

# Go for secure adherence monitoring.



## Digital solution provides secure end-to-end smart device integration to access therapy-relevant data.

- Standardised web-based integration point simplifies access to therapy-relevant data
- Secured device-to-cloud communication for therapy-relevant data
- Life cycle management of smart devices during clinical trials and commercial use



More confidence. More success. With Ypsomed Delivery Systems.



## Smart devices need to be embedded in a digital ecosystem

Introducing YDS SmartServices™ across self-injection device platforms

- **Tracking:** Connected real-time tracking of injection date, time and success e.g. use errors
- **Guidance:** Advanced guidance throughout the injection process e.g. advice on holding time
- **Transmission:** Seamless transmission of relevant data across communication protocols and interfaces



YDS SmartServices™ embed smart devices in a broader digital ecosystem. The managed digital services provide a turnkey solution to simplify adherence monitoring and provide secure smart device integration.



## Challenges related to smart devices

Need to address device-related complexities independent of therapies

### How to ...

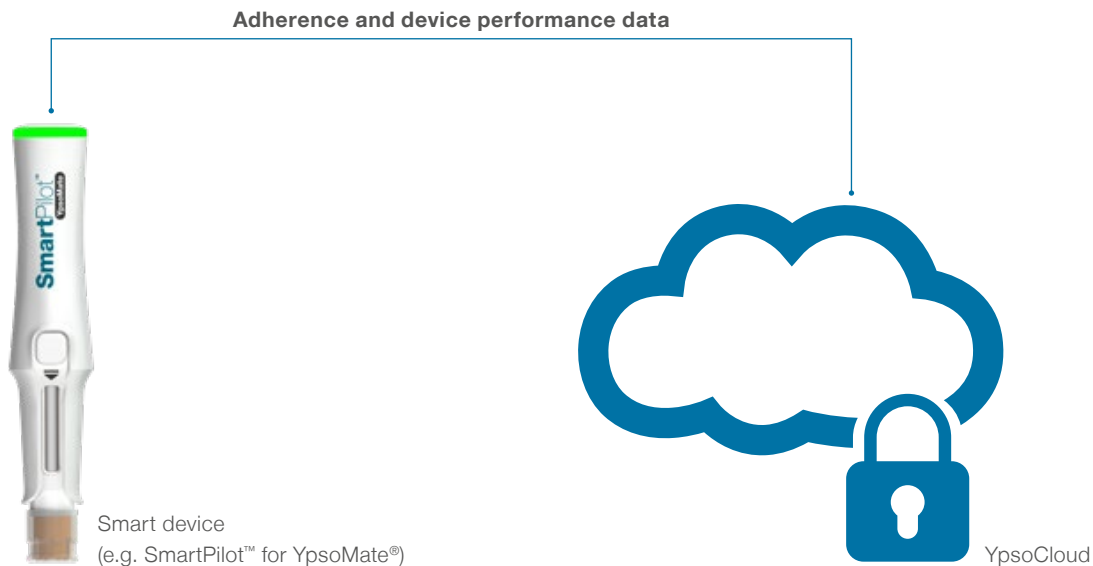
- ... constantly monitor smart devices once launched across regions?
- ... control access to different smart devices?
- ... easily integrate smart devices with a dedicated therapy app?
- ... configure and remotely push updates to smart devices?
- ... secure device-to-cloud communication for therapy-relevant data?
- ... ensure integrity of adherence and smart device performance data?

How to make available adherence and smart device performance data?



## YDS SmartServices™ simplify adherence monitoring

Three digital services address device-related challenges



YDS SmartServices™ provide an end-to-end secured turnkey digital solution that simplifies the development process and supports the market introduction of smart devices across therapy-specific use cases. YDS SmartServices™ are based on three distinct yet interrelated digital services:



### 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

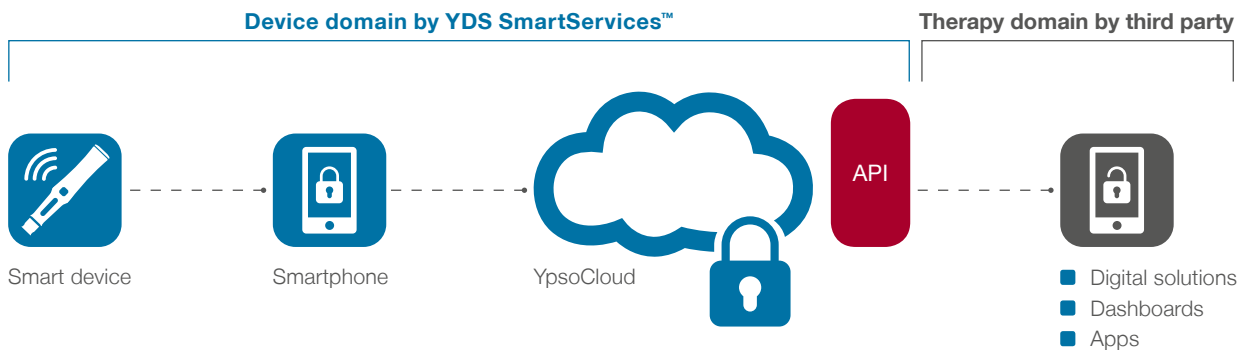
Securing the communication from smart devices to cloud. YDS SmartServices™ provide true end-to-end security for the entire product system taking into account both device and cloud.



