Medicom Innovation Partner
a Phillips-Medisize Company

THE PROMISE OF CONNECTED HEALTHCARE (AND WHY IT'S PROVING HARD TO GET THERE)

Although it seems inevitable that drug delivery devices are becoming part of the connected world, it is difficult to see the precise path to this transformation. Here, Kevin Deane, Executive Vice-President, Front-End Innovation, Medicom Innovation Partner, and Bill Welch, Chief Technology Officer, Phillips-Medisize, show that clear trends are emerging, some helping to push connected healthcare forward and some that are slowing down progress, and describe the opportunities and challenges arising.

Connected healthcare has moved from being an exploratory technology to a subject that is regularly discussed at the executive levels of most pharmaceutical companies. This is not surprising. Smart phones have proliferated, offering users instant access to information and the ability to interact in ways barely dreamt of 15 years ago. The number of connected devices has already surpassed the number of people on the planet, and is growing (Figure 1).

At the same time, devices have become central to the delivery of many new drugs. Biologics are the key blockbusters and, with this, injection systems have become the predominant form of drug delivery (Figure 2).

There is little question that connectivity and data analytics technologies could revolutionise healthcare. Companies such as Google and Apple are making significant investments in this space. Arguably, the increase in drug delivery devices provides pharmaceutical companies with a platform on which to build such technology. However, the entire industry remains remarkably resistant to change.

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THE OPPORTUNITIES

Patient-centric benefits are the primary source of opportunities for connected healthcare. Improved treatment, better patient education, patient empowerment and social support all help to build a patient-centric approach. Of course, improving adherence is also a key driver.

Other opportunities include new treatments and new business models that connected healthcare systems make possible. Connectivity is an enabler for reducing waste, saving costs, personalising treatments and improving clinical trials.

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Patients First

For several years, the entire healthcare industry has been adopting a patient-centric view; putting the patient at the centre of our systems. The pharmaceutical industry is adopting a similar approach. However, this is easier said than done.

Digitalisation and connectivity will help to realise this vision, pulling together patient-specific monitoring, diagnosis and treatment information. Helping patients monitor and administer their medication will be fundamental to this, and offers a range of benefits.

First, it will help to improve treatment efficiency. User-friendly devices that simplify drug administration allow for medicines to be taken in the home, easing the burden on hospitals and clinics. Connectivity provides continuous monitoring. Healthcare professionals can support patients in the community, providing additional coaching where necessary and spotting issues before these lead to exacerbations and further hospitalisation.

Connectivity empowers patients. It helps patients take greater control of their condition, providing access to information, the ability to communicate with nurses and physicians and the comfort that the data is monitored by healthcare professionals (HCP's). Interactive training and support tools can be built on these platforms, driving the correct use of devices, including expert guidance and online support where needed.

Finally, these systems can join with social media. Forums such as PatientsLikeMe (PatientsLikeMe, Inc, Cambridge, MA, US) provide a way to share experiences and learn from others going through a similar situation. Many patients find this comforting, supportive and even motivational. Moving care into a home environment has many advantages, but patients can become isolated. Social media and forums can fill this gap, linking patients to others with similar experiences.

Improving Adherence

The initial driver for connectivity is often improved adherence. Poor adherence of drug prescriptions is well documented, generally around 50%. This has a significant impact; hospitalisations increase, patient health deteriorates, costs rise and pharmaceutical companies lose revenue due to unfulfilled prescriptions.

