The digital health revolution has been fuelled primarily by growing use of wearable and other consumer devices to gather various health metrics. Connected medical devices are not far behind.

We have already seen Bluetooth connected glucose meters, and blood pressure and weight scales. However, the last year has seen several announcements along these lines from what has traditionally been a conservative group: big pharma in the respiratory disease market. There seems to have been a sudden rush with most of the major pharmaceutical companies embarking on product development or trials with connected inhalers, racing to launch commercially. While this appears to be a surprising development, a closer look indicates a natural evolution.

The healthcare industry is changing in the US and elsewhere, both in developed as well as developing countries. Rising costs have forced governments to take action, payment systems are changing and payers have increasingly started demanding evidence for therapy and medical procedures. As the pressure mounts on the industry to demonstrate cost efficiency and outcome improvements, it is increasingly turning to technology to provide a solution. Given that inhalers typically take five to eight years to bring to market, an early start to exploring new technology and connectivity solutions is therefore required by the pharma industry.

Development of connected medical devices and the solutions to support them is very different from traditional device and certainly drug development, both of which take a waterfall approach. Connected systems, especially those that include smartphone apps as part of their solution, must be developed in a rapid iterative or agile process. Moreover, their benefits can only be realized if the solutions are designed and delivered well – the user experience in particular plays a huge part in the success or failure of these systems.

Today, technology moves at a rapid pace and market trends as well as user preferences change drastically from year to year. While this is more the case for consumer products, home use medical devices – and to a large extent, clinical use devices – must be designed to accommodate or adapt to changing environments. Picking components and making technology choices for products that will only come to market three to five years later (or even longer in the case of a new drug product) pose significant challenges. Furthermore, where regulation is involved, keeping products relevant and minimizing chances of obsolescence are critical given the long approval cycles. Finally, one must note that the path to market, the target buyer, and revenue models for connected systems may not be the same as before. All of this means that a strong long-term strategy and solution roadmap should be put in place prior to making platform decisions or embarking on any design/development, and then continually revisited and updated often in light of market directions.

In response to these challenges facing pharmaceutical and device companies entering the connected technology business, let’s have a look through a few tips:
IDENTIFY THE VALUE PROPOSITION

A connected health solution may not be appropriate for every drug product or for every medical device. As part of the initial strategy, it is important to identify the right drug candidate or disease state/metric, to identify target users, as well as to determine what value you can provide them via a connected health solution. If suitable value cannot be identified for at least two stakeholders within the ecosystem, it is unlikely that the solution will result in a viable commercial proposition.

The path to revenue will dictate several aspects of the solution, including the platform architecture, the design, and the required features. It goes without saying that the business model must be constructed and validated early on and key items that revenue depends on must be identified to enable appropriate trade-offs to be made later if necessary. Connected systems lend themselves well to service-based revenue models, based on usage as well as analytics. Thus, the sources of revenue may be indirect and not strictly limited to device sales.

DESIGN THE EXPERIENCE

The success of connected systems depends heavily on positive user engagement, which in turn is governed to a large degree by the user experience and the value delivered by the solution. Any solution that requires regular interaction must fit seamlessly into people’s lives and should deliver something meaningful back to the user. Particular features to be included in the device, the app or web service must be determined following a detailed mapping of the user journey and an understanding of what different stakeholders might want out of the system. It is critical to remember that not all users are made alike. Preferences differ, and what works for one individual may not work for another.

With the advent of smartphones and apps, people have come to expect a level of personalization with everything they use – it is no different for healthcare products. Connected health solutions must incorporate a good balance between user-driven customisation and a sufficiently standard out-of-the-box experience. Moreover, the design and experience should bear in mind the target audience, their skill level, dexterity, and tech savviness as well as the amount of time they are likely to spend customizing the device. For example, surgeons who are typically very busy are less likely to commit to ‘designing’ their own dashboards, compared with a family caregiver.

