under the law, according to Deven McGraw of the law firm Manatt, Phelps & Phillips. She says HIPAA is a sectoral law, covering specific context of information use, but is not a data-protection law.~78

The US Department of Health and Human Services’ Office of Civil Rights, which oversees the administration of HIPAA, recognises that HIPAA guidance is not very

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clear and up-to-date with current technology. The office is working with The App Association, a lobbyist organisation that includes mobile health companies, to address making HIPAA guidance less ambiguous.79

Privacy and security concerns are paramount in light of recent data hacks that have raised fears about medical data.80 In addition, terms of service and privacy policies for many applications are confusing, and data might be sold to third parties who may have a different level of accountability. While it is legal for data brokers to sell de-identified health data, the concern is that with today's technology, this data may carry the risk of being re-identified.81

**FDA relaxes rules for wearables and mHealth apps in new guidance**

The FDA's recently announced guidance, “General Wellness: Policy for Low Risk Devices,” suggests the agency is not interested in regulating most wearable devices and mHealth apps.82 The FDA defines low risk devices as products solely intended for a general audience and presenting “a very low risk to users' safety.”

When the Apple Watch is released in April, it will contain an app that allows a diabetic user to see information from a continuous glucose monitor. The glucose app by Dexcom simply displays medical data, and met the criteria of a “low risk” device. However, the wireless receiver that needs to be used in conjunction with the app did need to meet approval under Class III, and was approved.83

Products claiming to “treat or diagnose” medical conditions, such as obesity or diabetes, need to be submitted for regulatory review.84


Regulatory Guidance in the EU

In September 2014, European data protection regulators, through the Article 29 Working Party (WP29), issued an opinion for the protection of individuals with regards to the processing of personal data. Recognising the growth and potential of the Internet of Things, WP29 goes into detail about data protection issues, including wearable technologies, remote patient monitoring systems and home automation.

According to WP29, providers of wearable technologies and smart home devices sold to users located in the European Union would be subject to European data protection laws in the processing of data originating through such devices.

A distinction WP29 makes is in defining who is a data controller and who is a data processor. WP29’s opinion is that device manufacturers and third party application developers act as data controllers of personal data processed through the device, unless the data are anonymised. This also applies to companies managing IoT platforms collecting data from different devices.

Data-driven health innovation by government

Figure 7: Key insights

Source: FirstWord research and analysis

In the US

Bryan Sivak is the Chief Technology Officer of the US Department of Health & Human Services (HHS). He says wearable technology presents an exciting opportunity to collect real-time data, but challenges include data ownership, privacy, data standards and clinical integration. He says, “At the moment, we are generating a massive amount of data on a personal level, but none of it is getting into the clinical record. Part of the reason for this is that no clinical care providers have the time to integrate that data stream into their system of care. We are data rich, but analysis poor – we need to improve our algorithms to highlight important events and bring them to the attention of the right person at the right time.” 86

Precision Medicine: patients at the centre

In February 2015, the US announced a “Precision Medicine Initiative” focused on accelerating medical research through the sharing of health data and information using the latest technologies. Its near-term goals will support clinical trials in partnership with pharmaceutical companies.” 87

The Initiative’s longer term goals are to recruit a network of scientists and perform a national cohort study of a million or more Americans “to set the foundation for a new way of doing research that fosters open, responsible data sharing with the highest regard to patient privacy, and that puts engaged participants at the centre.” 88

87 NIH. Precision Medicine Retrieved from: http://www.nih.gov/precisionmedicine/goals.htm
In the UK

UK Parliamentary Under Secretary of State for Life Sciences George Freeman announced the launch of “The Innovative Medicines Review” in November 2014 “to consider how to speed up patient access to cost-effective and innovative medicines, devices and diagnostics.”

