CONNECTED DRUG DELIVERY DEVICES: THE REALITY OF DESIGN AND DEVELOPMENT
INTRODUCTION

Connected drug delivery products – devices with attached or incorporated capability that includes connectivity to wider digital services – continue to be a driving force in medical devices. However, the world is still waiting for the first big commercial connected product success story.

Still, valuable lessons are being learned right now, suggesting what to do and what not to do, as these devices are developed. Cambridge Consultants has been at the forefront of these developments, working with many pharmaceutical clients and has experienced the success stories and challenges first-hand.

We have written before about general guidance for developing connected medical devices¹ and expected Human Factors challenges². Now that we have developed many of these products we decided to share our hard-won experience of how to successfully design and develop a connected drug delivery product.

We have brought these experiences together into three key lessons for pharmaceutical companies and aspiring developers. We recommend these lessons are considered before pressing the button to begin developing a connected product.

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LESSON 1: KNOW YOUR CUSTOMERS

It is typical in medical device development to refer to the people we design for as “users”, but the growth of digitally enabled medical devices is blurring the boundary between “users” and “customers”. Today, these customers have high expectations of their connected devices which go beyond the devices’ traditional areas of clinical efficacy and safety performance. This is because connected devices and digitally enhanced products emerged in consumer markets first and their rising quality and strong focus on customer needs have set a high standard. The rise of “wellness” products has blurred the line between medical and consumer devices further.

Because of this existing expectation, pharmaceutical companies need to reconsider how they view their intended users. They should regard them as customers as well as users, and consider the lessons learned in the consumer market.

EXPERIENCE AND BRAND

The area in which customer expectations have been most difficult to understand and satisfy has been product “experience”. In simple terms, this refers to the overall customer experience of using physical and digital products together. If we consider the example of the Amazon “Dash”, the physical button allows consumers to quickly place orders for many household consumables through Amazon.

The important point is that the success or failure of such a product is not driven by the physical side or the digital side, or even the back-end power of Amazon alone, but by the combination of all three working seamlessly together. If any individual component was poor, it would prevent the product being a success.

It would be highly risky to consider that “bolting on” connectivity to an existing product can be successful without proper consideration of how the addition will enhance the totality, especially in terms of product experience. Companies adding connectivity to products must consider if their drug delivery devices are ready to be judged on “experience”, as well as efficacy. The pharmaceutical industry must consider this seriously, as we have found that, for customers, unfulfilled expectations are far more damaging to a company’s brand than low expectations. This means that developers need to consider the overall product experience before beginning the development of any part of the product.

Part of this experience is also tied to how branding is applied to products. With a digitally enabled product, the brand will be visible on apps and websites, as well as the traditional print media of packaging and IFUs. Many pharmaceutical companies exhibit a superficial understanding of brand strategy in relation to multiple platforms.

VERY DIFFERENT USERS

When considering connected products and user experience, we often default to a mental image of the customers as tech-savvy ‘millennials’ who are comfortable with, and even expect to be connected to everyone and everything. However, developers and marketers must also, at the same time, consider an elderly relative: an uncle, mother or grandparent. This older person may be perfectly happy without a smartphone and hasn’t (for our example) touched that fitness monitor a friend thought to buy them for their birthday.

The truth is that for many drug delivery products, such as those for type 2 diabetes patients and COPD sufferers, the segment of older customers represents a significant proportion of the user base.

Over the course of our many formative studies we realised the level of understanding and adoption of technology varied widely from region to region. In Europe, for example, QR codes were commonly recognised, but in the US, many people had no idea what they were or what they were for.

Cambridge Consultants Human Factors Engineer
This is a challenge around highly different user groups that most consumer product companies don’t really have. They can design their products explicitly for the tech-savvy early-adopters or create a range of products that appeal to wider audiences. Pharmaceutical companies often have to design a single product for all types of users, even if some of them will not be able to, or want to, use all the features.

