# IT'S JUST AN APP ISN'T IT?

**Although the interest in connected devices and solutions is growing rapidly, there is limited understanding of what a successful digital health solution should encompass or how partnerships should work. Vaishali Kamat, Head of Digital Health, and Jaquie Finn, Senior Consultant, Digital Services, at Cambridge Consultants, outline some key questions that pharma companies should ask before embarking on the development of a connected health solution, and provide insights that could help companies make the most from their investment.**

The global digital health market reached a record-breaking value of $55 billion (£39 billion) in 2014 and is forecast to grow at a compound annual growth rate (CAGR) of 21.4% to 2020.[1]

BI Intelligence estimates that there will be more than 646 million connected devices used for healthcare within the same period.

This interest in connected devices and solutions is, to a large degree, driven by change in the healthcare industry landscape. While the availability of suitable technology at an acceptable cost point has made implementation simpler, the rush to develop connected medical devices in the last year or so can be primarily attributed to the focus on reducing cost of care and the pressure to demonstrate improved outcomes.

As healthcare payment structures move away from traditional pay-for-service methods, the burden on the pharmaceutical and medical device industry of proving the benefits increases. This in turn underscores the importance of harnessing the power of connected health for companies to stay relevant and competitive in this changing market landscape.

## THE RACE FOR THE SMART INHALER

As big pharma considers the likely changes in payment structures and looks to differentiate in the face of the threat from generics, the interest in connected drug delivery devices has increased rapidly. The respiratory disease sector has been one of the first to get attention, with significant moves towards smart inhalers from several major players in asthma and COPD. 2015 saw partnership announcements from both Boehringer Ingelheim and GSK with Propeller Health[2] and AstraZeneca with Adherium[3] for development of sensors for their existing inhalers. Novartis announced its collaboration with Qualcomm Life[4] for clinical trials, while generics maker Teva bought smart inhaler company Gecko Health Innovations[5] and announced its partnership with IBM to build global e-Health solutions on Watson Health Cloud.[6]

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While it is still early days for these partnerships, and the current focus seems to be on clinical trials with "smart" versions of existing inhalers, it wouldn't be surprising to see future inhalers launched with integrated electronics and embedded software.

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However, the big question is how many of these players – or others, who look to follow in their footsteps to tackle other diseases – have figured out what is really involved in deploying a successful digital health solution? Despite the plethora of partnership announcements for smart inhalers, these companies have said little with regard to a coherent digital health roadmap and how smart inhalers will fit in it. It remains unclear what type of connectivity they are aiming to achieve and why, what type of data will be captured, and who will access it and how.

This is perhaps because it is too soon. Yet it is uncharacteristic for pharma companies, which are typically generous in providing information about their products, e.g. molecular mechanisms, enzymatic activity, pharmacokinetics, clinical results, etc. Can the lack of clear messaging around digital health be attributed to the fact that, in the race to have the first smart inhaler in the market, people have not stopped to figure out what having a connected device in their portfolio will mean? Is it because they have not fully grasped the wave of change that connected devices will bring to their business? For example, have they planned how they will scale the solution and provide the services that will be needed to maintain it? Have people taken the time to think about how the smart inhalers will help them achieve their strategic long-term business ambitions? Is the path to achieving suitable return on investment (ROI) within a reasonable time frame identified?

Connected health can bring a huge upside – but only if solutions are well developed and efficiently deployed. Simply making a wireless inhaler will not achieve the goals that these solutions are meant to achieve. It is critical for anyone entering this smart device race to recognise and acknowledge that there is more to it than just adding a Bluetooth chip or developing an app.

## UNCHARTED TERRITORY

Development of connected devices and supporting digital services involves a substantial investment – and the risk of failure should not be underestimated. Electronics, software and IT are not core capabilities of pharma companies, many of which only have a limited engineering capability in-house, thus restricting their ability to understand what is involved and evaluate options. Furthermore, their existing device supply chain has historically focused on mechanical rather than electromechanical or electronic systems, so they face an expertise gap.