Connectivity offers the possibility of monitoring adherence, though this doesn't

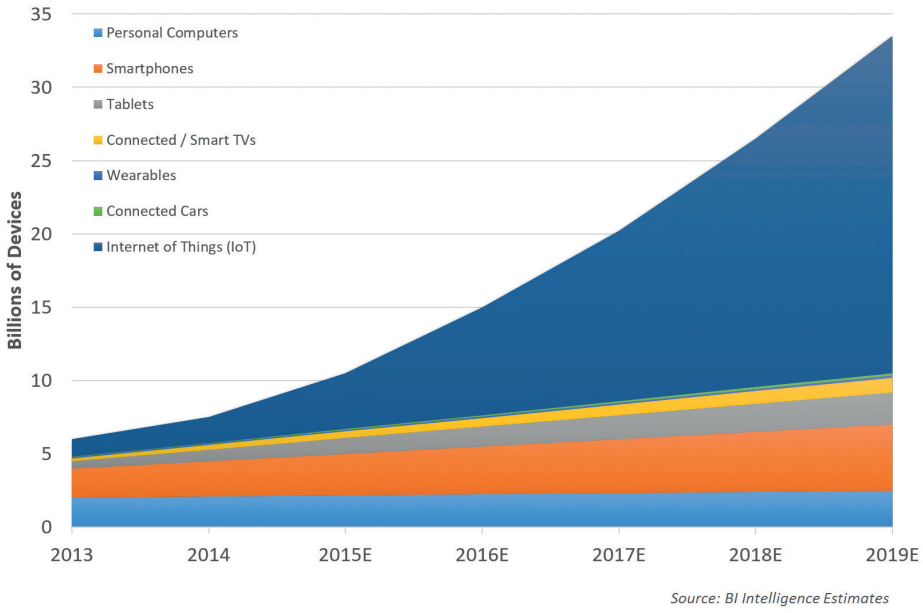

Figure 1: Number of connected devices globally, by year.

