

SHL GROUP

NOT JUST ANOTHER GADGET: INSIGHTS INTO DEVELOPING DIGITAL SOLUTIONS THAT WORK

Smart connected devices are becoming increasingly widespread in all areas of life but their actual value and usefulness can sometimes get ignored. To avoid this happening in healthcare, SHL Group believes that the answer is to address four key questions which help to ensure that patients' needs are kept at the centre of any innovation and the value of the new technology is clear.

Over the last decade, the Internet of Things has become a day-to-day phenomenon. Smart, connected objects are becoming so widespread in every aspect of life that sometimes the question of their inherent value is left out. Picking up on this trend a website called the Internet of Useless Things¹ has even appeared, listing a number of particularly meaningless hypothetical applications of the new technology. To avoid developing devices that illustrate this tendency, it is important to take a step back and consider how to apply the available technical solutions.

"The main purpose of any innovation must be centered on the idea of making patients' lives as healthy and comfortable as possible."

In the area of drug delivery, it is important to remember that the ultimate gatekeeper for any innovation will always be the final user – the patient. An important difference from consumer gadgets is that patients do not want a connected device just to stay on top of the latest trend. From a wider perspective, they would prefer to be healthy and not to have to use any device at all. So, the main purpose of any innovation

must be centered on the idea of making patients' lives as healthy and comfortable as possible.

At SHL, we take patient-centric design and innovation seriously. To guide our research and development, we ask the following questions:

- Will it be accepted in the real world?
- Where do we start?
- How do we create additional value?
- Who will benefit?

Below we will introduce some insights into how these questions might be answered when starting a project.

WILL IT BE ACCEPTED IN THE REAL WORLD?

In short, the answer is yes. More people around the world are accepting digital tools in healthcare, including electronic health records (EHRs), wearables and mHealth. According to one survey, more than 75% of respondents would like to use digital healthcare services, as long as those services meet their needs and provide the level of quality they expect.² Moreover, older patients, often considered reluctant to accept new technology, are almost as likely to turn to digital solutions as younger ones.^{2,3} Finally, even doctors, who remain somewhat sceptical about the value of digital health, are actively engaging with it –

