YPSOMED
SELFCARE SOLUTIONS

SIMPLE AND SECURE ADHERENCE MONITORING: YDS SMARTSERVICES™ FOR END-TO-END SMART DEVICE INTEGRATION

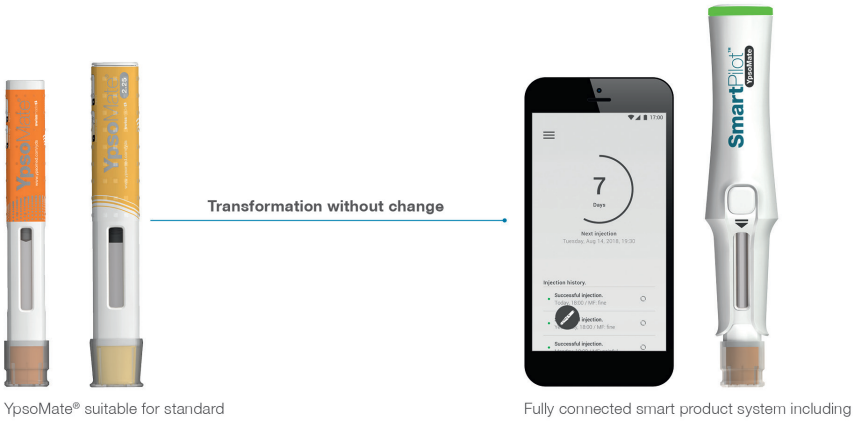
Whilst there is much discussion on how to apply connectivity and smart devices to therapies, there is far less dialogue concerning the challenges inherent to the digital architecture needed to make such innovations work in practice. Here, Andreas Schneider, Innovation & Business Development Manager, Ypsomed Delivery Systems, introduces YDS SmartServices™, Ypsomed's digital turnkey solution to effectively embed smart devices in a broader digital ecosystem.

INTRODUCTION

The self-injection industry is experiencing a transition from purely mechanical devices to digitally enhanced, connected smart drug delivery systems. Novel approaches to the self-management of diabetes highlight this emerging paradigm shift. For instance, smart self-injection pens may support patients with capturing information about dosage and timing of insulin administration. Mobile applications remind patients to monitor blood glucose levels regularly or assist in the calculation of prandial insulin doses.

CONNECTIVITY & SMARTPILOT™

Although diabetes management has a history of pioneering patient-centric drug delivery technologies, the concept of connected drug delivery has applications well beyond the administration of insulin. Other chronic disease states that similarly require repeated self-administration of drug products also benefit from novel connected technologies, for example SmartPilot™ for YpsoMate®, a reusable connected add-on module with built-in sensor technology and wireless communication capabilities for the two-step autoinjector YpsoMate® (Figure 1).



YpsoMate® suitable for standard 1 ml long and 2.25 ml pre-filled syringes

Fully connected smart product system including YpsoMate®, SmartPilot™ and mobile application

Figure 1: Illustrating the transition from mechanical self-injection devices to connected drug delivery systems, SmartPilot™ for YpsoMate® is a reusable smart add-on transforming the two-step autoinjector YpsoMate® into a smart product system.

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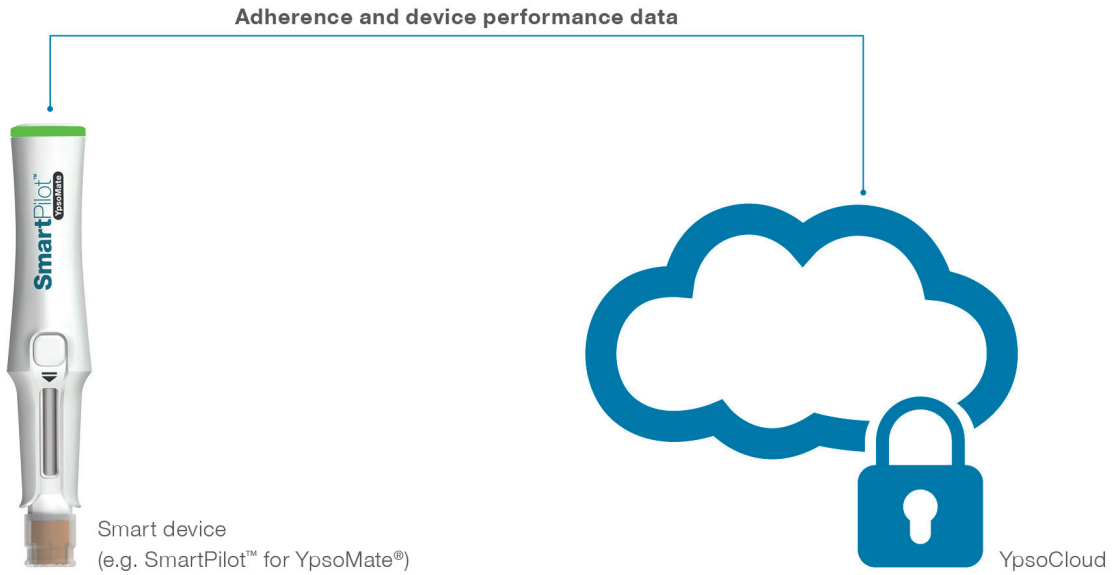
SmartPilot™ is used across molecular entities and disease areas both in clinical trials and as part of commercial product lifecycle management. The sensor concept has been developed so the standard proven autoinjector platform is compatible with SmartPilot™ without further modification.