Speaking at the FT Global Pharmaceutical and Biotechnology Conference 2014, Freeman says, “This sector will be unrecognisable in five years.” His focus is to make it easier to carry out clinical trials in the UK, and is exploring the use of National Health Service (NHS) patient data to aid the clinical development process.89

89 Ward, A. (November 20, 2014) Drug Summit aims to inject urgency into innovation Retrieved from: http://www.ft.com/cms/s/0/f339daf4-6fe9-11e4-a0c4-00144feabdc0.html#axzz3S1izg8QS
What's Next

Bridging the language barrier for technologists and healthcare

In an interview with BIO Buzz Center, Papanek says great technologists who have built magnificent products for consumers are challenged by healthcare. “Instead of steps, or number of reads or engagement, the conversation is around primary endpoints, surrogate endpoints, registries,” Papanek suggests.

“As I think about that language barrier, I think it’s a part of how these companies have to think about product market fit and selling into these corporations [healthcare], for profit and nonprofit, that have a need for these mobile technologies and wearables, and these sources of data that give insight into their customers,” she adds.⁹⁰

“It’s a very rapidly moving space. We need to pay attention, or it’s going to sweep right past us. I see movements happening in different parts of the pharma sector. Some are moving more quickly than others, but clearly there is a new language we need to learn to be more successful and learn how to partner with the tech world to really continue to provide lifesaving medicines and prevention.”

– Michael Greenberg, MD, MPH, Sanofi Pasteur, FR

Will pharma be partnering wearable and mobile devices with therapies?

Omada Health is an example of a new type of medicine called Digital Therapeutics, which are digital technologies used prescriptively to avoid disease. As more clinical trials prove the efficacy of wearable technology and mHealth to produce outcomes, experts say pharma will be partnering wearable and mobile devices with therapies.

“We are certainly going to be launching devices in the very near future that will complement our therapies. If you look at how medical tests are packaged with a specific therapy, for example, and the progression of ECGs on mobile devices.

Portable ECGs are very consumer-friendly now, and can be used by patients themselves for reporting to their doctor. You don’t actually need to have a [general physician] performing an ECG anymore really. If you take those two things into consideration, there’s definitely a natural progression to partnerships between therapy and devices.

What is more likely to come first is the partnership of the software with therapy – packaging and partnering of software or apps alongside therapy. Then, as the wearable market matures and is more cost-effective, there will be a device provided as part of a prescription, or at least recommended alongside a prescription and part of a licence."

– Paul Jacobs, LEO Pharma, UK and IE

“I believe you will see more and more drug/device synergy; that diagnostics and monitoring will go with therapeutics, and this will be along the trend of personalised and precision medicine.

One example is type 1 diabetes. You prick your finger, or you have a continuous glucose monitor. You adjust your insulin dose and your food based on the data you get from that monitoring device. You have drug/device synergy, diagnostics and monitoring working with therapy to improve outcomes.

Another example is atrial fibrillation. With a device like AliveCor, you now have the ability to tell someone they are in atrial fibrillation – a rhythm that oftentimes comes and goes – and when it is appropriate to use their medicine.”

– Dave Albert, inventor of AliveCor, the ECG heart monitor and mobile app

**New Features Being Developed in Wearable Tech**

**Notifications**

Some question the need for a smartwatch if a smartphone is available to receive updates from a device. But some advantages include unobtrusive notification alerts and increased mobility. Glancing at a watch when receiving a notification alert is much more acceptable in many social situations, in lieu of pulling out a phone. Wearable tech rings and other jewellery offer the same unobtrusive notification alerts, and also allow the user to continue activities, such as exercise or driving, without interruption.
Beacons and Nearables

Beacons add a contextual layer to static locations, such as stores, museums, airports and hospitals. Estimote’s Nearables are even smaller computers powered by ARM processors with their own memory and Bluetooth connectivity that monitor and relay data about location, temperature and motion. Beacons are larger and are meant for more static use in locations such as rooms, while Nearables can be attached to everyday objects, such as cars, handbags, shoes or even pet collars.91

Forbo flooring is used in hospitals and assisted living settings to track staff and patients. Sensors in the flooring can alert a nurse that hand washing was missed or that a patient has fallen out of the bed.

