YPSOMED
SELFCARE SOLUTIONS

DEVELOPMENT OF SMART INJECTION DEVICES: INSIGHTS FROM THE YPSOMATE SMART CASE STUDY

Here, Andreas Schneider, PhD, Business Development Manager, Ypsomed, provides insights into recent development activities at Ypsomed in the area of smart self-injection systems, reflecting on the case study of YpsoMate Smart, a two-step auto injector with built-in connectivity and status sensor. YpsoMate Smart is one example of how Ypsomed has taken up the emerging market needs for injection devices with built-in intelligent functions requiring electronics and software. The article first looks at the aspects driving innovation around smart devices. It then focuses on how integrating information technology and cloud connectivity into smart injection devices necessitates opening up internal R&D engines and adopting open innovation methodologies. Finally, the article describes how development activities around smart devices have triggered Ypsomed's shift from traditional routines of problem solving toward broad and flexible technology assessments beyond industry boundaries.

Improvement in therapy outcomes is increasing the need for injection devices that support the administration of medicine with intelligent built-in electronics and software, so-called smart devices. In particular, four major forces are driving innovation around smart devices:

1. Recently developed formulations of new-generation biologics, necessitate only weekly, every- two-weeks, or even monthly, subcutaneous injections. Less frequent dosing is of great value to patients, but the lack of routine calls for more intense patient guidance and feedback before, during, and after injection, beyond the visual and audible feedbacks that current injection devices offer.
2. Health insurers – particularly in US and Europe – are moving away from unit priced payment toward outcome-based compensation models for therapies that generate superior clinical results, particularly for chronic illnesses where self-administration devices are most popular. This, again, increases the need for technical solutions that accurately record whether and how the patient follows the therapy guidelines in addition to providing patient education and coaching. Indeed, improving adherence holds enormous potential. Recent figures, from the US market only, estimate costs of some US$290 billion (£200 billion) – or approximately 8% of total healthcare cost – that result from lack of adherence on the part of the patient.
3. Healthcare stakeholders are starting to accumulate vast amounts of data around therapies from clinical trials as well as "real-world" environments. However, one piece in the jigsaw largely missing so far is whether patients in selfcare environments have correctly administered their medicine.

"Less frequent dosing is of great value to patients, but the lack of routine calls for more intense patient guidance and feedback before, during, and after injection, beyond the visual and audible feedbacks that current injection devices offer."

Dr Andreas Schneider
Business Development Manager
T: +41 34 424 32 06 (direct)
M: +41 79 691 10 65 (direct)
E: andreas.schneider@ypsomed.com

Ypsomed AG
Brunnmattstrasse 6
CH-3401 Burgdorf
Switzerland

www.ypsomed.com

Copyright © 2016 Frederick Furness Publishing Ltd

4. The responsibility for treatment outcomes is moving from physicians to patients and health insurers. As mobile devices, social networks and internet forums become an integral part of everyday activities, patients' awareness for their therapy is increasing significantly.

Together, these four factors accelerate the development of smart injection devices that support the administration of medicine with supplementary intelligent, built-in functionalities. Specifically, information technology, cloud connectivity, and smart phone access are penetrating the fields of drug delivery devices. Such development opens up a new phase of device innovation that looks at interfaces beyond the device.

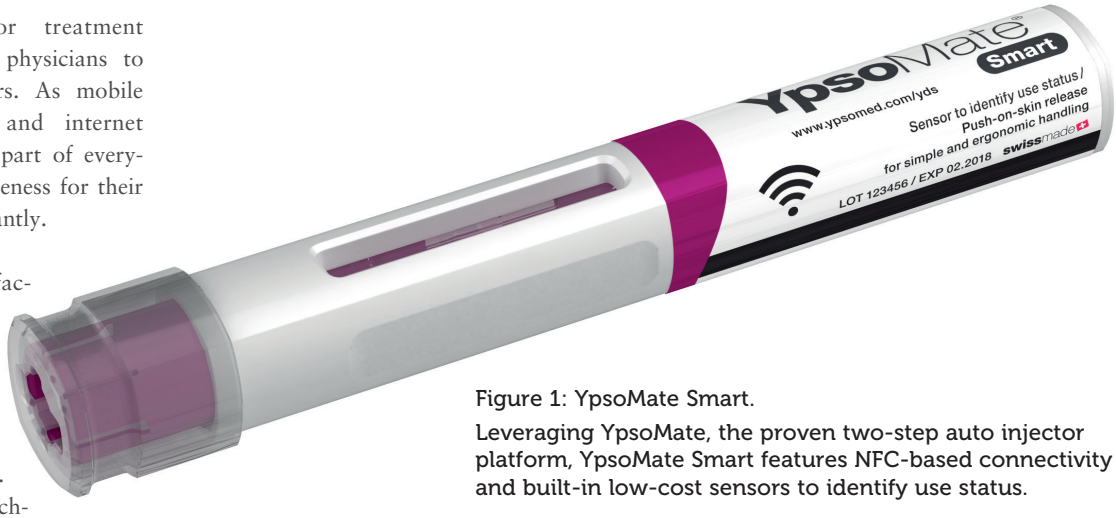

Figure 1: YpsoMate Smart.