**I WANT VERSUS I NEED**

I’ve seen many users that take adherence very seriously, but just as many that are terrible at remembering to use their device or using their device correctly, and they don’t care. Even those with serious conditions may purposefully miss days of medication as an act of self-empowerment.

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Cambridge Consultants Senior Usability Expert

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It is an unfortunate truth for drug delivery developers that a significant proportion of users with chronic conditions are not particularly interested in those conditions, and are even less interested in using their drug-delivery products correctly. It is not just that they have poor adherence or technique, but also that they are not particularly interested in improving it. They may even hold to the idea that their technique is good, in the face of evidence to the contrary. Developers must be able to create products that cope with this understandable and natural human reaction to their condition and lifestyle.

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I have an app to remind me to take my dose, but if it beeps at me when I’m out, and my inhaler is on the bathroom shelf, it is just infuriating, not helpful.

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Asthma patient

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Improved effectiveness, through better adherence or technique, is common driver for adding connectivity to these drug delivery devices, we need to study how we might convince the users that it is good for them, rather than an unwanted intrusion into their lives?

**ACCIDENTALLY CREATING PROBLEMS**

There are more subtle challenges around using connected products to broaden an existing product portfolio. For example, the introduction of a connected device intended to improve compliance may imply that the current devices are inadequate.

For example, assume a company decides to create an electronic inhaler add-on, that aims to improve efficacy by helping the users to coordinate their inhalation with activating their inhaler. It initially sounds like a great idea, but what does that communicate to the regulators about the safety of the current inhaler? If the current inhaler is safe and easy to coordinate, what purpose does the add-on serve? If the current inhaler is difficult to coordinate, and the add-on makes a big difference, why can the current inhaler be approved as safe and effective?

**LESSON 2: KNOW YOUR PRODUCT**

It is an absolute necessity for developers to understand what they are developing and why. Development is a long process with many compromises and tough decisions along the way. Understanding and communicating the core benefit of the product acts as a guiding star during these challenges.

**THE VALUE OF DATA TO YOUR CUSTOMERS**

A connected product is very different to a non-connected one. The addition of a digital service and data to a product’s ecosystem radically changes how pharmaceutical companies should think about what they are offering. It is beneficial to think of the product in terms of “value”.
Connected products must add value to the product’s developers or there is no commercial reason to create and launch them. Typically, the value to the products’ developers is profit from the product’s revenues. Similarly, a connected product must be seen to be of value to its intended customers, or it won’t be purchased, let alone used. The value to the user can be more difficult to fully define.

Cambridge Consultants Strategist

With traditional drug delivery devices, value was strongly connected to the therapeutic benefit. A user buys (or their insurer buys) the product to improve health outcomes. However, with connected drug delivery devices (as with almost all connected devices) the value is also intrinsically connected to the data flowing to and from the device. This data may be valuable to the user, the product developer, or to someone else and it is vital to understand this before designing the overall system.

When we think about value, relevance is key. As a technology company it is not unusual for us to come across value propositions that are driven by the underlying technology, rather than from the customer need. This is where we take a step back and think about which problems new features, such as connectivity, can solve for the users, and which benefits they can deliver. Value is only generated where a relevant problem is solved, or relevant information is provided.

Cambridge Consultants Service Expert

Customers have shown that they greatly value the right sort of data or information in existing products. Health data is rapidly becoming valued in the personal space and activity monitors are driven by the customers’ desire for instant feedback on their personal health and the impact of their lifestyle. Apple have recently moved this to a new level, with ECGs in the newest Apple Watch. But value can also come from access to other data, such as instant access to weather or traffic data that many of us use daily. However, to date, compliance data has not been shown to be valued by the user. If a customer is to pay for a new product, they need to value it.

THE VALUE OF DATA TO DEVELOPERS

For developers, the data can be valuable in different ways. For example, it can be used to gather market feedback and clinically relevant feedback on correct or incorrect usage, or to streamline the supply of repeat prescriptions.

