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SELFCARE SOLUTIONS

PAVING THE WAY TO INTEGRATED DEVICE-DIGITAL SOLUTIONS

In this article, Andreas Schneider, PhD, Innovation and Business Development Director, and Philippe Müller, Innovation and Business Development Manager, both of Ypsomed, discuss the potential benefits and challenges of implementing connected device-digital solutions within the healthcare sector to improve the treatment of chronic conditions.

“Seems like you have just missed another dose, Adam, let’s discuss how to best fit your injections into your daily routine. Surely, I can help you with that.” The warm and empathic voice gently gives the necessary instructions to Adam, who has suffered from atopic dermatitis for years and has been prescribed a new biologics treatment that must be self-injected every two weeks. Surprisingly, however, this voice does not come from his attending physician, but from an artificial intelligence engine that issues its commands straight from the speakers of his smartphone. It is barely recognisable as a robotic voice.

The algorithm that fuels the digital solution recognised that Adam had repeatedly missed his dose and identified him as a patient at risk of prematurely stopping self-injection and not achieving his treatment goals due to medication non-adherence. If Adam continues like this, he will suffer from debilitating pruritus, disturbed sleep and mental distress. As with up to half of the more than 26 million other Americans diagnosed

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with atopic dermatitis, these effects will also negatively impact Adam’s lifestyle, work and education. These are effects that Adam is well aware of in principle, but which are only marginally present at this time.¹⁻⁶

RECENT ADVANCES WITH DIGITAL THERAPEUTICS

Integrated device-digital solutions to support behavioural change and empower patients diagnosed with chronic conditions to manage and improve their symptoms are currently gaining traction within the healthcare sector. Since 2017, the US FDA alone has approved more than 40 digital therapeutics and health apps addressing chronic conditions, including diabetes, back pain, ADHD and asthma.

These solutions encourage patients to engage with their specific disease and symptoms to optimise their treatment pathway and outcomes (Figure 1). Moreover, new pathways are presently being established for digital health apps to be paid for through existing healthcare systems. For example, in Germany, 12 digital solutions have provided sufficient clinical evidence to be permanently approved and reimbursed.¹¹

TOWARDS INTEGRATED DEVICE-DIGITAL SOLUTIONS

Consider Adam, who may require a device-digital solution that provides sustained and holistic support to achieve effective disease control and comfort. Such a solution



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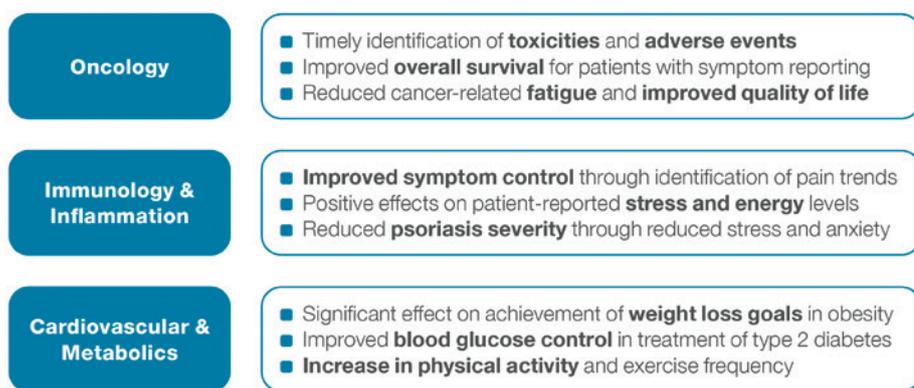


Figure 1: Added value of digital therapeutics per exemplar chronic disease areas.⁷⁻¹⁰

should fully support him in managing, and ultimately improving, his medication intake and disease symptoms. Ideally, the digital health app is paired with a connected drug delivery device that seamlessly feeds data into the digital system. The connected device should require minimal user interaction, passively log injection events and support Adam through the most critical use steps. After being integrated with other data sources and enriched with electronic patient-reported outcomes, the data aggregated from such a system can be presented to the attending physician to enable them to manage medication and evaluate treatment for their patients efficiently and effectively.