The connected reusable add-on not only tracks injection date, time and success, but also provides advanced real-time guidance throughout the injection process. As such, it supports patients at each use step – including advice on the holding time – and confirms that the correct medication is being injected.

Streamlined connected device innovations, such as the SmartPilot™ for the YpsoMate® autoinjector, will provide innovative functionalities for patients, which digital health organisations can link with therapy-specific value propositions. While significant efforts are being made to link device functionality with disease-specific behavioural interventions or use cases, there still remains the key challenge of embedding connected devices into an end-to-end internet of things (IoT) ecosystem. This raises questions like:

- How to constantly monitor connected devices once launched across regions?
- How to control access to different smart devices?
- How to easily integrate smart devices with a therapy app?
- How to make therapy-relevant adherence and smart device performance data available?



Service 1: Ease-of-integration

Web-based application programming interface (API) as a standard interface for smart devices. The standard interface simplifies access to adherence and smart device performance data.

Service 2: Smart device life cycle management

Insights into and control of smart devices during clinical trials and commercial use. Ypsomed enables smart device life cycle management across disease areas.

Service 3: Securing device-to-cloud communication

Securing the communication from smart devices to cloud. YDS SmartServices™ provide true end-to-end security for the entire product system taking into account both device and cloud.

Figure 2: Overview of YDS SmartServices™, providing an end-to-end secured solution that integrates smart devices in order to simplify adherence monitoring.

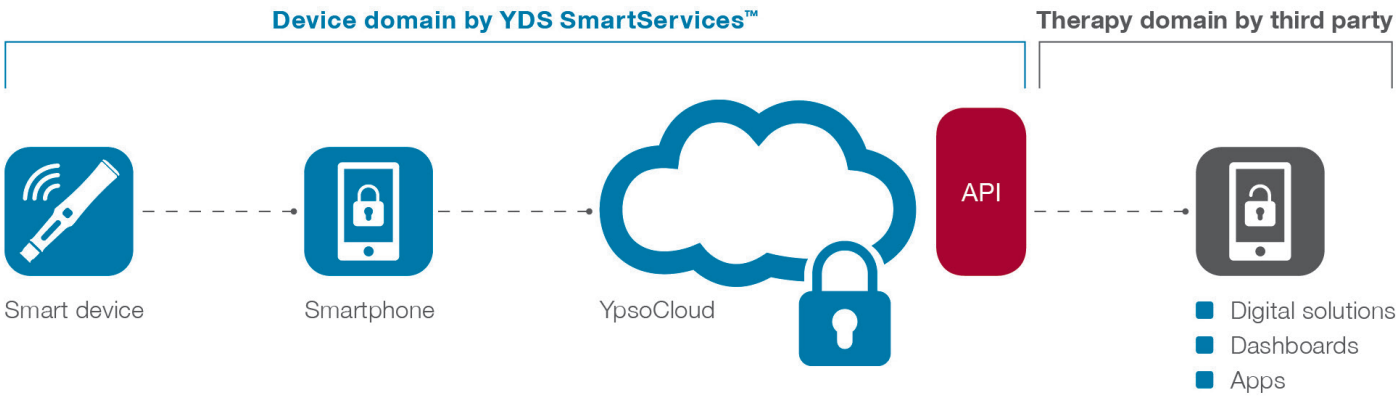


Figure 3: Service 1 – Introducing ease-of-integration across therapy-specific product systems. YDS SmartServices™ features a standardised web-based API to simplify reading and writing data to other third party services.