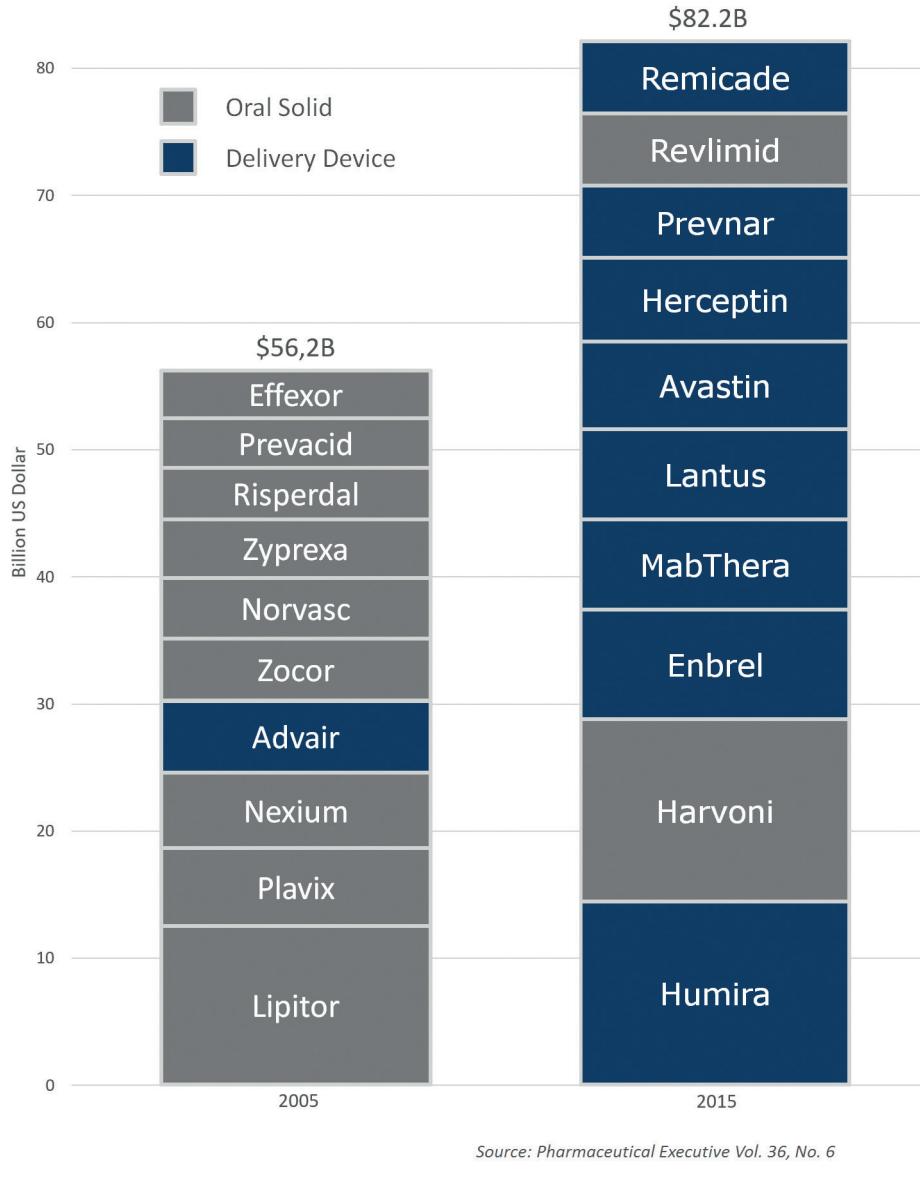

Figure 2: Top 10 drugs in 2005 and 2015.

necessary improve it. We need to understand the root causes of non-compliance to lift adherence rates. Root causes are complex and varied. Simple forgetfulness, feeling better, conflict with lifestyle and image, reinforcing the feeling of illness – all these factor in to the deep-seated psychology of not taking our medications.

So, to improve adherence, connectivity needs both to monitor drug administration and provide motivation and incentives to take medications in a timely and effective manner.

Novel Business Opportunities

Providing a direct line from HCPs to medication use opens up broader monitoring opportunities and new treatment options (Figure 3). Pharmacovigilence could be improved through more accurate knowledge of dose frequency, levels, timing and locations. More accurate data on dosing regimens can help determine if links exist between adverse events and drug intake.

Being able to monitor and control dosing frequency and levels is a key enabler of personalised and stratified medicine. Connectivity to drug delivery devices allows HCPs to individualise dosing regimens and monitor the impact on outcomes. As data sets build through real-world feedback, it will be possible to narrow therapeutic indexes for specific patient groupings, increasing the effectiveness of treatments.

This opens up novel business opportunities for pharmaceutical companies. As healthcare becomes more digital, data on a per-patient basis and across entire disease populations will lead to greater knowledge and improved decision making. This ongoing collection and analysis of data will help refine treatment regimens across patient segments to improve outcomes. In this world, data has value. Ethical concerns exist around monetising the value of this data, but the direct link to patient dosing will be a critical piece of the overall treatment data, and will certainly carry value.

Another area of growing business interest is building service models on top of drug delivery. As outcome-based payment gains traction, pharmaceutical companies are incentivised to ensure patients follow their prescriptions. Companies are establishing a broad range of support services to help patients use their drugs effectively. These services are generally provided free of charge, as pharmaceutical companies look to increase market share or demonstrate effectiveness. Other industries would look to generate revenue from these service models. Such concepts raise legitimate ethical concerns. However, there are a number of specialist service examples, such as dialysis centres, where treatment involves both medication and service delivery to provide improved care.

These models will expand with connectivity, offering improved care models for patients, and potential revenue sources for pharmaceutical companies.

THE CHALLENGES

Although the opportunities are truly transformative, sometimes the industry only sees challenges. These align around technical issues, poor business cases and concerns around data and regulatory risks, as discussed in more detail below.

Is the Technology Ready?

Smartphones have changed our perception of "connectedness". We have instant access to friends, news, music and access to countless other sources of information. This explosion in connectivity has provided significant benefits, but also brings new problems. App fatigue, password overload, constant upgrades, poor signal strength, complex user interfaces – general irritations for most of us. However, these minor concerns become significant in healthcare applications.

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The underlying issue is that the technology on which we want to "piggyback" has been designed for another purpose by another industry; consumer products. The dynamics of this industry directly influence the areas of greatest concern to healthcare developers; stability, usability and cost.