The digitally enabled Breezhaler®, by Novartis, is a connected inhaler which is explicitly designed for clinical trial use only. This significant investment demonstrates Novartis’ confidence that value can be derived from improved access to clinical trial data through connectivity, resulting in streamlining their clinical route to market, rather than any direct revenue stream.

THE VALUE OF DATA TO OTHERS – ANOTHER SOURCE OF REVENUE?

It is also important to investigate whether data could be of value to a third party. In the drug delivery market, healthcare professionals are the obvious example. However, more data is not always valued, just as most people don’t appreciate the constant stream of special offers in their email inbox.

However, with proper consideration, third party access to data can be enormously valuable. It’s worth considering the example of Facebook, which derives its profits almost entirely from the advertising value of user data. Nevertheless, this is an extremely challenging way of generating value as it depends greatly on customers’ willingness to share their data. It was not surprising that Facebook users felt uncomfortable with the claims about Facebook’s activity in the wake of the Cambridge Analytica scandal in 2018. This caused a number of users to close their accounts and saw a reduction in the numbers of new joiners. The new GDPR regulations now in effect rightly have a huge impact on what data you can gather and how you can use it. If the data had included medical records from a hypothetical pharmaceutical website, the consequences could have been far worse.

3 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC59957057/
An emerging theme from recent human factors studies is that healthcare professionals are wary of being provided with more patient data, such as the data that could be generated by apps. In our discussions, they describe concerns surrounding whether they could trust the data fully; whether they could use it effectively; who would be liable if they acted upon incorrect data or failed to act upon data; and the amount of time it could take to access and interpret data from various patients using different platforms.

Cambridge Consultants Human Factors Engineer

HOW DATA AFFECTS DEVELOPMENT COSTS

Knowing that data is at the heart of connected products, we need to know how this will affect both device development and the company developing and launching the product.

If you are including the ability of your customers to access information and potentially to purchase refills etc. then the “visible” front-end of your digital product – the app – may be the smaller part of the development cost. To ensure seamless integration between the ERP (Enterprise Resource Planning) or CRM (Customer Relations Management) systems, the back end can be significantly more.

Cambridge Consultants Digital Services Expert

Cambridge Consultants Electronics Engineer

Developing a new drug delivery device can cost anything from £1m to £3m, depending on the complexity of the device. Developing the digital element of a connected drug delivery device, to create a full digital service, will typically cost significantly more than that. A cost that pharmaceutical companies may not expect and not initially include in their development budgets.

These are not one-off costs. The developers will need to run these digital systems and handle customer data in a way that meets all the current (and rapidly evolving) regulations. This includes software updates and continuous monitoring of arising issues that could affect quality or safety, which are normally more cost intensive than for a purely mechanical product and requires different skills in the team responsible.

HOW DATA CAN CHANGE YOUR ORGANISATION STRUCTURE

Launching a connected device comes with other considerations which must be taken into account at the early stage of development. For example, how will the data be handled, and who will handle it? Is it wise for a pharmaceutical company to handle the digital side of their business and incorporate it into the existing organisation structure? The cost could be significant and the challenge of integrating a new business unit with a very different skillset is considerable. It may be cheaper and more effective to create new organisational structures for the digital side of a business.

HOW DATA AFFECTS OTHER TECHNICAL AREAS

What data is gathered, where, how and for whom, is a key factor, possibly the key factor, that will define the electronics and mechanical elements of a connected device. Moving data from place to place (connectivity) is a major use of power in the product.

Data needs to be moved from the device to the wider digital world and, unless motors are required, when, how and how often a device communicates with the rest of the world is normally the dominant power use of most connected drug delivery devices.
Power use is a critical challenge in these developments and will be a primary focus of the technical team. Consider the following trade-off, which is relevant to all connected products:

On the one hand, the developer wishes to minimise the need to recharge the device (or change the battery), particularly for users that are not used to charging their phones, etc. Recharging can be annoying for users and, worse, can lead to user errors (if the battery runs flat) that need to be mitigated through design.

On the other hand, regular communication is required to stay synchronised with paired devices (usually the phone or a website) to avoid the device becoming out of sync with the rest of the ecosystem. It is worth considering whether it would be acceptable if an app only agrees with its partner device once a day (while charging)?