YDS SMARTSERVICES™

The pharmaceutical industry has been focusing extensively on the therapy and paying less attention to the device-oriented domain of connected drug delivery systems. This has resulted in a fragmented and distorted understanding of effectively embedding connected devices in a broader IoT ecosystem. Here we will present YDS SmartServices™: a turnkey digital solution that provides three key digital services to simplify adherence monitoring providing secure end-to-end smart device integration (Figure 2).

Firstly, YDS SmartServices™ simplifies access to adherence and smart device performance data, shifting the integration point to a standard web-based application-programming interface (API) as shown in Figure 3. Integration via web-based APIs reflects the emerging good practice for reading and writing data to services and third-party applications.

The web-based API connects the device domain with the therapy-oriented domain of connected drug delivery systems. Therapy-relevant adherence data that would normally be time consuming to obtain can instead be accessed easily. As such, the web-based API reflects the starting point for pharmaceutical partners to build therapy-specific mobile applications and to realise therapy-specific use cases and behavioural interventions in order to provide the most value to the targeted patient population.

Secondly, another device-oriented challenge is that the pharmaceutical industry has not systematically implemented therapy-agnostic digital lifecycle management services. It is the very connected nature of smart drug delivery devices that has a dramatic impact on launching, maintaining and retiring such devices during clinical trials or commercial use. Smart devices require constant monitoring once introduced across regions. Organisations must continually improve and collect data around smart device performance. YDS SmartServices™ offers a set of digital lifecycle management services in order to provide complete insights into and control of smart devices (Figure 4).

YDS SmartServices™ supports all five lifecycle management processes, independent of disease area:

1. **Plan:** Design and testing of end-to-end connectivity systems.
2. **Provide:** Effortless advanced onboarding and managed access to secure device usage data.
3. **Configure:** Effective implementation of network security.
4. **Monitoring:** Real-time analysis and interpretation of smart device performance.
5. **Retire:** Controlled end-of-life management of smart devices, e.g. after successful completion of a clinical trial.

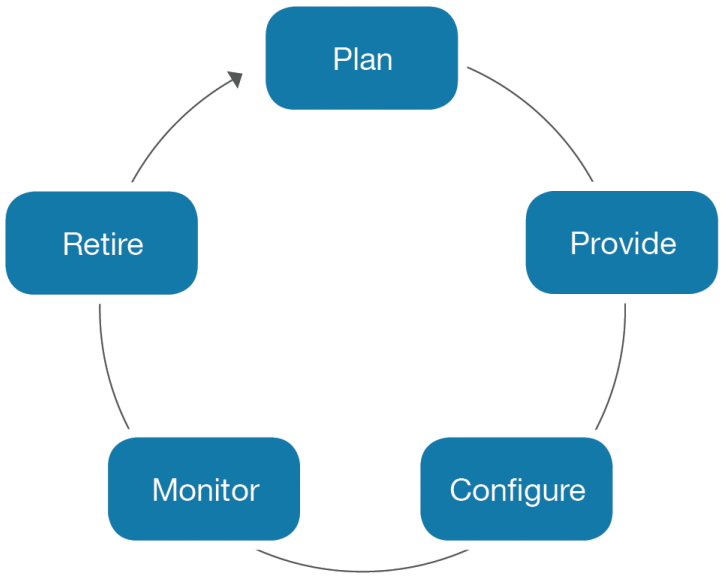


Figure 4: Service 2 – Smart device lifecycle management. YDS SmartServices™ provides digital lifecycle management services, thereby offering insights into and control of smart drug delivery systems during clinical trials and commercial use.

Thirdly, YDS SmartServices™ provides true end-to-end security for the entire product system, controlling both device and cloud (Figure 5). In so doing, the managed digital services not only meet the requirements concerning data privacy and security (e.g. HIPAA, GDPR, 21 CFR Part 11) but also act as differentiating factor to gain patient trust and motivate long-term usage of smart drug delivery systems.