Leveraging YpsoMate, the proven two-step auto injector platform, YpsoMate Smart features NFC-based connectivity and built-in low-cost sensors to identify use status.

It requires the opening up of internal R&D competencies to encompass sensor technologies, big data analytics, and management of cloud data services. Inter-organisational collaborations – within and beyond industry boundaries – are necessary for the successful development of smart devices. As Henry Chesbrough, Adjunct Professor and Faculty Director of the Center for Open Innovation (Haas School of Business, University of California, Berkley, CA, US) stated on open innovation in 2003: "Not all the smart people work for us. We need to work with smart people inside and outside our company".

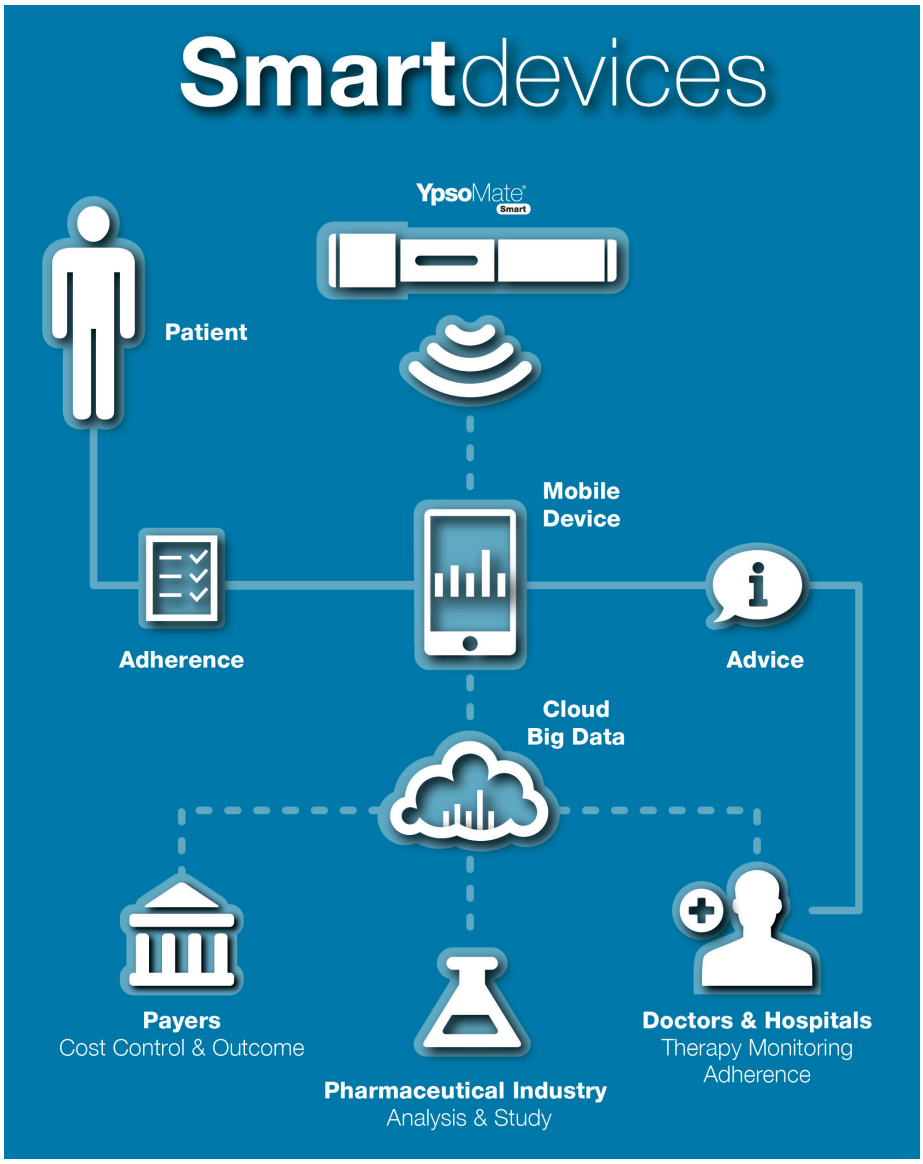

Figure 2: Visualisation of how smart devices integrate into the complex healthcare environment.