It takes years and significant investment to get drugs to market. Demonstrating safety and efficacy across increasing numbers of disease sufferers is paramount to the ultimate success of a product. Once proven effective, there is reluctance to change. Compare this with the mobile phone business, where even Apple admitted

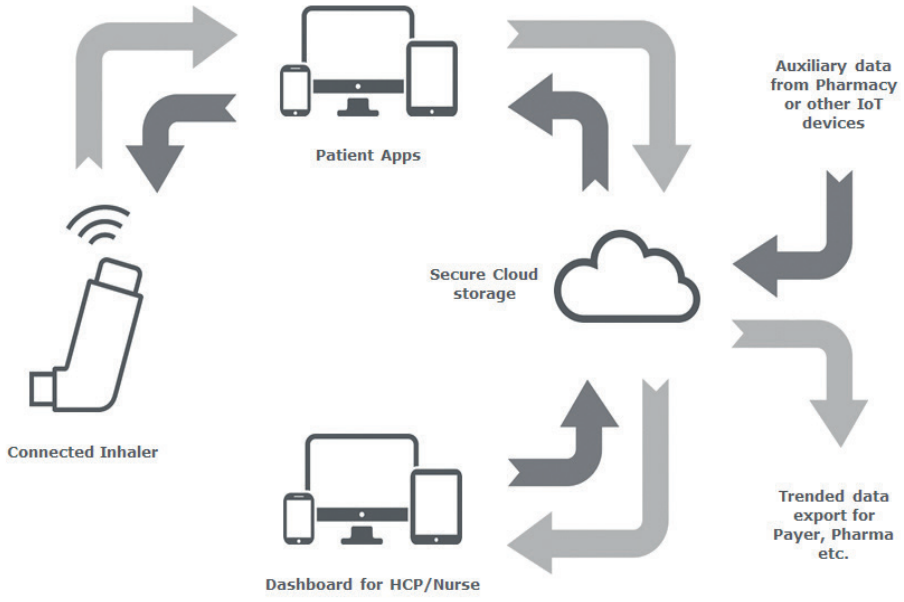

Figure 3: Taxonomy of a connected healthcare system.

last year that it expects customers to change their devices every three years, and target two major operating system (OS) updates over this time frame.

To address this, companies need to define an architecture that segregates the medical elements from the general user elements. Getting this separation right is critical to the viability of a connected healthcare product. Even then, investment is needed to support continual lifecycle management. Maintaining compatibility across multiple platforms is time consuming, but necessary to ensure great patient experiences.

Usability has been a major focus in recent years, driven by a push from the regulators coupled with critical feedback from patients and HCPs. These gains could erode with the advent of connectivity and mobile apps. The majority of connectivity systems are add-ons, requiring additional user steps to fit them onto injectors and inhalers. Without providing clear and immediate benefits, many patients stop using these systems. Connectivity cannot add complexity to taking medication.

Great user interactions will be fundamental to the success of connected products, and will continue to be a requirement of regulatory approval (Figure 4).

Figure 4: Evolving technology supporting healthcare.

Show Me the Money

Many of us can see what the technology can offer, but it is incredibly difficult to build a solid business case around these ideas. Looking at it simplistically, it appears that connectivity adds cost without delivering increased revenue. There are not many CFOs who will fund such programmes for long. Perhaps there are lessons to be learned from new digital technology companies who launch minimal viable products quickly and use these with consumers to find where the greatest benefits are delivered and revenue realised.

It is difficult for pharmaceutical companies to think about minimally viable products. Tight regulation combined with a deep focus on patient safety has driven the industry to relatively long development cycles. With fewer launches, companies squeeze as much as possible into each cycle. However, until the revenue channels are clear, controlling cost is critical. Defining basic feature sets reduces development costs and cost of goods. As it becomes clearer where revenue is generated, further features can be added to grow these revenue channels.

In today's healthcare market, it is very challenging to increase revenue within an existing drug franchise. Drug prices are under significant pressure and the payers won't reimburse for better devices or new service offerings. The best opportunities seem to be around increasing market share (or preventing erosion), demonstrating improved outcomes, increasing drug sales due to improved adherence and offering premium services direct to patients and caregivers at additional cost.