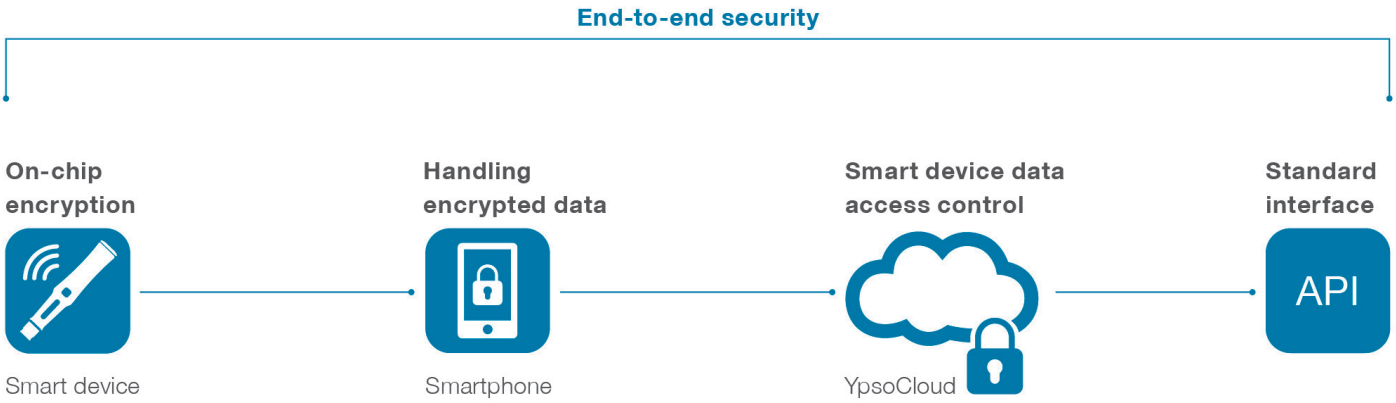


Figure 5: Service 3 – Securing device-to-cloud communication. YDS SmartServices™ implements security-by-design for the entire product system.

CONCLUSION

Soaring interest in smart drug delivery is urging the healthcare industry to fully understand the complexities related to embedding such connected smart devices into broader digital ecosystems. However, such device-domain challenges have received limited attention to date. The industry has been more concerned with the development of therapy-oriented use cases and linking device technology with disease-specific behavioural interventions.

This article calls for enlarging the scope from therapy-oriented to device-oriented challenges. Focusing on digital lifecycle management services, ease-of-integration and end-to-end security, YDS SmartServices™ addresses these often neglected device-oriented challenges independent of specific therapies. Leveraging Ypsomed's experience in and insights from the global marketing of a diabetes management IoT ecosystem, YDS SmartServices™ has established an industry-leading reference IoT architecture for embedding smart devices into digital ecosystems. In so doing, YDS SmartServices™ offers a new means to simplify and secure therapy-relevant adherence monitoring (Figure 6).

ABOUT THE COMPANY

Ypsomed is the leading independent developer and manufacturer of innovative self-injection and insulin pump systems for self-administration. Within the Delivery Systems business unit the customisable