The combination of previously unrelated technologies means that this guiding principle for innovation has become more important than ever. This principle is well illustrated by the case of a recent innovation announced by Ypsomed, that is, the development of YpsoMate Smart (see Figure 1).

YpsoMate Smart leverages the proven two-step auto injector platform, YpsoMate, and enhances this popular auto injector platform with electronics and built-in connectivity. Starting from the fully industrialised YpsoMate platform, this enables customers to upgrade their customised YpsoMate device flexibly to YpsoMate Smart as part of lifecycle management.

Specifically, YpsoMate Smart introduces low-cost integrated sensor technology to detect the use status of the auto injector which is wirelessly transmitted to a smartphone using Near Field Communication (NFC). YpsoMate Smart is a first outcome of Ypsomed's strategic initiative that embraces a portfolio of innovation projects supporting the seamless provision of information to patients, physicians and pharmaceutical companies with smart self-injection devices (see Figure 2).

YpsoMate Smart supports all stakeholders in a number of ways. For instance, novel medicines that require infrequent dosing prevent patients from developing an injection routine. It is therefore beneficial to guide patients through the injection process

Copyright © 2016 Frederick Furness Publishing Ltd

closely as well as supporting them by recording therapy events. By scanning YpsoMate Smart with a smartphone, the patient calls up video-enhanced operating instructions before using the device. Once the medicine is administered and the patient scans the device again with his smartphone the patient receives conclusive confirmation that the injection has been successfully administered – including an automatically generated entry in the injection diary and a reminder for the next injection (see Figure 3 for an illustration of YpsoMate Smart's handling concept).

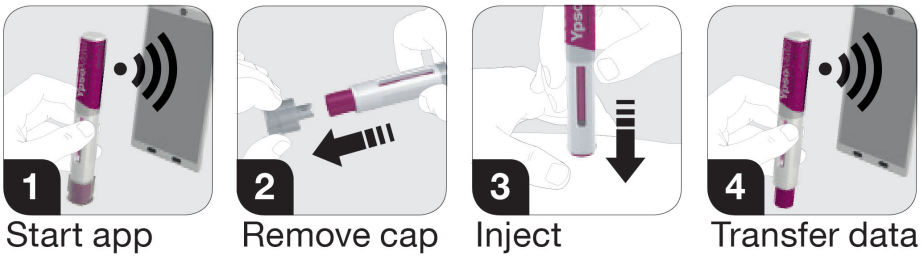

Figure 3: Illustration of YpsoMate Smart handling concept. Before injection, the patient scans YpsoMate Smart with their smartphone to, for example, read video-enhanced instructions for use or check authenticity, perform the injection, and reconnect YpsoMate with the smartphone in order to transfer relevant data.

> "Such development opens up a new phase of device innovation that looks at interfaces beyond the device. It requires the opening up of internal R&D competencies to encompass sensor technologies, big data analytics, and management of cloud data services."

YpsoMate Smart is also of great interest to pharmaceutical companies, allowing devices to be tracked individually on their journey from end-assembly to their use by the patient. Uniquely identifiable NFC tags provide new possibilities for supply chain management. Tracing patient behaviour, it similarly unlocks new dimensions of data collection and analysis during clinical trials as well as in the real world environment. YpsoMate Smart also allows medical practitioners to monitor patient adherence and tailor their patient guidance and advice accordingly. For instance, patients may be asked to self-assess their perceived wellbeing after each injection. Physicians are provided with more information regarding the therapy and have the opportunity to interact with patients between consultations.

The YpsoMate Smart case study reveals how opening up internal R&D processes has become more important than ever to meet emerging market requirements for smart devices. In order to access the cutting-edge technology for development of YpsoMate Smart, Ypsomed collaborates with Thinfilm Electronics (Oslo, Norway).

Thinfilm is a market leader in the area of "printed electronics", that is, electronic circuits manufactured at low cost that can be flexibly scaled up for commercial production. Interestingly, Thinfilm's unique NFC-based tags have initially been used for consumer goods, to fight counterfeits or unauthorised refills, rather than self-injection devices (see Figure 4 for an illustration). As such, Thinfilm's sensor tag has already provided fast-track development of a "smart whiskey bottle", smart enough to detect – by help of a smartphone – whether a given bottle has already been opened or not. The consumer then receives relevant messages guiding his future behaviour.

The big question in forming the collaboration between Ypsomed and Thinfilm was: how exactly to link Thinfilm tags with delivery systems? Systematic external technology assessment concluded that the NFC tag's capabilities add value to auto injectors. The case study thus re-emphasises the importance of broadly scanning seemingly unrelated external technologies and knowledge sources beyond industry boundaries.