Such an integrated device-digital solution, as illustrated in Figure 2, may be available on prescription and rolled out in conjunction with the medication to improve medication adherence, preventive measures and programme engagement, as well as to deliver improvements in health outcomes. In addition, the anonymised connected device and patient-reported outcomes data can provide valuable real-world evidence for pharma companies, including for medication adherence, therapy persistence and quality of life. These insights might then be used as inputs to feed predictive algorithms for treatment evaluation and further research activities.

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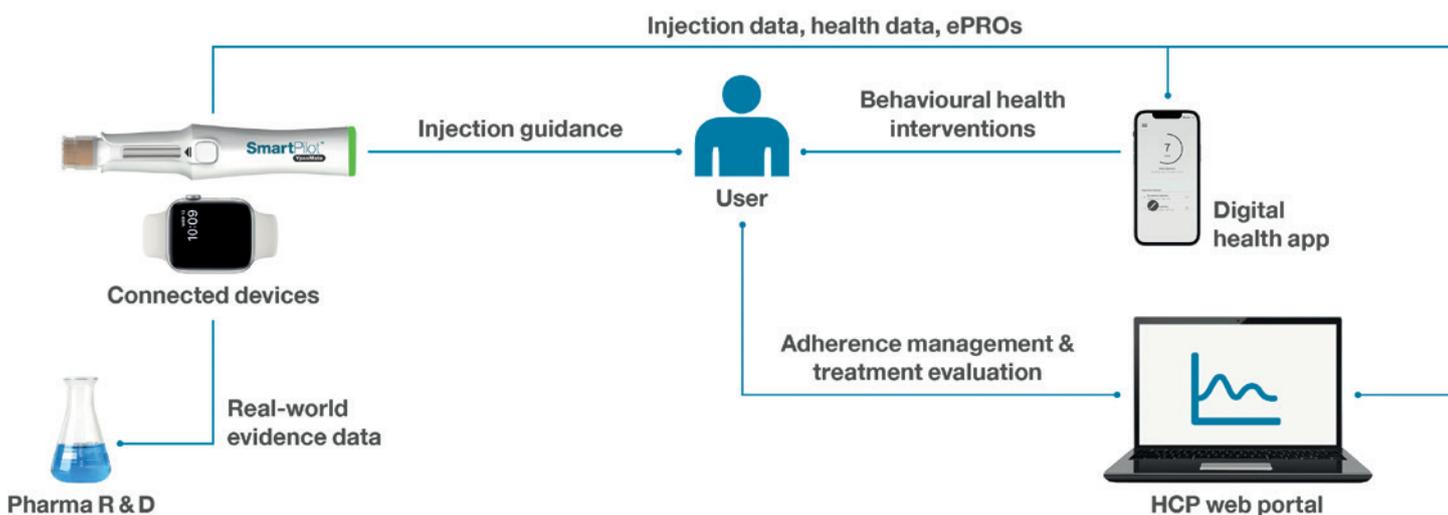


Figure 2: Illustration of an integrated device-digital solution to support behavioural change and empower patients to manage adherence and disease symptoms.

Regardless of the focus disease area, significant efforts are being made to improve treatment adherence. Medication non-adherence is a major problem across the healthcare sector that affects treatment outcomes and imposes significant costs on healthcare systems. In fact, 50–60% of patients being treated for chronic conditions either miss doses, take the wrong doses or discontinue treatment within the first year.¹² Non-adherence to medication results from patient-specific interactions within five sets of factors (Figure 3):

1. Disease-related factors
2. Socio-economic factors
3. Health-system-related factors
4. Therapy-related factors
5. Patient-related factors.⁹

NEED TO ADDRESS SPECIFIC ADHERENCE BARRIERS

Consequently, any device-digital solution aimed at improving medication adherence must address specific barriers and should be tailored to the specific needs of the patient and their therapy context.¹³ A device-digital solution boosts medication adherence by adapting to the patient's needs – not the other way around. This observation has been echoed by the pharmaceutical industry, which has shifted its attention from the development of generic adherence management systems to the development of personalised and therapy-specific device-digital solutions.