SHL Group
#136, Kuo Sheng 2nd Street,
Taoyuan District,
Taoyuan City,
Taiwan

www.shl-group.com

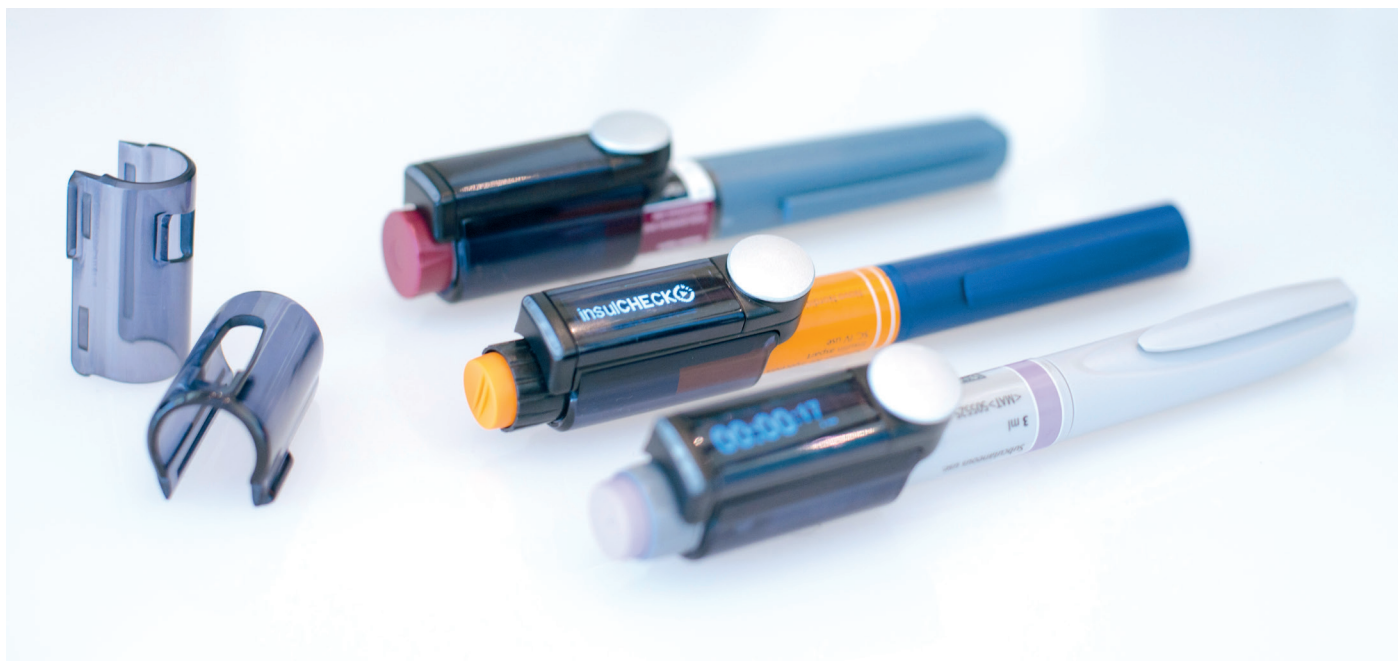


Figure 1: The InsulCheck add-on device for existing insulin pens illustrates a gradual approach to functionality: starting from a simple timer that is already available, InsulCheck is also being developed into a connected device to which further functions such as dose and temperature measurement can be added.

“It is better to have one good function that works properly than ten functions that are of no use.”

recommending apps, asking patients to wear devices for monitoring and, in general, feeling that these innovations are not just momentary trends.^{3,4}

WHERE DO WE START?

The patient-driven approach to device development starts with the question: “What are the patient’s needs?” At the very basic level, a well-designed device should fulfill the patient’s needs while at the same time possess functions that are reliable and of good quality.² No innovative feature will be appreciated if the device doesn’t work as it is supposed to, or if it is difficult to understand or use.

For the data records collected by a smart device, the same rule would apply to data management and representation. It is important to make it easily understandable and show real insights rather than a vast flow of raw and meaningless data points.

It is better to have one good function that works properly than ten functions that are of no use. Therefore, it might

be a good approach to start small and increase functionality incrementally to ensure the usefulness and quality of each new feature (Figure 1).

HOW DO WE CREATE ADDITIONAL VALUE?

Once we have got the basics right, it is time to consider how and by what means we can create additional value with the new features. The availability of sensors and wireless technology means that we

can track, guide and record almost every step of a user’s interaction with the device. Segmentation and customisation become particularly important at this stage as different patient groups, therapies and use scenarios will require different functionality.

For example, people with multiple conditions using several different medications would clearly benefit from a therapy management system that could automatically incorporate and analyse the data about different medications and their interaction (Figure 2).

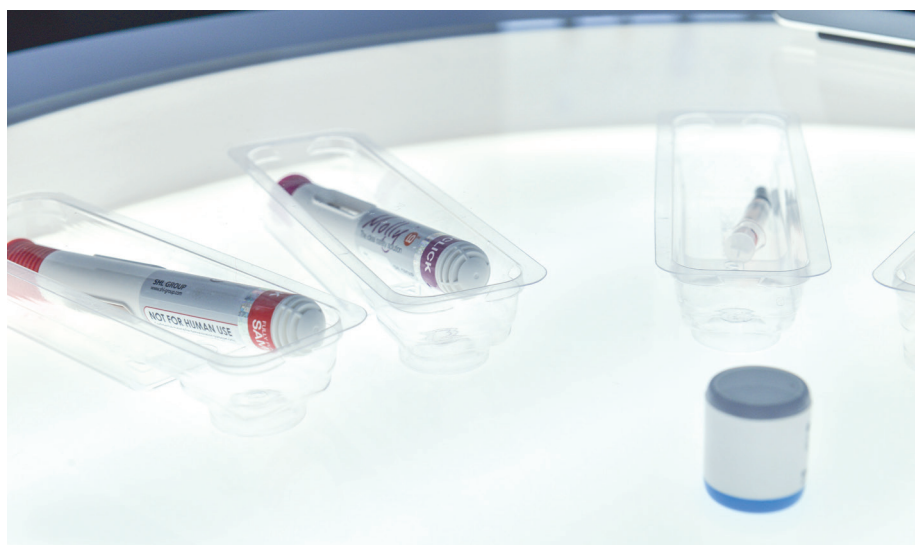


Figure 2: An extension of the Molly C RU (Figure 3) technology, the FlexRec system for multi-medication tracking illustrates how connectivity can work across different drug delivery formats. Paired with a therapy management platform, this concept design can significantly improve and simplify the patient experience.