YpsoMate Smart is the result of Ypsomed's strategic initiative to broaden the scope of technology and knowledge search activities – with a particular emphasis on the consumer electronics industry, in order to minimise costs and speed up time to market. This enables Ypsomed to meet requirements such as connectivity and data handling via the readily available capabilities of external partners.

Entering strategic collaborations allows Ypsomed to focus on its core competences – the design and development of the interface between device and electronic components.

There's yet another lesson to be learnt from the YpsoMate Smart case study. It shows how the need to integrate information technology or cloud connectivity with injection systems has altered innovation routines at Ypsomed. In particular, the case study highlights how Ypsomed is rethinking how it engages in technology problem solving. Ypsomed broadly scans its environment for technologies that possibly fits the context of injection devices. Ypsomed does not depart from a problem statement narrowly defined before scanning its environment. In addition, it has increased its efforts in technology screening and aims at broadly assessing technologies that offer potential utility to the development of innovative injection devices.

Opening up our internal R&D processes and shifting toward broad technology search patterns reflects two key drivers of innovation around smart devices at Ypsomed. These innovation routines complement other success factors for the development of intelligent injection systems. For instance, consider Ypsomed's unparalleled 30-year experience in design and development of insulin pumps, pens and auto injectors, its ability to anticipate customer needs and translate these into flexible platform products, with a clear focus on fully automated high-volume manufacturing processes. This unique set of capabilities puts Ypsomed in a favourable position to develop exciting novel smart product platforms beyond YpsoMate Smart, the final result being smart functionalities, which can be reliably integrated into disposable pens, auto injectors and wearable injectors.

ABOUT YPSOMED

Ypsomed is a leading developer and manufacturer of innovative auto injector and pen injector systems for self-administration of injectable drugs. The customisable product platforms cover auto injectors for prefilled syringes in 1 mL and 2.25 mL formats, disposable pens for 3 mL and 1.5 mL cartridges, reusable pens that include automated injection mechanisms, and easy-to-use injection devices for drugs in dual-chamber cartridges such as lyophilised drugs.

Copyright © 2016 Frederick Furness Publishing Ltd

Our modular and proven custom product technologies guarantee that Ypsomed injection systems are rapidly available for clinical studies and market introduction. Innovative and patented technologies offer our customers user-friendly injection systems with which they stand out successfully in the market. All our products are characterised by reliable and well-thought-out technical concepts, which are optimised for automated manufacturing. Unique click-on needles and infusion sets complement the broad self-injection systems product portfolio. Ypsomed provides its partners excellent technological expertise and full regulatory support for the device relevant aspects of the registration process.

Ypsomed's injection systems are developed and manufactured in Switzerland with strong in-house competencies covering concept and product development, tool-making, injection moulding and automated assembly. Ypsomed is ISO 13485 certified and all processes are run according to design control and cGMP guidelines with operational QA/QC experts on-site at each location. Ypsomed's US FDA-registered manufacturing facilities are regularly inspected by both pharma customers and regulatory agencies and supply devices for global markets including US, Europe, Japan, China and India. Ypsomed has more than 30 years of experience and well-established relationships with numerous leading pharma and biotech companies.

Figure 4: Thinfilm's sensor technology used in combination with YpsoMate Smart. The sensor is a printed integrated circuit for use in electronic read-only transponders (passive sensor). The tag transmits data (128 bits) at a frequency of 13.56MHz used by HF RFID and NFC (operating in a Tag-Talks-First manner). The code of the NFC signal changes as the linker of its antenna is physically disrupted. As such, the change in the NFC signal corresponds to the actual use status of YpsoMate Smart.

MANAGEMENT FORUM

THE AUTHORITY IN CONFERENCE EXPERIENCES FOR MEDICAL DEVICE PROFESSIONALS

www.management-forum.co.uk

International Conference

CONNECTIVITY IN MEDICAL TECHNOLOGY

The Future of Medical Devices Has Arrived…

22-23 June 2016, The Rembrandt Hotel, London

- Hear the latest trends in wireless medical device development
- Discover advances in mobile health products
- Keep abreast of new technologies
- Get an insight into advanced patient monitoring
- Clarify the FDA and EU guidance on medical device software

Understanding connected medical devices, medical mobile Apps and the Medical Device Internet of Things

For more information contact: Andrea James +44 (0)20 7749 4730
email: *andrea.james@management-forum.co.uk*
website: *www.management-forum.co.uk*

Copyright © 2016 Frederick Furness Publishing Ltd