Modern designs aim to improve medication adherence by adapting the provision of support, including type, timing and intensity, to an individual's

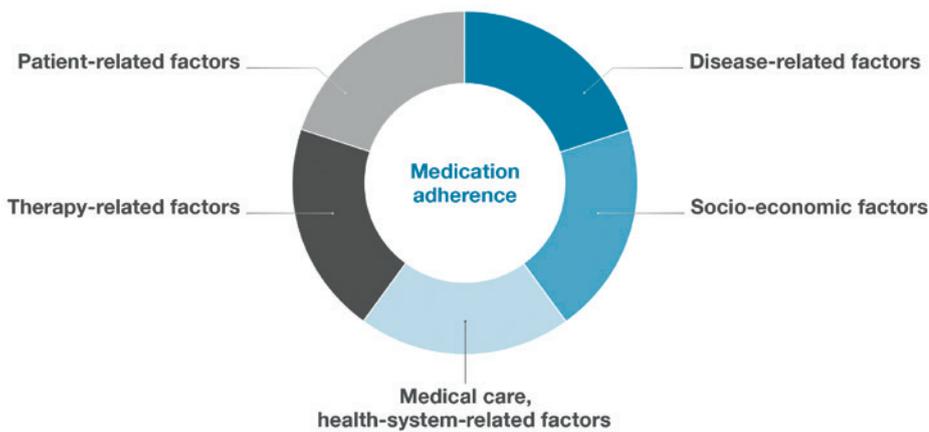


Figure 3: The multidimensional nature of medication adherence.

changing status and contexts over time. The underlying goal is to deliver support when the patient most needs it and is most likely to be receptive – the point at which they are most likely to change their behaviour.¹⁴ To this end, smart connected drug delivery devices are key because they can act on both the timeliness and adaptive nature of these interventions by monitoring the dynamics of an individual’s state and context in real time (Figure 4).

Consider Adam, who may have concerns relating to the use of his drug delivery device. Should his connected drug delivery device detect a use error, it may trigger a digital health intervention that is carefully tailored to the type of use error and Adam’s specific user profile. In addition, the connected device reports the use error in nearly real time, which allows it to trigger an intervention at the point when the error happens, which is when Adam will be most receptive to tips on how to improve his behaviour.

Thus, data from connected devices serve as an important input for digital therapy management solutions, enabling effective behavioural health interventions in terms of both content and timing. Such functionality can help patients to more

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effectively manage their injection regimens and set their expectations regarding their treatment that may, in turn, propel more successful treatment outcomes.

ADVANCING A BROAD PORTFOLIO OF CONNECTED DEVICES

Therefore, Ypsomed is advancing a broad portfolio of connected injection devices that can be structured both into connected add-ons for its proven mechanical self-injection devices and into autoinjectors with

integrated connectivity (Figure 5). First, SmartPilot is the reusable connected add-on for the two-step autoinjector YpsoMate. SmartPilot captures injection events, detects use errors and provides comprehensive real-time injection support, including drug authentication at point of use and step-by-step guidance. Second, YpsoMate On is a prefilled autoinjector with integrated connectivity that can automatically log injections based on advanced proximity measuring protocols, similar to the working principle of covid-19 contact tracing apps.

While YpsoMate On provides a narrower feature set compared with SmartPilot, it retains YpsoMate’s proven two-step device handling and enables automated data capture. Moreover, the device includes LED-based visual feedback to signal an ongoing injection and completion of the injection, including the hold time. The device choice ultimately depends on the intended use of the overall system, as well as the specific user population, injection frequency and other disease-and therapy-specific aspects.