Stickables

Sensors can now be attached via adhesives to the skin or physical objects. Adhesive patches were one of the most exciting wearables at CES 2015. TempTraq by Blue Spark Technologies monitors a baby’s temperature, and AmpStrip by FitLinxx helps athletes know how hard to train or when to rest.92

Meanwhile, Estimote’s stickers turn a connected object into a nearable that broadcasts data about location, motion and temperature.93

Haptics

Haptic feedback, often referred to as “haptics,” is the use of the sense of touch in a user interface design to provide information to an end user. In smartphones, this generally refers to the use of vibrations for notifications and interfaces.

Haptics were held back because of a lack of accuracy, but several companies are working to improve accuracy. Apple says it has found a way to make haptics work that will be part of the Apple Watch. Its “taptic engine” in the watch will deliver sensations to the wrist.

The experimental Babybe system uses haptics to transmit a mother’s heartbeat to a premature baby when the baby is in isolation and receiving treatment. The idea is to speed up the baby’s recovery time.\(^{94}\)

**Gestures**

Gesture technology allows users to interact with technology without physically touching an interface. One example is Logbar’s Ring, a Bluetooth device that allows a user to perform activities with one gesture, such as turning on music, playing games or controlling smart home devices. The Ring Hub, being introduced in March, is an infrared remote control that works with the Ring.\(^{95}\)

**LED displays**

LED displays offer unobtrusive notifications for smart clothing, jewellery and watches. LED sensors are being used in new tech apparel that can display a person’s emotions by changing colour. LED sensors in an exercise shirt can change colour to warn that heart rate is too high.\(^{96}\)

Another example, the LED engagement ring, designed by Ben Kokes, is embedded with a copper coil assembly that inductively powers the LEDs and illuminates the stones when in close proximity to an induced alternating magnetic field.\(^{97}\) While there is not a medical application for this type of ring yet, one possible scenario could be that seniors or the disabled use the ring to be alerted when a caregiver is in close proximity.

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Voice recognition

Speech recognition technology is becoming more sophisticated, less expensive and will be increasingly available on more devices. Google researchers say breakthroughs in speech recognition and artificial intelligence allow machines to understand context and nuance.  

Nuance’s Dragon technology, popular in healthcare, is available via an application program interface (API) to developers.

Although marketed as a consumer device and not a wearable, the Amazon Echo is a relatively inexpensive portable speaker with voice recognition technology that could be used to help seniors or the disabled who have mobility issues.

Waterproof

Consumers want wearables to be waterproof, and more devices will be incorporating this feature. The FitLinxx AmpStrip, mentioned earlier, is a thin, adhesive and waterproof device that continuously tracks heart rate and activity.

Extended Battery Life

The Apple Watch’s one-day battery life is one barrier to the device. On the other hand, activity trackers have longer battery lives, such as the Garmin vívofit 2, which claims its battery will last a full year.

Chip manufacturers are exploring ways to extend battery life, including Ineda systems and Cadence. Asus claims it is building a smartwatch with seven-day battery life.  

Ingestible

Even with wearable technology advances, the future of health monitoring and preventive medicine will most likely come from inside the body, even residing in the bloodstream.\(^{103}\)

PillCam Capsule Endoscopy is an ingestible pill-sized camera that allows a physician to see inside a patient’s gastrointestinal tract.\(^{104}\)

Proetus Digital Health has conducted several clinical trials with ingestible sensors that are taken alongside medicine. In the future, the ingestible sensor will be integrated directly inside active pharmaceuticals in select therapeutic areas, including heart failure, central nervous system and transplant procedures.\(^{105}\)

“I’m shifting my University Medical Center towards prevention with the help of devices. I expect that soon we will replace wearables with what I coined as ‘insideables’ in 2012.”

– Lucien Engelen, Reshape Innovation Center at RadboudUMC, Netherlands

“Things will get smaller, and wearables will become implantables. Things will become even more ambient and passive: we won’t have to think about wearing something every day. I’ve ruined two or three Fitbits because I threw them in the wash, or I stepped on them. Someday, we won’t have to worry about that either. Apple Watch won’t be around forever. It will be a stepping stone to the next thing.”

