

YPSOMED

SELFCARE SOLUTIONS

SMARTPILOT FOR YPSOMATE: TRANSFORMING A PROVEN AUTOINJECTOR INTO A FULLY CONNECTED DEVICE

In this article, Orfeo Niedermann, Business Development Director, Ypsomed Delivery Systems, provides insights into how connectivity enhances existing autoinjectors and adds value for users, physicians, pharma companies and insurers. Specifically, he sheds light on how SmartPilot, a re-usable add-on with built-in wireless communication and advanced sensors, transforms the standard YpsoMate 2-step autoinjector into a fully connected self-injection system. The article then illustrates how smart devices offer new possibilities to monitor adherence patterns during clinical testing and improve therapy outcomes with real-time, in-use patient guidance and tracking of injection history and success.

With the large number of new biologics the demand for devices for the subcutaneous (SC) self-injection of biopharmaceuticals continues to grow and develop. The need for simpler self-injection procedures and improved patient adherence for autoinjectors, pens and large-volume patch injectors is increasing. Smart technologies offer new possibilities to

improve patient adherence and therapy outcome. There are a number of drivers stimulating the development and use of smart and connected devices.

LESS FREQUENT INJECTIONS

With improved formulations and larger injection volumes, new biologics typically require weekly, biweekly or even monthly SC injections. On the one hand, less frequent injections reduce patient exposure to the moments of injection discomfort and the hassle of storing and preparing the drug product. The lack of injection routine, on the other hand, calls for even simpler use of the device and need for more guidance and feedback before, during and after injection.

CHANGES IN DRUG REIMBURSEMENT MODELS

With healthcare costs soaring for newer biologic therapies health insurers are looking to move away from unit priced payment towards outcome-based compensation models for therapies aligned with superior clinical results. This also drives the need for technical solutions that automatically record whether, and how successfully, the patient follows therapy guidelines.

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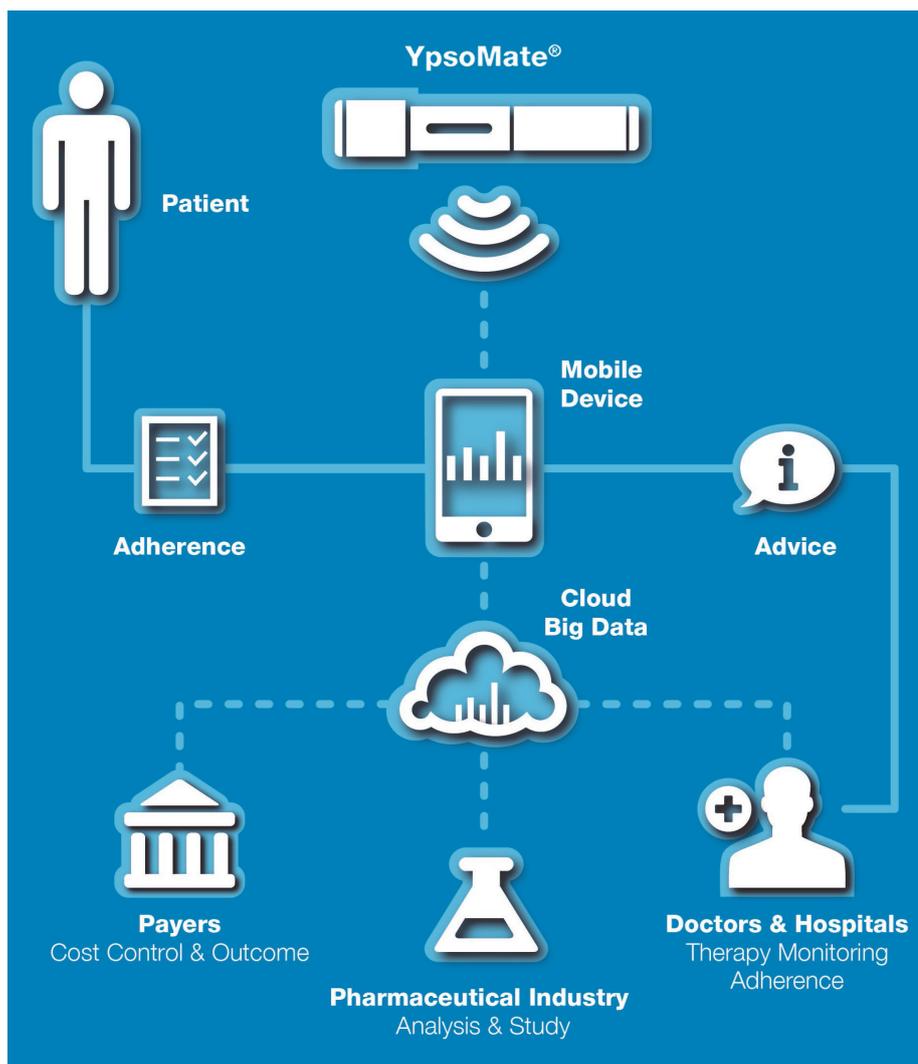


Figure 1: Environment and network interacting with the patient.