CONCLUDING REMARKS

There is growing evidence of the benefits of device-digital solutions across various disease areas. However, to ensure broad market acceptance, the industry must overcome the challenges associated with the implementation of such device-digital solutions. As Norbert Lauber (Director Autoinjectors & Pump Systems, Novartis Pharma) aptly put it at the SMi Wearable Injectors and Connected Devices conference in 2021, “Adding connectivity expands the combined product into a complex collection of components”.¹⁵

As such, close collaboration between device manufacturers and digital therapy management providers is needed both to

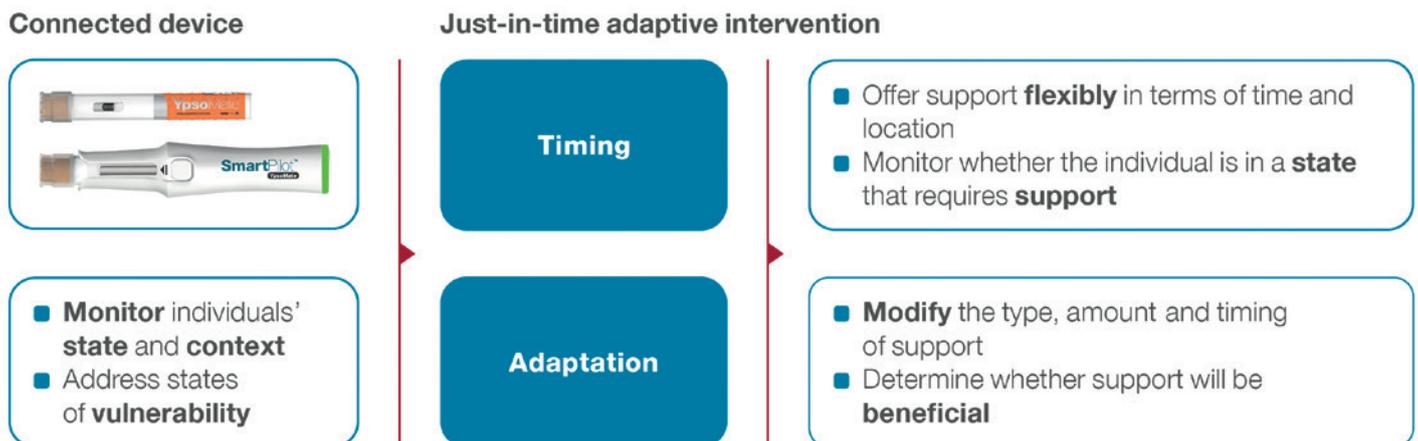


Figure 4: Smart connected devices as a basis for personalised digital health solutions.