HOW OTHER COMPANIES CONSTRAIN THE PRODUCT

Pharma companies are not the only stakeholders with an interest in the overall product ecosystem. As a result, certain development decisions will be out of the developer’s control. For example, part of their ecosystem will almost certainly run on an operating system and hardware (the phone) that is developed and managed by a third party, with their own goals that may not align with the developer’s.

When there are paired devices, for example a device that is linked by Bluetooth to a phone, the former stays in regular contact with the latter through a process called “polling”. This means the phone briefly communicates with the device to check it is still in range and what state it is in. For medical devices, this may not appear to be the best approach for efficient power management. It requires the electronics to “wake up” and respond to the poll, which uses power, thereby shortening the battery life or time between charges, for no perceived benefit. It might seem best to ignore these polling requests from the phone, stay in a power-saving state and reserve the power for when you need it to record the device delivering drug, or downloading its data.

However, Apple does not allow connectivity apps to be available on its App Store if they do not “poll” the connected device regularly. The reason for this is understandable if you consider Apple’s business: if the phone tries to contact the device but cannot – if it is in a power-saving state – it can appear to Apple’s customers (who are also the pharma company’s customers) that their phone is not working properly. Apple need to safeguard their own brand of product experience, and they place that need above the device’s need to save power.

It’s clear then that developers are not in control of the operating systems of the phones, hubs, tablets or PCs that the complete digital product will exist on. This is one of the driving reasons why the ongoing cost of running a connected device can be high. There will be a continuous need to update and quality check the device’s software, as the operating systems’ owners update theirs. Furthermore, with smartphone connections, a company may be running apps on multiple operating systems, which require managing separately.

Until recently, Apple devices were unable to connect to the WiFi in many UK homes, due to an ongoing dispute between Apple and Virgin Media (one of the UK’s largest internet service providers). This was inconvenient – or a disaster of mythical proportions if you ask my children. But imagine if you had medical apps running on those devices, that relied on connection to the wider cloud. You would effectively be unable to resolve the problem, as it is not in your product, but your users could be experiencing a very hazardous situation.
LESSON THREE: KNOW THE RISKS

The third lesson worth considering relates to an appreciation of the added risks that will be part of the development and launch of such a connected system.

NEW PARTNER RISKS

Any pharmaceutical company planning to develop a connected device needs to realise that it will be doing business with a different group of development partners, not limited to digital design companies. Software developers, chip suppliers, electronic assemblers and data server companies will all be part of the development and launch processes. Many of these companies are only just beginning to engage with the medical device industry and pharmaceutical companies in particular and there are many differences in how they work.

The most obvious risk related to software developers is the use of Agile development. At its core, it is a development method that uses fast loops of ‘define-design-test-learn’ iterations, to move towards a goal. It is very difficult to align this method with the requirements for submission to the FDA and MHRA.

AGILE’S UNEXPECTED IMPACT

Developments can be set back significantly when, for example, application designers decide to make a slight improvement to their interface, which is typically developed using Agile. In consumer products, it is normal for the digital design to be modified and evolved right up until launch, and beyond. However, for a medical device where the interface could be safety critical, a small change can result (and previously has) in a complete repeat of the validation user studies, with a huge cost and delay to launch.

NEW TECHNICAL RISKS

The technical risks during the development of a connected drug delivery device will be new, if the developer’s previous products have been mechanical. As with most new risks, these are typically higher than expected.

One particular risk with connected device development relates to the electronics system that enables connectivity. There is usually significant pressure on the size of electronics module, particularly when the module is being added to existing devices and it is hard to disguise the additional bulk in careful design.

This pressure means that the technical team will almost certainly be pushing some of the core components to the threshold of their operating envelope: Trying to get processors to work to their maximum speed limits; using every last bit of the battery’s power; driving the memory hard, etc. This is a normal dynamic during the development of wearable consumer electronics, and an inexperienced development team might not realise the risk in this approach, but the difference for medical device developers is in the impact of potential device failure. Pushing components to their limits can significantly drive up the cost and time for design verification. In addition, component suppliers are typically out of their comfort zone when dealing with the demand for ultra-low chance of failure that medical products need.