To address this, some companies are bringing on staff from the technology industry to help them navigate this new landscape. However, often these new hires have limited understanding of the pharma industry – making joining the dots difficult.

But, technology aside, the bigger struggle many companies seem to face is to answer some fairly basic yet important questions that should ideally help inform the technology choices and solution definition. For example:

- What do we want to achieve with a connected solution?
- Do we need to be first or does it make more sense to follow?
- Which stakeholders do we want to target? What will they gain from our product and service?
- How can we differentiate? What will be needed to truly protect market share?
- Do we want to influence parts of the ecosystem? How can we do so?
- Should we develop an open or closed system? What is the impact of each?

The following sections provide some suggestions and best practice to help inform the creation and deployment of connected health solutions. While we use smart inhalers as an example, most of these insights apply to other types of medical devices as well.

## DEFINE STRATEGIC INTENT

There are many reasons to develop connected devices – and why pharma companies seem to be locked in a race for the first smart inhaler on the market. But prior to entering this race, it is important to think and articulate the strategic intent of a connected device solution.

Each company has a different ambition and a different appetite for risk based

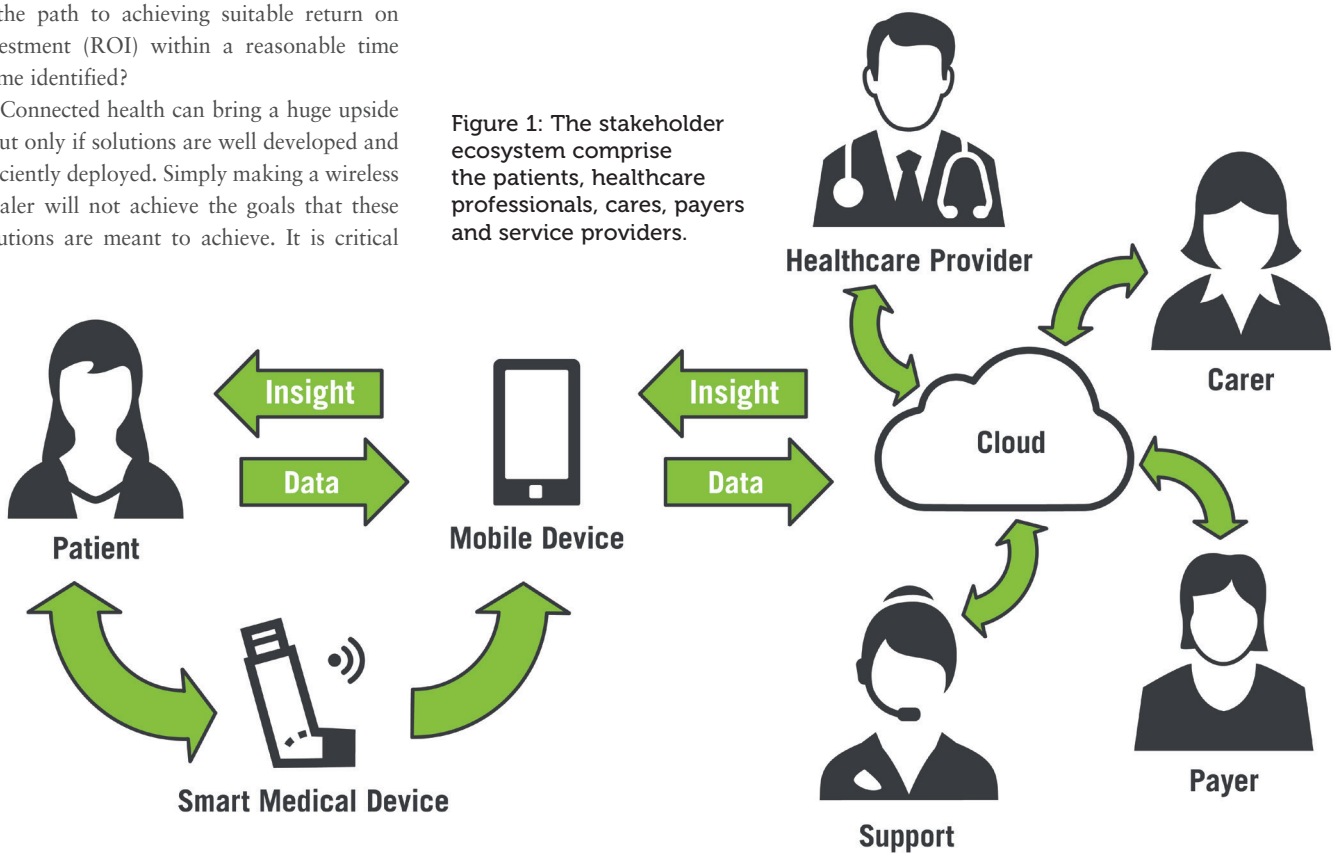


Figure 1: The stakeholder ecosystem comprise the patients, healthcare professionals, cares, payers and service providers.

on their current competitive market position. Thus, the nature of solutions and services that each company develops will – or should – be different. Moreover, the drivers pushing particular players into the connected device space vary slightly per organisation which in turn will define the goals to be achieved via connected health, e.g. some want to streamline clinical trials and run them in a more cost-effective manner, while others have a wider ambition and see themselves transforming from a pharma or device company into a healthcare services company.

Unless these goals are identified, understood, and disseminated within the organisation, it is difficult – if not impossible – to make appropriate technical decisions and select suitable implementation partners. It is equally important to define metrics for success, both short- and long-term, as well as work out the commercial value proposition – the business model – for the new offerings. Defining these will help the implementation team pick direction and stay on course.