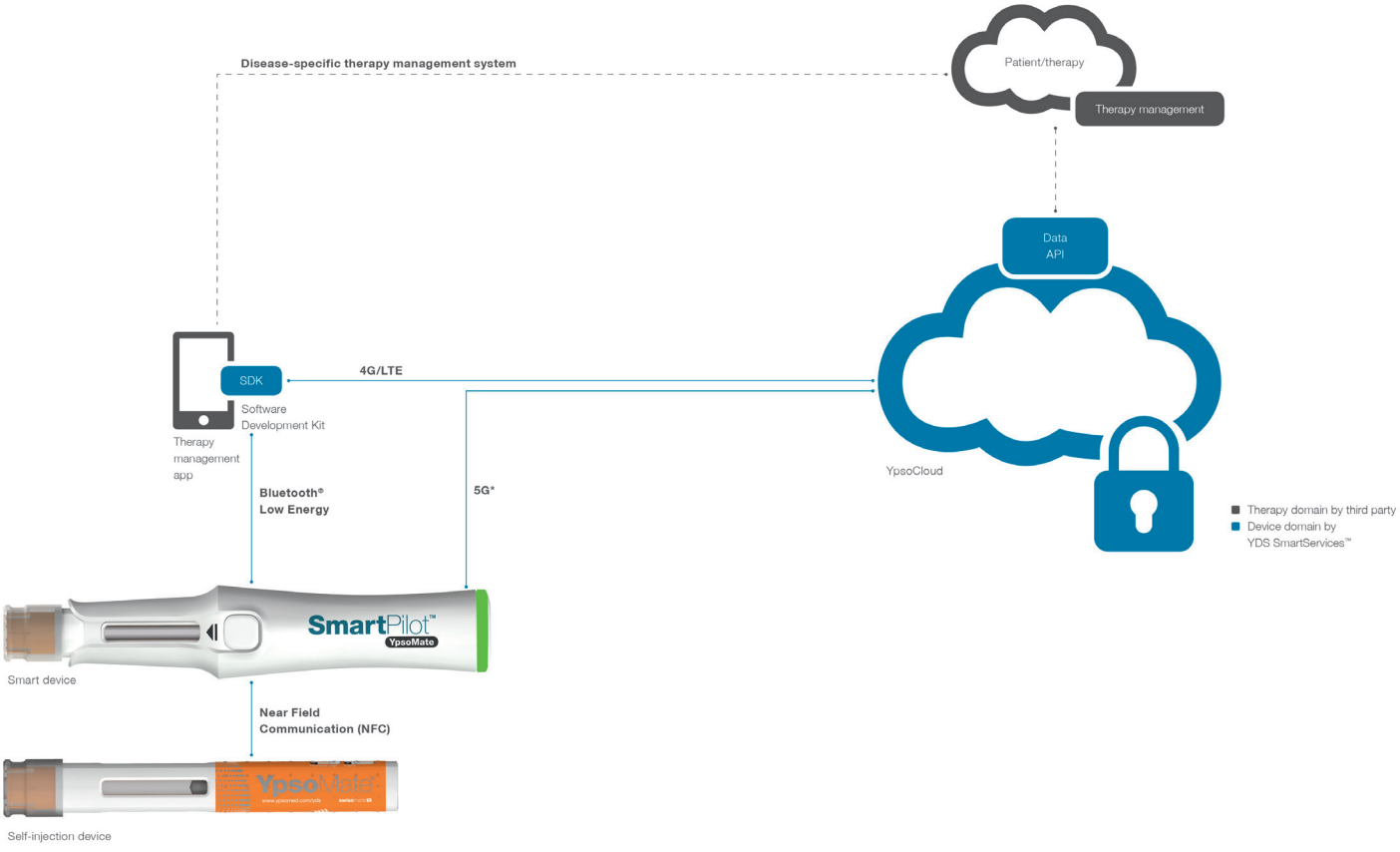


Figure 6: YDS SmartServices™ introduces an IoT architecture to provide secure end-to-end smart device integration and simplify access to therapy-relevant data.

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 and easy-to-use injection devices for lyophilised drugs in dual-chamber cartridges. Unique click-on needles and infusion sets complete the broad self-injection systems product portfolio. The 3–10 mL YpsoDose patch injector draws on Ypsomed's depth of expertise in diabetes care with fully connected insulin pump systems. Ypsomed provides its partners with excellent technological expertise and full regulatory support for the device relevant aspects of the registration process.

The 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 the US, Europe, Japan, China and India. Ypsomed has more than 30 years' experience and well-established working relationships with numerous leading pharma and biotech companies.

ABOUT THE AUTHOR

Andreas Schneider is Innovation & Business Development Manager with Ypsomed Delivery Systems. His responsibilities at Ypsomed include the definition and development of new platform devices with a particular emphasis on connected and smart device systems. As such, he has been actively involved in the design and development of SmartPilot for YpsoMate, a reusable connected add-on that transforms the proven two-step autoinjector into a connected system. Dr Schneider has published various articles and held presentations in the areas of innovation management and drug delivery. He received his PhD in Innovation Management and Organisation Sciences from ETH Zurich, Switzerland.

ON drugDELIVERY

2018/19 EDITORIAL CALENDAR

Publication Month	Issue Topic	Materials Deadline
Nov 2018	Pulmonary & Nasal Drug Delivery	PASSED
Dec 2018	Connecting Drug Delivery	Nov 1st 2018
Jan 2019	Ophthalmic Drug Delivery	Dec 6th 2018
Feb 2019	Prefilled Syringes & Injection Devices	Jan 3rd 2019
Mar 2019	Skin Drug Delivery: Dermal, Transdermal & Microneedles	Feb 7th 2019
Apr 2019	Pulmonary & Nasal Delivery	Mar 7th 2019
May 2019	Injectable Drug Delivery	Apr 4th 2019
Jun 2019	Connecting Drug Delivery	May 2nd 2019
Jul 2019	Novel Oral Delivery Systems	Jun 6th 2019
Aug 2019	Industrialising Drug Delivery Systems	Jul 4th 2019
Sep 2019	Wearable Injectors	Aug 1st 2019
Oct 2019	Prefilled Syringes & Injection Devices	Sep 5th 2019
Nov 2019	Pulmonary & Nasal Drug Delivery	Oct 3rd 2019
Dec 2019	Connecting Drug Delivery	Nov 7th 2019

YDS SmartPilot™ YpsoMate

Go for smart guidance.

swissmade

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Reusable add-on transforms YpsoMate® into a fully connected smart autoinjector.

- Bluetooth®-based wireless tracking of injection date, time and success
- Advanced patient guidance throughout the injection process
- NFC-based identification of combination product label to increase patient safety
- YpsoMate® autoinjector compatibility with SmartPilot™ without further changes
- No need to charge SmartPilot™ during its entire lifetime

For more information visit www.ypsomed.com/yds

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