ANALYSIS OF REAL-WORLD DATA

Pharma companies are accumulating vast amounts of data about therapies and disease states during clinical trials and post-market surveillance. However, one important factor in the equation is whether patients in self-care environments have correctly administered their medicine. This also calls for a simple and automatic log book for all patient administered doses.

PATIENT & HEALTHCARE INVOLVEMENT

As the internet, mobile devices, social networks and patient forums gather information, patient awareness for their therapy status and effectiveness increases significantly. The acceptance and demand for electronic, connected devices and software is growing quickly and further supporting the need for smart self-injection devices (Figure 1).

SMART ADD-ON TRANSFORMS AUTOINJECTOR INTO A FULLY CONNECTED DEVICE

The world of self-injection pens and autoinjectors has seen a clear trend to prefilled disposable devices. Key drivers are simplicity of use in combination with pharma company needs to improve efficiency of the supply chain and simplify device replacement.

For connected devices the necessary sensors, transmission and power sources are not yet affordable to be fully integrated into disposable pens and autoinjectors. This is why Ypsomed is developing solutions to combine the strengths of a ready-to-use disposable device with the technical possibilities of reusable add-ons.

At this year's PDA Universe of Prefilled Syringes & Injection Devices Conference (Huntington Beach, CA, US, October 17-18, 2016), Ypsomed presents its latest advancement in smart devices that

"The device detects and communicates different use states and allows the smartphone to provide real-time step by step instructions in written, animated and audible formats."



Figure 3: Illustration of a patient loading a standard YpsoMate 2-step autoinjector into the fully connected SmartPilot add-on.

leverages the proven and fully industrialised YpsoMate autoinjector platform.

SmartPilot (see Figure 3) is a reusable add-on for the standard YpsoMate autoinjector that not only tracks and wirelessly transmits the success of injection events but also pilots the patient in real-time throughout the injection process. This is achieved with advanced visual and audible feedback from the add-on, display of complementary information on a related mobile app, and individualised ergonomics. SmartPilot flexibly transforms a standard YpsoMate autoinjector into a fully connected device.

As SmartPilot is compatible with YpsoMate autoinjectors without further modification, it offers an ideal solution for existing and future YpsoMate customers who want to equip their device with connectivity flexibly as part of product lifecycle activities. SmartPilot may also be used as a means for monitoring and analysing progress of and patients' adherence patterns during clinical trials. In addition, the complementary mobile app may be enriched with questionnaires for patients to self-report their wellbeing and other disease-relevant parameters.

IN-USE GUIDANCE INCLUDING HOLDING TIME INFORMATION

In conjunction with the use of a smartphone and the related mobile app, SmartPilot can provide patients with video-enhanced instructions on how to use the autoinjector. The device detects and communicates different use states and allows the smartphone to provide real-time step by step instructions in written, animated and audible formats. This includes the option of providing precise advice on recommended holding time to reach complete delivery of the drug.

SmartPilot identifies handling errors and instructs patients on corrective actions with the help of the mobile app. As such, the technology complements conventional training methods and trainer devices. Data exchange between SmartPilot for YpsoMate and a patient smartphone is established via Bluetooth Low Energy (BTLE), an emerging standard compatible with all available smartphones and standard operating systems.

ADVANCED TECHNICAL SOLUTION

A key challenge when developing SmartPilot was to identify relevant device status

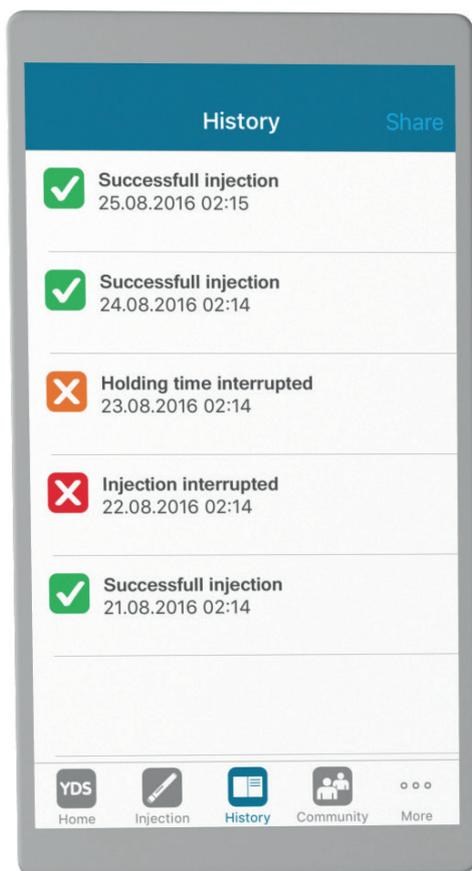


Figure 4: Illustration of information displayed on SmartPilot mobile app: the injection history provides an overview of injection events and indicates handling errors.

information without physically modifying the existing YpsoMate autoinjector platform.

Ypsomed has developed a concept based on a contactless sensor solution that detects and differentiates between:

- Pushing the device on skin
- Completion of needle insertion and start of injection
- End of injection
- Removal of device from skin
- Locking of needle shield.