Companies seem to be focusing on lifecycle extensions of existing products to build pilot systems for connectivity. There is perhaps less risk in this approach. Existing data can be used as a baseline when assessing the effectiveness of new technologies. Clinical studies are also attracting new connectivity technologies. Larger budgets can support the higher costs during a clinical study, and having real-time reporting of actual dosing can lead to faster, clearer results.

Data Security & Regulatory Risks

Finally, there are a number of data and regulatory concerns. Healthcare information is very sensitive. Patients and healthcare professionals are rightly worried about medication data being transmitted over commercial technologies. Ultimately, patients will continue to own their own data and will need to opt in to applications that want access or use. However instances have arisen where patient data has been used without consent, leading to a culture of mistrust. Sharing data should lead to improved monitoring and care of individual patients, while at the same time allowing anonymised, disease-specific data sets to be analysed for larger trends. It is possible that such analysis will reveal new insights that will improve treatment.

The proliferation of connectivity and mobile apps has been challenging to regulate as well. The US FDA and the EMEA are clarifying their positions and guidelines in this rapidly evolving space. The number of apps approved by the regulators for medical use has increased significantly in the past two years, driven both by clearer guidance and development companies refining their own internal processes. But this remains a challenging area, as software systems by their very nature span multiple hardware domains. Current practices tend to drive revalidation (at some level) for every new OS release. This can add a significant burden, and cost, to the maintenance of these systems.

SUMMARY

Digital systems and connectivity have the potential to transform healthcare provision. Many different companies will play a role in this. Although these technologies are not their core area, pharmaceutical companies have a leading role to play. Understanding how patients take their medication, and providing support to improve adherence, will be fundamental in this journey. Adding this technology to new and existing drugs will help empower patients to manage their conditions with less hospitalisation, reducing overall healthcare costs and improving treatment effectiveness.

ABOUT THE COMPANY

Medicom Innovation Partner (a Phillips-Medisize Company) is a leading global innovation, development and low-volume production provider focused on drug delivery devices and connected health solutions. Medicom Innovation Partner was established as a technology venture of Bang & Olufsen A/S in 1989 and the company has been a dominant player within the drug device world for more than 25 years. Medicom holds a dedicated staff of more than 90 high-calibre innovation specialists, mechanical, hardware, software, quality assurance, regulatory and production engineers based in Struer, Denmark, and Cambridge, UK. Medicom has experienced considerable growth over the last five years.

As of May 31, 2016, Medicom became part of Phillips-Medisize Corporation. Phillips-Medisize is a leading global outsource provider of design and manufacturing services to the drug delivery and combination products, consumable diagnostics and medical device, and specialty commercial markets. The company has annual sales of over US$700 million with 80% of the total revenue coming from drug delivery, medical device, primary pharmaceutical packaging and diagnostic products such as disposable insulin pens, glucose meters, specialty inhalation drug delivery devices, single-use surgical devices and consumable diagnostic components.

Together Phillips-Medisize and Medicom are becoming one of the leading players within the growing drug delivery device and connected health market.

ABOUT THE AUTHORS

Kevin Deane is the Executive Vice-President, Front End Innovation for Medicom Innovation Partner, a Phillips-Medisize company. With over 25 years of experience developing new products, Mr Deane has supported a broad range of drug delivery and medical devices to market, working across the US, Europe and Asia Pacific. He leads Medicom's early-stage development team and coordinates our large-scale developments in Connected Health, from devices to data, pulling together the deep capabilities across Phillips-Medisize, Molex and Medicom. Kevin is based in Medicom's Cambridge, UK office.

Bill Welch has more than 25 years of contract design, development and manufacturing experience, primarily serving customers in the drug delivery, health technology and diagnostics markets. In his current capacity as Chief Technical Officer at Phillips-Medisize, he leads a global, over-500 person development, engineering, tooling, program management and validation organisation with more than 75 concurrent schemes. He has been with Phillips-Medisize since 2002.