– Wendy Blackburn, Intouch Solutions, US

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105 Proetus Health Therapeutic Areas Retrieved from: http://www.proteus.com/future-products/therapeutic-areas/
The future of electronics for the human body

Materials for electronic devices are rapidly advancing to match the human body’s soft and curvilinear design. The future points to ubiquitous computing merged with biological systems. In the *Journal of the American Medical Association* (JAMA), John H. Rogers identifies three classifications of electronic devices that “can intimately integrate onto or into the human body for diagnostic, therapeutic or surgical function with important unique capabilities in biomedical research and clinical medicine.” The author describes these electronics in detail in an 8-minute audio recording on JAMA.\(^{106}\)

**Soft electronics**

Examples of soft electronics are those that match the epidermis, enabling “intimate, yet imperceptible, lamination onto the surface of the skin.” Applications include continuous health monitoring and clinical diagnosis.

**Injectable electronics**

In a minimally invasive fashion, microscale device components can target regions via thin, releasable injection needles. In one example, multi-stacked components have the dimensions of a single cell, and can be used to stimulate and monitor collections of neurons in the nervous systems.

**Bioresorbable electronics**

Materials that dissolve completely in a controlled fashion include electronically programmable vehicles for drug release.\(^{107}\)

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What is the future of wearable tech for pharma?
Is there opportunity in wellness or chronic disease?

Figure 8: Key insights

Benchmark is “quality of life”
Future of wearables is both wellness & management of chronic disease
Doctors demanding patient at the centre
Data is important for caregivers and adherence

Source: FirstWord research and analysis

“With a more complete dataset, Pharma will better understand their patients and people with conditions of all sorts, chronic and otherwise. As we know, the life sciences industry is receiving external pressures and internal pressures to focus more on the real value of therapies. We all want our quality of life improved. There’s no better way than to be tracking the actual physiology of patients, along with the subjective data about how they’re feeling. I think that’s where mHealth is going to play a huge role. The benchmark is changing, and it’s based on people’s ‘real’ quality of life. There’s no better evidence of value.”

– David McNierney, Medidata, US

“This is the only future if pharma companies really want to be competitive in this new landscape, where all drugs are commodities and there are no significant differences between each of the drugs. The doctor is demanding a new way of relating with pharma companies, and is demanding at the same time to have the patient at the centre of the system. This leads to the principle of participatory health. If pharma really wants to be a part of that principle, not just...
as a concept, they will have to take advantage of wearable health technologies. Not only for getting an augmented product with the drugs, but also embracing preventive health.”

– Ángel González, Ideagoras, SP

“Being able to include wearables and digital medicine in a way that actually monitors adherence is a huge step. Not just for the patients, but also the caregivers. Having access to that data through mobile devices enables and enhances that interaction.”

It’s an opportunity to do an outreach to the consumer and the caregiver community and let them know that we get you, we hear you, and we understand you. It’s a trust factor, and a big opportunity for pharma.”

– James Driscoll, Concentric HX, US

Planning a strategy for a future connected world

“The next three to five years will be critical as pervasive computing moves into the mainstream and the number of connected devices and related applications skyrockets,” according to Chris Brahm of global management consulting firm Bain & Company.108

He says executives across industries should focus on the critical questions that will position them as leaders in the future, including:

- What capabilities and assets need to be developed?
- Who should we partner with, up or down the stack?
- Which standards should we back?
- What is the risk of not acting?

Thoughts for the future

Figure 9: Key insights

“"We still are struggling to understand what consumers want. When you look at health technologies today, people on average stop using their health apps after about two weeks, and will stop using wearables after about six months. These are averages. But they don’t stop using their iPhone. So, there’s obviously something different. What is it that will create that stickiness? What is it that really is of value to people that they will want to come back? We need to get out and actually listen, and understand what people want and need. That’s new for us.”

— Michael Greenberg, MD, MPH, Sanofi Pasteur, FR

“"It’s a really exciting time to be in digital and in healthcare. There’s been a huge boom, especially with wearables. There are so many different players out there who are really pushing the health agenda alongside all of those tech start-ups that you see popping up all over the place. It’s a very exciting time to be involved with healthcare and looking at the digital agenda.
There’s a lot of work to do especially in the pharma field, and quite a lot of catching up to do. But I do believe that at the moment there is a real will to push forward actual action on this agenda.”