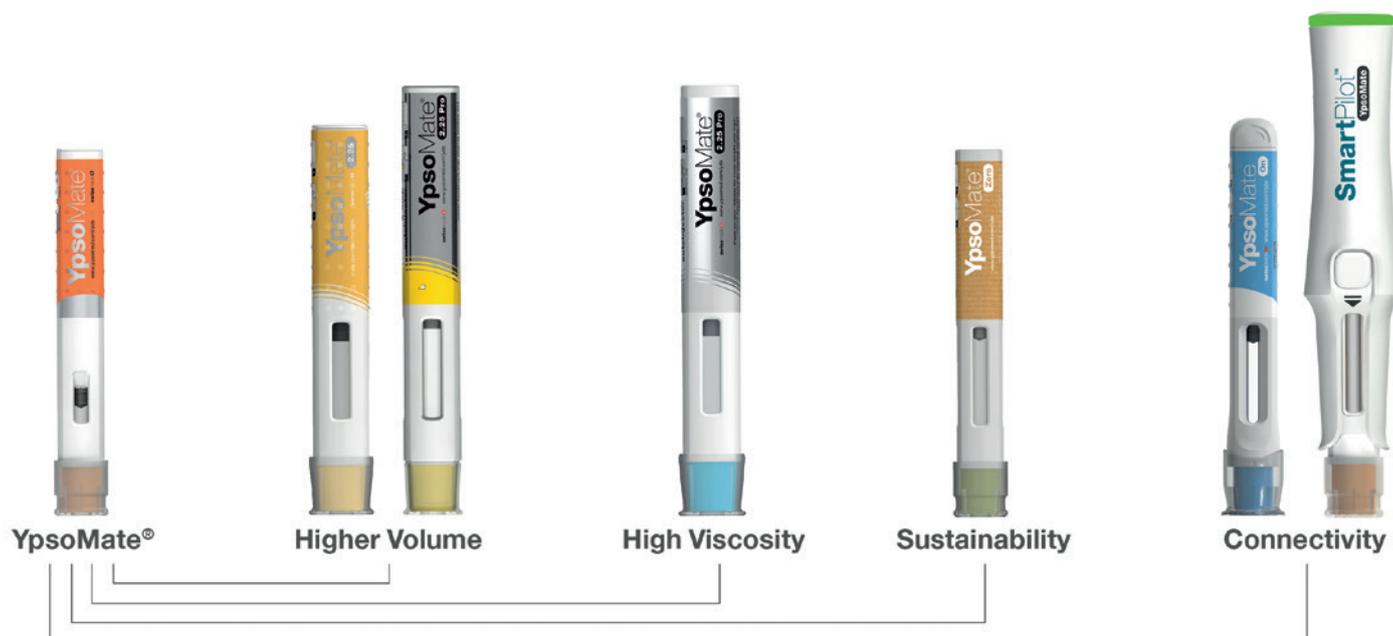


Figure 5: Evolution of the Ypsomed autoinjector portfolio.

lower the complexities of implementing a digital system and to design effective just-in-time interventions tailored to the specific needs of individuals. Joining forces between digital and device solution providers will be a winning formula to deliver substantial value-add for the pharmaceutical industry, patients and the entire healthcare system.

ABOUT THE COMPANY

Ypsomed's comprehensive drug delivery device platforms consist of autoinjectors for prefilled syringes in 1 mL and 2.25 mL formats, disposable pens for 3 mL and 1.5 mL cartridges, reusable pen injectors, ready-to-use prefilled wearable patch injectors and injection devices for drugs in dual-chamber cartridges. Unique click-on needles and infusion sets complement the broad self-injection systems product portfolio.

With over 30 years of experience in the development and manufacture of innovative injection systems, Ypsomed is well equipped to tackle digital healthcare challenges and has strategically invested in the development of connected solutions and therapy-agnostic digital device management services. Anticipating the future needs of patients, pharmaceutical customers, payers and

healthcare professionals, Ypsomed moves beyond manufacturing connected sensors. Ypsomed's smart device solutions strive to transform patients' lives by capturing therapy-relevant parameters, processing them to facilitate self-management of chronic diseases, and integrating these insights with digital therapy management ecosystems.

The company leverages its in-house capabilities in electronics, software and connectivity for the development of new devices and digital product systems. Ypsomed is ISO 13485 certified and all its processes comply with design control and cGMP guidelines with operational QA/QC experts on-site at each location. Ypsomed's FDA-registered manufacturing facilities are regularly inspected by pharma customers and regulatory agencies to supply devices for global markets, including the US, Europe, Japan, China and India.

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ABOUT THE AUTHORS

Andreas Schneider, PhD, is Innovation and Business Development Director at Ypsomed Delivery Systems. He leads a team that drives the definition and development of new drug delivery device platforms, such as next-generation autoinjectors, wearable bolus injectors, connected systems and digital solutions. Dr Schneider has published various articles and given presentations in the areas of innovation management and drug delivery. He holds a PhD in Innovation Management from ETH Zurich, Switzerland.

Philippe Müller is Innovation and Business Development Manager at Ypsomed Delivery Systems. His responsibilities at Ypsomed include the definition and development of new platform devices and business models with a particular emphasis on connected device systems. As such, Mr Müller has been actively involved in the design and development of YpsoMate On – Ypsomed's prefilled connected autoinjector. He holds an MSc in Applied Economic Analysis from the University of Bern, Switzerland.

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