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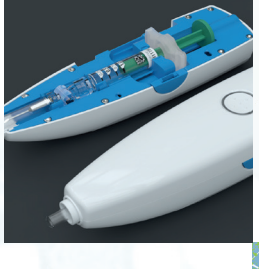

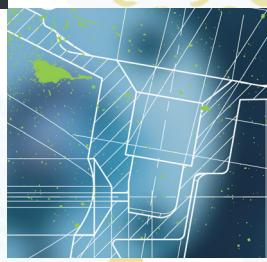

Devices
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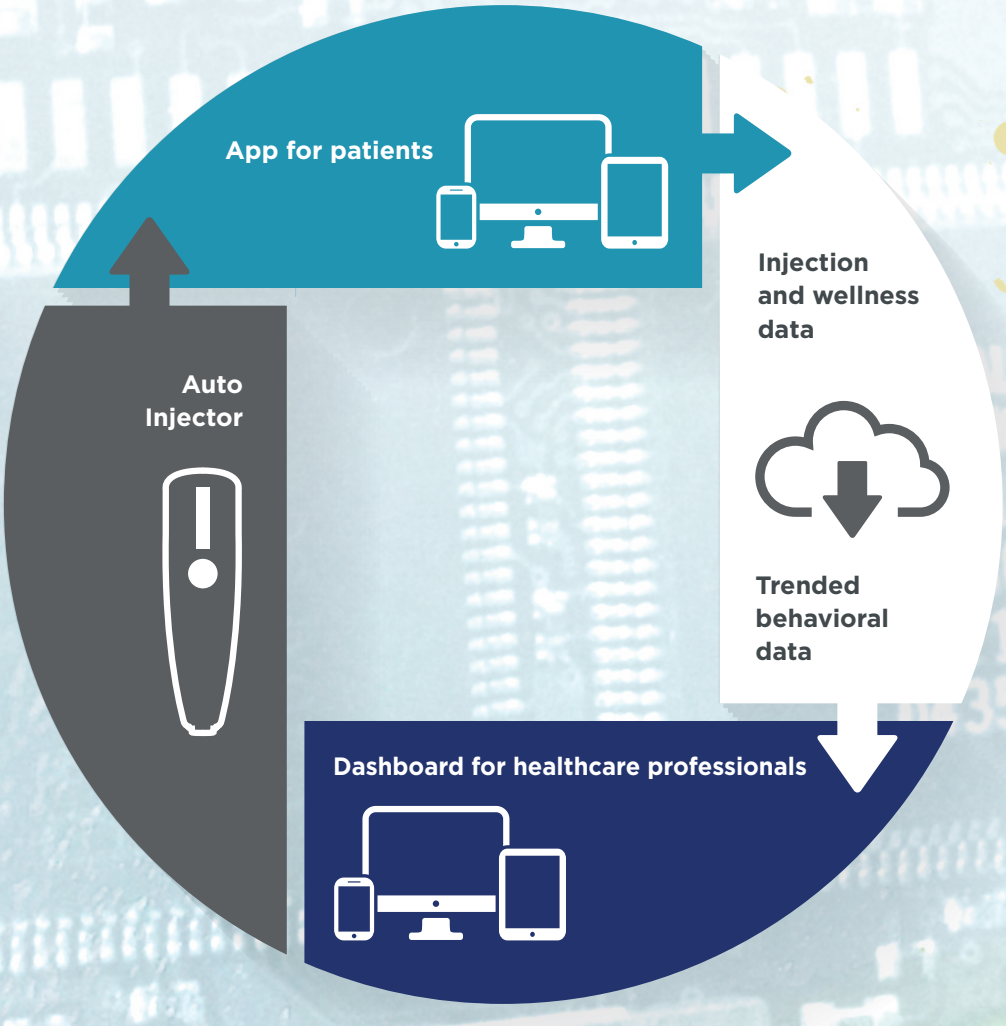

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