## UNDERSTAND STAKEHOLDER NEEDS

Let's assume that smart inhalers are being developed because of the belief that by tracking device usage and reminding patients to take their doses, one can improve adherence to therapy. However, improved adherence may not result if the new system does not deliver a better user experience or if the reason for poor adherence is not forgetfulness. It is critical to understand the real unmet needs that a connected solution can help meet – and ensure it does not present an additional burden.

Connected devices and their data-driven solutions can and should be targeted not just at the patients but also other stakeholders in the ecosystem (Figure 1). Caregivers, clinicians and payers, as well as the industry players themselves, are all important stakeholders who can benefit from a connected health solution. Whether it is to reduce a concerned parent's worries or manage the cost of care for a population of chronic disease patients, identifying how the same data can help various stakeholders will enable you to maximise your return and realise the full potential of connected health.

Different disease conditions, different types of patients, different socio-economic groups and different geographies all have an impact on the requirements of a connected health solution. Everything from the choice of wireless technology to the features in an app depends on the needs you are trying to meet or the problems you are trying to solve.

Gaining insights from patients and other stakeholders is critical in tackling these issues, and specifying the optimal solutions. Similarly, testing prototype solutions with real users can help refine the offering. But user studies and trials can only go so far. Digital solutions need to be rolled out to a sufficiently large population in order to uncover issues that come with scale, obtain a wide enough perspective on user preferences and ultimately to gain actionable insights from the data.

You will never know what is going to work and what will fail unless you get feedback from real users in an uncontrolled setting. Thus the pilot-launch-iterate-launch cycle must be undertaken. This is counterintuitive to traditional medical device development, but a necessity for digital solutions.

## SELECT A SUITABLE TECHNOLOGY PLATFORM

The technology stack required to realise an end-to-end connected health solution consists of much more than just a Bluetooth chip and a smart phone app. Unfortunately, much of this stack is invisible and its impact ill-understood. For example, some interpret the "cloud" as this enigmatic and tangled web that they want to stay away from for fear of the regulatory implications, whereas others simply equate it to a data storage system like AWS, Microsoft Azure or an in-house server farm. The back end of a connected health solution needs to do so much more – it is, in fact the backbone that enables the solution to be deployed, maintained, upgraded and, more importantly, monetised.