The regulatory landscape is also a source of risk for developers. For European markets, both the MDR and the GDPR are new, but many companies are only just beginning to understand the impact they could have on the way they collect and handle personal data. The FDA also has a particular focus on digital security, after several high-profile failures and hacking scandals.

The addition of software – and potentially machine learning in the future – has massively widened the scope of medical devices to improve patient outcomes, but the potential for new risks is also very high.
The new MDR has specific sections to cover software as a medical device and it includes the potential of different classifications for the software and physical device. But as of October 2019, no one has actually submitted against the MDR, so it is a big unknown for our clients at the moment.

Cambridge Consultants Regulatory Specialist

PASSING THE TEST OF TIME

Being first to market, with a product that cannot be matched (at least for a few years) would be hugely valuable to any company. But the final risk in this section relates to understanding the difference in development time between a medical device and a consumer device, and why that impacts the choices available.

It will be at least two to three years before you can release your device and connected system, and more if you need to work with a new drug or formulation. Take a minute and think back to what connected devices looked and felt like five years ago. Think about what apps were like five years ago. That’s when iOS 5 launched – and we’re on iOS 12 now – Microsoft inadvisably bought Nokia and Facebook went public. This will give you a good perspective on how challenging these developments are.

Cambridge Consultants Strategy Specialist

The fact that medical devices take longer to launch than consumer devices might seem obvious to pharmaceutical companies, but our experience is that designers, technologists and marketeers can too easily become excited by the latest consumer products, and base their concepts for their connected drug delivery devices on those products. Companies must think extremely carefully about product ideas that will stand the test of time. Medical devices cannot be quick to market and then improved in later versions based on real customer feedback in the same way that consumer products can. To repeat from the first lesson, a failure to match customer expectations has a worse impact on a brand than low expectation. ‘Safe and boring’ is a valid strategy, if ‘exciting and buggy’ is the alternative.

The NEXThaler was developed in the early 2000s. At that time, the iMac was the sensational new product, marking the beginning of Apple’s golden age. The inhaler was designed, at least partially, to aspire to the colourful, friendly style that Apple had introduced. But the NEXThaler was approved for market in 2013, almost a decade after that model of iMac had been discontinued. If the NEXThaler did not have a competitive design, its colourful appearance would not have passed the test of time.

CONCLUSION

In this paper we have outlined three lessons for successful development of connected drug delivery devices: Know your Customer; Know your Product; Know the Risks. These lessons were learnt through triumphs and setbacks at all stages of the development cycle. Development teams and medical device companies can improve their chance of launching a product that is successful in the market and valuable to them, by building on this experience.

At Cambridge Consultants, we have developed inhalers and injectors with many different levels of electronic and digital enhancement to improve adherence, usability and value.

https://www.cambridgeconsultants.com/case-studies/chiesi-next-generation-inhaler
About Cambridge Consultants

Cambridge Consultants is a world-class supplier of innovative product development engineering and technology consulting. We work with companies globally to help them manage the business impact of the changing technology landscape.

With a team of more than 800 staff in the UK, the USA, Singapore and Japan, we have all the in-house skills needed to help you – from creating innovative concepts right the way through to taking your product into manufacturing. Most of our projects deliver prototype hardware or software and trials production batches. Equally, our technology consultants can help you to maximise your product portfolio and technology roadmap.

We’re not content just to create ‘me-too’ products that make incremental change; we specialise in helping companies achieve the seemingly impossible. We work with some of the world’s largest blue-chip companies as well as with some of the smallest, innovative start-ups that want to change the status quo fast.

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For more information, or to discuss how this approach could fit your business, please contact:

Max Middleton, Senior Consultant, Medical Devices
Max.Middleton@CambridgeConsultants.com