Figure 3: The Molly C Recording Unit (RU) is a concept design that demonstrates how connectivity can be utilised in an existing auto-injector device. The concept is based on pairing it with a smartphone to transmit information about injections.

“A connected medical device is not merely another gadget that will entertain the user for a few months and then be forgotten.”

In the case of chronic diseases, adherence is one of the most important factors affecting outcomes. Thus, for these therapies it is important to design a drug delivery and therapy management system that will support patients’ existing contextual cues (such as particular routines or locations) and will aim to modify long-term behaviour.⁵

In a setting of clinical trials, connected solutions can increase efficiency and patient recruitment by removing the need to input data manually and travel regularly to the study site. Moreover, with continuous monitoring and reliable data records, the results of such studies would be more powerful and might provide novel end points (Figure 3).^{6,7}

The important thing to remember is that with the addition of new functionality, user experience must remain accessible and simple. It should also be customised in accordance with user needs, providing relevant information as well as proactive feedback and guidance.

WHO WILL BENEFIT?

Taking into account the needs of all stakeholders is essential in any healthcare project. The patient must be at the centre of our thinking, but other players have to benefit too.

The value of new technology for the patient is clear. First and foremost, improved adherence leads to better health. A study by Minnock⁸ shows how a simple add-on device to remind users about the time since last injection can significantly improve health outcomes and reduce hypo- and hyperglycaemic incidents for diabetics (Figure 4).



Figure 4: A simple add-on device can significantly improve outcomes for diabetics.

Patient comfort and freedom is an important benefit of using connected solutions. More independence away from healthcare services, training and advice at patients' fingertips, the opportunity to share information with loved ones – all these features make lives easier and safer.

Doctors already agree that the use of wearables helps patient engagement.³ Even though they may not see mobile technologies replacing face-to-face visits, the availability of data on, for example, whether the patient administers the medication properly, will help to assess, evaluate and modify the therapy. Together with environmental factors recorded by the app or a wearable device, this will provide a more detailed picture of the condition's management.

Pharmaceutical companies are also interested in increasing adherence to make sure that prescriptions are filled so as to secure optimal treatment outcome. As mentioned above, connected technology creates several benefits and opportunities in clinical trials. Moreover, as the competition in many therapeutic areas is constantly increasing due to the maturity of the market and research in generics and biosimilars, a connected device paired with a therapy management tool will allow market differentiation and product lifecycle management.

Payers will benefit from the reduced costs and evidence of outcomes. According to a US study on an mHealth-based diabetes monitoring device, it creates a potential total saving of US\$34 billion (£27 billion) annually in direct medical costs.⁹ In addition, the availability of rich, real-world data can ensure that the effectiveness of treatments is evaluated in more informed and personalised ways.

Another valuable effect of the data is that it can provide device manufacturers with an unprecedented amount of real-world feedback on the use of the device. Even though human factors studies are already an essential part of the design process, they are subject to the limitations created by the artificial environment of the study. At the same time, looking at how people use the device in their day-to-day lives,

what problems they face and what prevents them from compliance can guide the design process for future models.

NOT JUST ANOTHER GADGET

A connected medical device is not merely another gadget that will entertain the user for a few months and then be forgotten. To provide a truly valuable experience for patients and other stakeholders, it needs to be developed with a thoughtful approach. By answering the four questions described in this article, it is possible to develop a successful product that will provide both short- and long-term benefits. The key lessons to learn are:

- Patients of all ages are open to the digital healthcare experience
- Start small with good quality core functions
- Gradually increase and personalise the new features ensuring at every step that they satisfy unmet needs
- Incorporate the device into a wider architecture by providing a therapy management system or an app and making good use of data.

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ABOUT THE COMPANY

SHL Group is one of the world's largest solution providers in design, development and manufacturing of advanced drug delivery systems. We work with leading biotechnology and pharmaceutical companies to develop drug delivery devices, including compact disposable auto-injectors, reusable pen injectors and complex inhaler systems.

SHL has been investing significantly into R&D allowing us to enhance our broad pipeline of "next-generation" drug delivery devices. In particular, we initiated several forward-looking initiatives exploring new technologies and future developments, including comprehensive connectivity offers. Developing these projects in-house allows us to customise existing platforms in our pipeline or develop completely new bespoke devices based on the unique requirements of our customers. With locations in Taiwan, Sweden and the US, our experienced engineers and designers develop product enhancements and breakthrough drug delivery solutions for clients globally.



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