Behavioural economics are important to understand, as they can guide the design of an appropriate end-to-end solution – for instance, a blend of ‘carrot’ and ‘stick’ in your approach is known to work better than just the ‘stick,’ and blatant reminders are less effective than gentle nudges in capturing users’ attention. Frequently undertaking human factors evaluations throughout the development process will help you confirm that you are on the right track and can increase chances of successful adoption. Formative studies with interim versions of the intended solution can help you understand how users relate to what you are building – remember, people will view a medical app very differently from Instagram. Besides, a full human factors analysis and output for the end-to-end solution (including the app and perhaps even the back end) is required for FDA approval anyway.
DEVELOP THE TECHNOLOGY

One of the most critical aspects in developing a connected system is choosing the right platform and setting up a robust, scalable architecture for the system. It is important to correctly partition functionality in order to simplify the regulatory process as well as future product iterations and upgrades. Moreover, hardware choices have to be made bearing in mind the long approval cycle and time to market, so various strategies to reduce unnecessary churn should be considered, including planning for drop-in replacements and choosing reliable suppliers known for long-term support of their components.

If connectivity is being added to an existing and approved medical device, it is critical to determine upfront whether the design will impose constraints that prevent accurate capture of signals or pose challenges for the electronics (and battery) required to enable key features or deliver a good user experience. For handheld wireless devices, power budgets tend to be tight in order to minimize device size (batteries tend to dictate device size), so appropriate choice of technology and components as well as low-power electronics design is critical.

Additionally, significantly better power consumption can be achieved via smart software design. To ensure reliability of the communications, which in turn impacts the user experience, pay attention to the antenna design – invest in a custom antenna if size constraints prevent a standard antenna achieving desired performance. Remember to test performance of body-worn devices in realistic use scenarios, not just in free space.

The app architecture and design is a key aspect of the system – one that often poses problems because the smartphone platform is not under your control. The radio on the smartphone is controlled by the OS, so you may not be able to control how it behaves with an app in the background or with other radios running. Especially in the case of iOS, be prepared for significant constraints, which you need to compensate for in your device design in order to achieve the desired performance and user experience. Finally, do request an opinion from regulatory bodies early in the development process on how they will regulate the app. Apps supporting connected drug delivery products, especially dedicated ones, are likely to be considered part of the combination product, thus requiring the appropriate development process, and verification and validation, to be executed.

Partnerships are likely to be required to enable the data infrastructure supporting a connected system. One of the key decisions to be made is a selection between custom development versus an off-the-shelf solution for the data handling and service infrastructure. There are pros and cons of both – the right choice for you will depend on your longer-term ambition. Make this decision early and ideally with the help of an independent, well-informed team. Picking the right partners who share your vision and are vested for the long term is key. Access and ownership of data often tends to be a sticking point.
LAUNCH AND LEARN

Connected systems will continually evolve. The software and the services you deliver will need to be iterated even if the device stays the same, so it is important to agree on a minimally viable solution, launch as quickly as possible and learn from real-world experience. Clinical trials and pilots are controlled settings and will never provide real insights that can be gained from market launch, even if it is on a limited scale. Technology will change sooner than you anticipate – plan for it and use it to your advantage rather than allow it to wear you down.

SUMMARY

Connected drug delivery and other medical devices can add a lot of value, improve adherence to therapy, enable better chronic disease management and, in the long term, improve outcomes. But solutions need to be designed carefully, deployed smartly, and adopted by users and clinicians. We are seeing signs that patient-generated data (PGD) will soon be accepted within the mainstream care pathway. The ONC contracted Accenture earlier this year to develop a framework for PGD in care delivery – one that will address issues around testing reliability of the data, its authenticity, etc. Healthcare delivery as we’ve known it will soon change – and connected medical systems will have a big hand in this transformation.
ABOUT CAMBRIDGE CONSULTANTS

Cambridge Consultants has an exceptional combination of people, processes, facilities and track record. Brought together, this enables innovative product development and insightful technology consulting. We work with companies globally to help them manage the business impact of the changing technology landscape.

We’re not content to deliver business strategy based on target specifications, published reports or hype. We pride ourselves on creating real value for clients by combining commercial insight with engineering rigour. We work with some of the world’s largest blue-chip companies as well as with some of the smallest innovative start-ups who want to change the status quo fast.

With a team of more than 750 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 optimise your product portfolio and technology roadmap, investigate new opportunities or refine your operations.

Cambridge Consultants is part of the Altran Group, a global leader in innovation. www.Altran.com

For more information, or to discuss your requirements, please contact:

Jaquie Finn, Head of Digital Health
Jaquie.Finn@CambridgeConsultants.com