– Paul Jacobs, LEO Pharma, UK and IE

“As much as I get excited about technology, and I see the possibilities of wearables, it is important to keep in focus meshing the right message, with the right technology, and making sure that technology has been fully vetted, that it’s been regulated and it’s safe for them to use.”

– James Driscoll, Concentric HX, US

“Pharma has specific capabilities and specialisations that tech companies don’t, and the tech companies have the specialisations that pharma doesn’t, so it would be a natural evolution for them to partner up.”

– Gillian Tachibana de Llull, Pharma, EU

“Have collaborative dialogues with your pharma partners around where trials could go, and what new endpoints could look like, and new ways of keeping subjects or patients engaged in a clinical trial process. Then use developing technology, and provide feedback on technology. Right now this process is very fast moving. We’ve found close collaboration and a lot of feedback to be really important.”

– Kara Dennis, Medidata, US

“We need to change the paradigm for how people think about clinical trials, and make sure that we keep the same data so scientific rigour is involved in the process. But try to have partners who are running clinical trials embrace some of the newer technologies. Embrace the concept of BYOD [Bring Your Own Device], and the concept of running a clinical trial using a patient’s cell phone, for instance, instead of a very controlled type of environment.”

– Matt Noble, Medidata, US

“We have an enormous set of opportunities - some involving the large tech giants…some involving the pharma…some involving the medical device industry. We are at a nexus point where all of those industries are looking at this device we carry around in our pocket, and that will be in everyone’s pocket…People at Qualcomm have told me that in five years, there will be no ‘dumb phones,’ not in Africa, not in
India, not in South America. The cheapest phone will be a smartphone able to run apps. It might look like a flip phone, but it’ll be a smartphone.

The problems of healthcare in the developed world are cost. The problems of healthcare in the developing world are access. The smartphone in a person’s pocket can address both problems of cost and access. That’s the promise of digital health. That’s the promise of mHealth. That’s the promise of mMedicine.”

– Dr. Dave Albert, AliveCor, US

“Pharma knows so much about its products, the disease states they serve, and the patients they help. It would be a real shame for someone else to come in and fill that space. Pharma has a lot to contribute to the discussion of wearables and data, and a lot to contribute to the products and services that will come out of this movement. Maybe that means forming a partnership, maybe it means something else, but it would be a shame for pharma not to be involved.”

– Wendy Blackburn, Intouch Solutions, US

“There will be implantables with drug delivery systems. Everything will be driven by technology, not by compounds. Compounds will probably be the same, and I see tremendous opportunity in actually revisiting how we deliver existing drugs, and how we monitor adherence in a way this is accurate as opposed to today, which is basically counting pills and tracking patients when they take it.”

– Tomasz Sablinski, Transparency Life Sciences, US

“One thing that often gets left out of this conversation, in general, in society, is automated intelligence, machine learning and robotics.

The natural thing to look into, especially from pharma’s standpoint, is senior care. Combine the Internet of Things, wearables and pharma – and you start to see a picture of a robotic assistant in the home. The home is connected. The individuals have wearable devices or embedded devices. And they don’t have to think too much about it.

The automated assistants and the home can adjust to that person. Pharma is involved from an expertise standpoint, providing data and insights on various disease states in a very personalised way. It’s not as simple as putting a person in
one box. Pharma really gets involved, and says, ‘Okay, we know about diabetes, weight issues, heart disease, and other things – how do all of these medications play together?’

There will be start-ups, tech companies dealing with the hardware. Pharmaceutical companies can just spread their expertise. It’s not going to be with hardware or software. It’s going to be with the data, their influence and the information. How exactly that falls into place is a question mark right now. But I think it’s easy for people to hold that picture in their head, and see how there could be a lot of success for everyone involved.

– Andrew Rangel, Intouch Solutions, US

“This invites us to wonder what is going to be next. It forces all of us to be more creative. The best is yet to come. More and more people understand this is the right way to keep moving. Not just because of the technology. We are transforming our understanding of healthcare.”

– Ángel González, Ideagoras, SP