SmartPilot can therefore distinguish and recognise errors such as removing YpsoMate from the skin during injection or interruption of the holding time. Such information is recorded, transferred to the smartphone and processed for subsequent analysis (see Figure 4). Availability of such

data not only instructs patients on how to use YpsoMate correctly but assists healthcare professionals, caregivers, and pharmaceutical companies. For instance, it may be used specifically to further improve patient training materials, to explain previous unexplained variations in clinical studies, or to support outcome-based payment scenarios.

USE WITH OR WITHOUT SMARTPHONE

SmartPilot also directly provides visual and audible feedback to patients on injection success or errors, without needing to have a smartphone connected during the injection



Figure 5: SmartPilot for YpsoMate, ready for injection.

process. SmartPilot provides integrated visual and audible feedback that guides the patient through the injection process and indicates use errors. It even advises the user on the recommended holding time by means of a flashing LED light and audible feedback (Figure 5).

In addition, SmartPilot has built-in memory to record and store information covering multiple injection events. It saves use data including date, time and potential use errors on the device itself. Such information then can be read out either by patients and caregivers at a later point in time or by HCPs during a periodic check-up.

LEVERAGING SMART TECHNOLOGIES & INTERNET

The possibilities to enlarge the benefits of the associated smartphone app and internet connectivity are countless and will certainly evolve. The patient can easily be reminded when to perform the next injection. If an injection was not performed as scheduled, the patient will receive a reminder or a friendly personal call to motivate adherence for the next injection.

SmartPilot-related software may also track other health-relevant information around the patient or log patient self-reported health status or wellbeing. For more frequent or larger injections it may be helpful to track and recommend the subsequent injection site (see Figure 6). The patient may also have access to virtual patient forums and online communities to share experiences or injection-relevant information.

CONCLUSION

The YpsoMate family of 1 mL and 2.25 mL devices is enjoying significant success for both originator and biosimilar biologics due to their ease of use based on 2-step, button-less, push-on-skin technology. This is reinforced by Ypsomed's focus on well thought out, flexibly customisable designs manufactured on fully automated manufacturing infrastructure.

The development of SmartPilot for YpsoMate provides pharma companies with the ideal clinical and marketing tool to pioneer the next phase of self-administration device development in a connected world.

SmartPilot allows YpsoMate to be flexibly upgraded into a fully connected device and also provides advanced real-time user feedback. The related mobile app further enables display and analysis of complementary information, such as instructing patients on how to avoid use errors or advising on where to inject next. SmartPilot is suitable to monitor patient behaviours and adherence patterns during clinical trials. However, it also

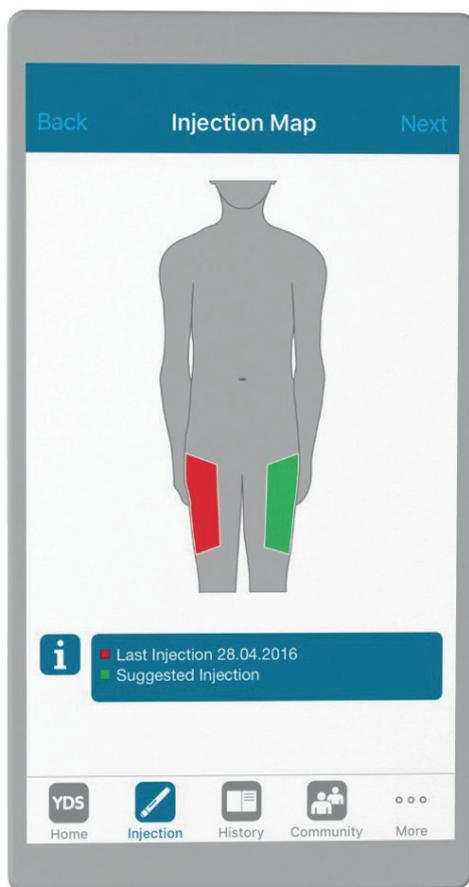


Figure 6: Injection map advising the patient where to inject next.

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reflects a tool to transform the proven 2-step autoinjector into an internet-of-things enabled device to accelerate further the transition towards outcome-based payment models.

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ABOUT YDS – YPSOMED DELIVERY SYSTEMS

Ypsomed is the leading independent developer and manufacturer of innovative autoinjector and pen injector systems for self-administration of injectable drugs. The customisable product platforms cover autoinjectors for prefilled syringes in 1 mL and 2.25 mL format, 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. 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 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 ISO13485 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 companies 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 working relationships with numerous leading pharma and biotech companies.

Go for simplicity.



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The complete range of 2-step autoinjectors

- Suitable for standard 1 ml long and 2.25 ml pre-filled syringes
- Push-on-skin release for most simple and ergonomic handling
- Clear confirmation “clicks” and large viewing window for optimum patient control
- Easy to customise and flexible platform product assures short timeline and low project risks
- YpsoMate® 2.25 Pro with constant force drive is suitable for a large range of viscosities



For more information visit www.ypsomed.com/yds

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