## DEFINING THE SYSTEM

Of the various components required to enable a connected health solution, only a few will constitute the "medical device" or "system" from a regulatory perspective. Where the boundaries of your regulated product/solution will be drawn will depend on the features you put into the device, the app and the backend, as well as the fundamental nature of the device itself. For example, an app that goes along with a smart inhaler will very likely be considered part of the combination product and thus require the same amount of rigour during development and sufficient documentation for regulatory submission.

On the other hand, an app that works with several devices, or is drug independent may qualify for an independent 510(k) submission or – in some instances – fall under the discretionary category and thus not require clearance. It is important to define "the system" related to your smart inhaler or other connected device early in the development cycle so that feature partitioning and other design decisions can be made appropriately (Figure 2).

## DEVICE HARDWARE

The primary additions required to turn a traditional mechanical inhaler into a smart inhaler are:

- A means to sense and record device usage
- Actuation
- Storage and communication protocols to transmit that data/event to a collection device usually a smart phone or home hub.

The sensing technology – and its placement within a device – is critical as it will define how accurately you can capture device usage as well as what aspects of the usage can be recorded, e.g. airflow, aerosol formation, other physical parameters, etc. This in turn will dictate the claims you can make about your smart inhaler, e.g. can you claim that a successful dose has been delivered or do you need to simply state that the device has been actuated? The difference between the two seems minor but can have a big impact on the system and its end user benefit.

The choice of wireless technology has been made simple by the widespread adoption of Bluetooth Smart (also called Bluetooth Low Energy) in mobile phones. Most connected devices are thus incorporating Bluetooth Smart. However, thought should be given to the associated complexity and hence user experience of such a system.

Moreover, since you are making decisions today for a device that won't get to market for two or more years, attention must be paid to longevity of the selected technology / hardware and to alternatives that may become available / suitable in that time frame.

## SOFTWARE

When dealing with a connected device, you need to consider three software elements. The first is firmware in the device itself, next is the

smart phone app and finally the technology stack that constitutes the backend.

The firmware will be dictated by the choice of wireless technology, sensors and other functions of the device. The app will need to be developed suitably, based on its regulatory classification and key stakeholders that must interact with it, bearing in mind the impact of phone hardware changes and the even more frequent OS updates that are beyond your control.

Finally, the backend technology stack needs to consist of the basic data storage and handling with appropriate user access control and privacy protection, along with other functionality to enable data analysis, and reporting, as well as maintenance. The ability to fix bugs, add features and roll out updates on a regular basis is critical when dealing with consumer electronics platforms – a concept that is alien to the medical device and pharma industry.

It is safe to assume that it will not be necessary for the medical device or pharma company to develop all this software from scratch. Several big technology vendors have compelling offerings that can give you a leg up. However, selecting the appropriate solution for each of the software elements can be confusing and complex. Moreover, we recommend that you only enter partnerships where you have control over the user experience as well as unfettered access to the data gathered – the two elements which are of utmost value. To make your job easier, you may want to solicit assistance from technology savvy yet independent partners who can help you make an informed decision rather than pushing one particular option.

## PREPARE FOR ORGANISATIONAL CHANGE

Last but not least, you must acknowledge, prepare and be ready for the changes that owning a connected device solution will bring to your organisation. Everything from your marketing strategy to customer service and technical support services will need to be revised and updated to meet the needs of this new offering. The business operations, as well as the development operations function that you will need to put in place for ongoing maintenance of the connected solution are a non-trivial undertaking. Once again, we recommend choosing an experienced partner to hold your hand and guide you on this path – which is very much worth taking but does need some significant effort and investment.

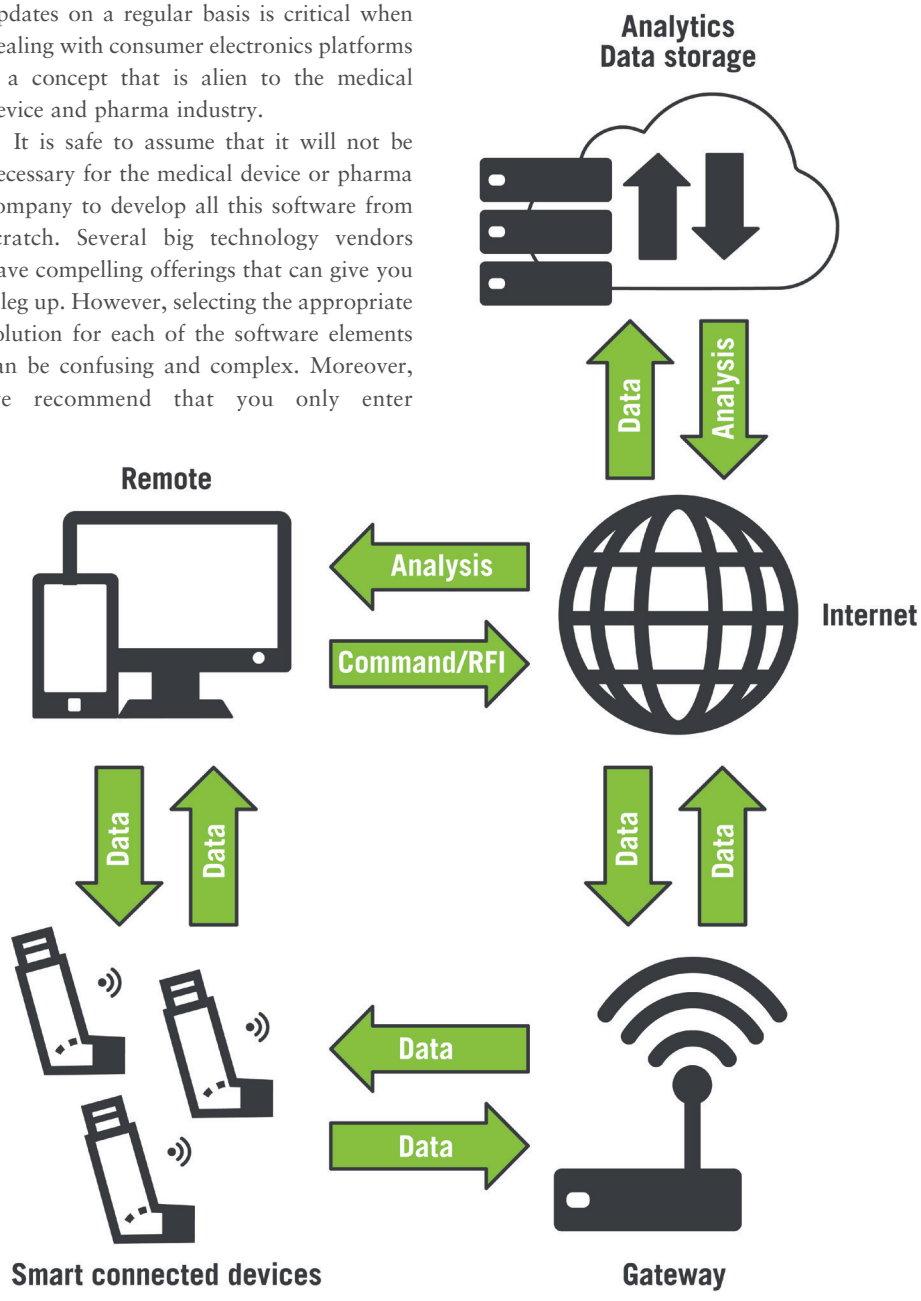


Figure 2: The digital system goes beyond a smart connected device.

## CONCLUSION

Digital health solutions have the power to offer an improved user experience by enabling people to use – for healthcare purposes – technologies that they are already familiar with. Increased patient engagement and motivation to manage disease can result in improved outcomes and reduced cost of care.

The medical device and pharmaceutical industry along with significant technology players have a huge role to play in realising this dream. COPD, asthma, diabetes, cardiovascular disease, neuro-degenerative disease and other chronic disorders will be among the first targets.

While it may seem simple to trial a connected device and show results in a controlled setting, it is imperative to recognise that the dream of shifting the outcome and cost needle will not happen unless these solutions can be launched at scale. And that is a complex task which should not be underestimated.

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