## Service 1: Ease-of-integration

Standard application programming interface (API)

YDS SmartServices™ simplify access to adherence and connected device performance data by moving the integration point to a standard web-based application programming interface (API). The standard API connects the device domain to the therapy domain. Therapy-relevant data that would be time-consuming to obtain can be easily accessed.



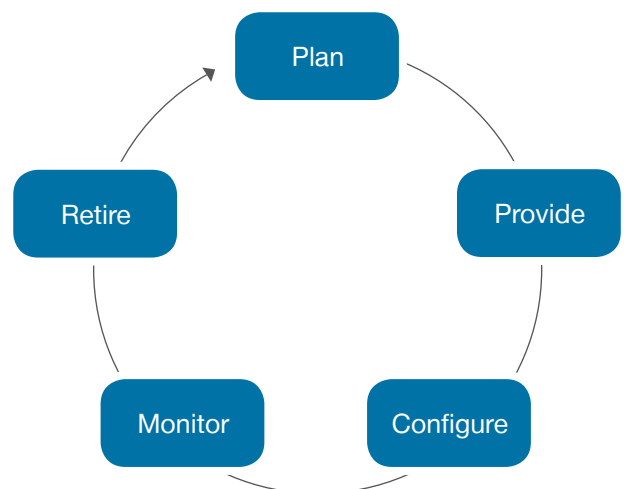
- Standard interface to read and write data to other services
- API to build therapy-specific apps
- No need to deal with complex smart device protocols and security topics



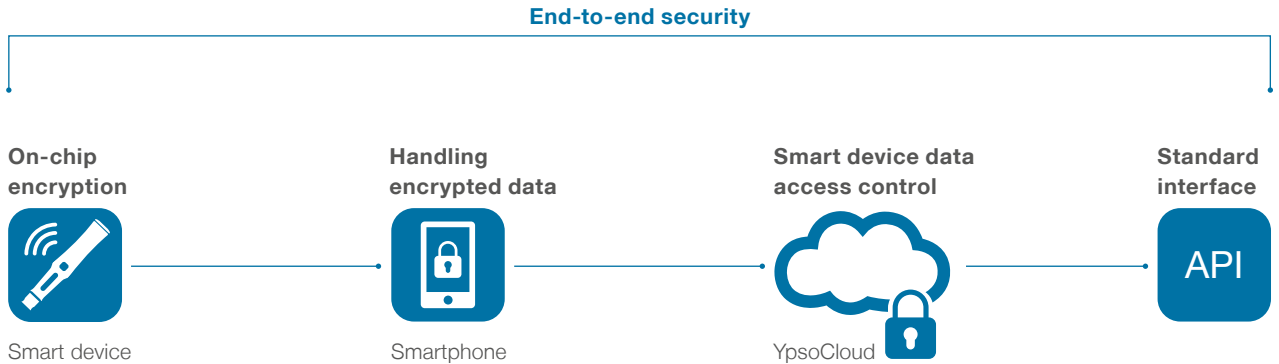
## Service 2: Smart device life cycle management

Insights into smart devices during clinical trials and commercial use

- **Plan:** Design and testing of end-to-end connectivity ecosystems
- **Provide:** Effortless advanced on-boarding and managed access to secure device usage data
- **Configure:** Effective implementation and update of network security
- **Monitor:** Real-time analysis and interpretation of smart device performance
- **Retire:** Controlled end-of-life management of smart devices, e.g. after successful completion of a clinical trial



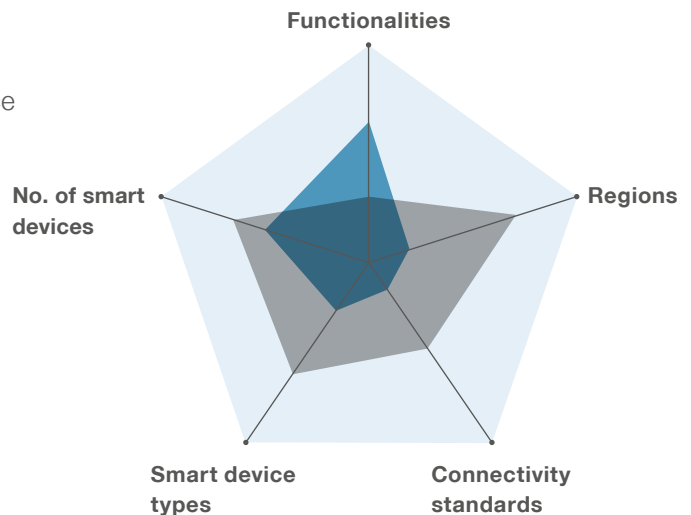
**Service 3: Securing device-to-cloud communication**  
 Security-by-design for the entire product system



- Manages both device and cloud to implement true end-to-end security
- Meets relevant requirements around data privacy and security

**Scalable and configurable digital services**  
 Flexible service levels and pricing models

- Scale digital services according to device volume, functionality and region
- Flexible service levels to support clinical trial conduct and commercial launch
- YDS SmartServices™ leveraged across device platforms and connectivity standards



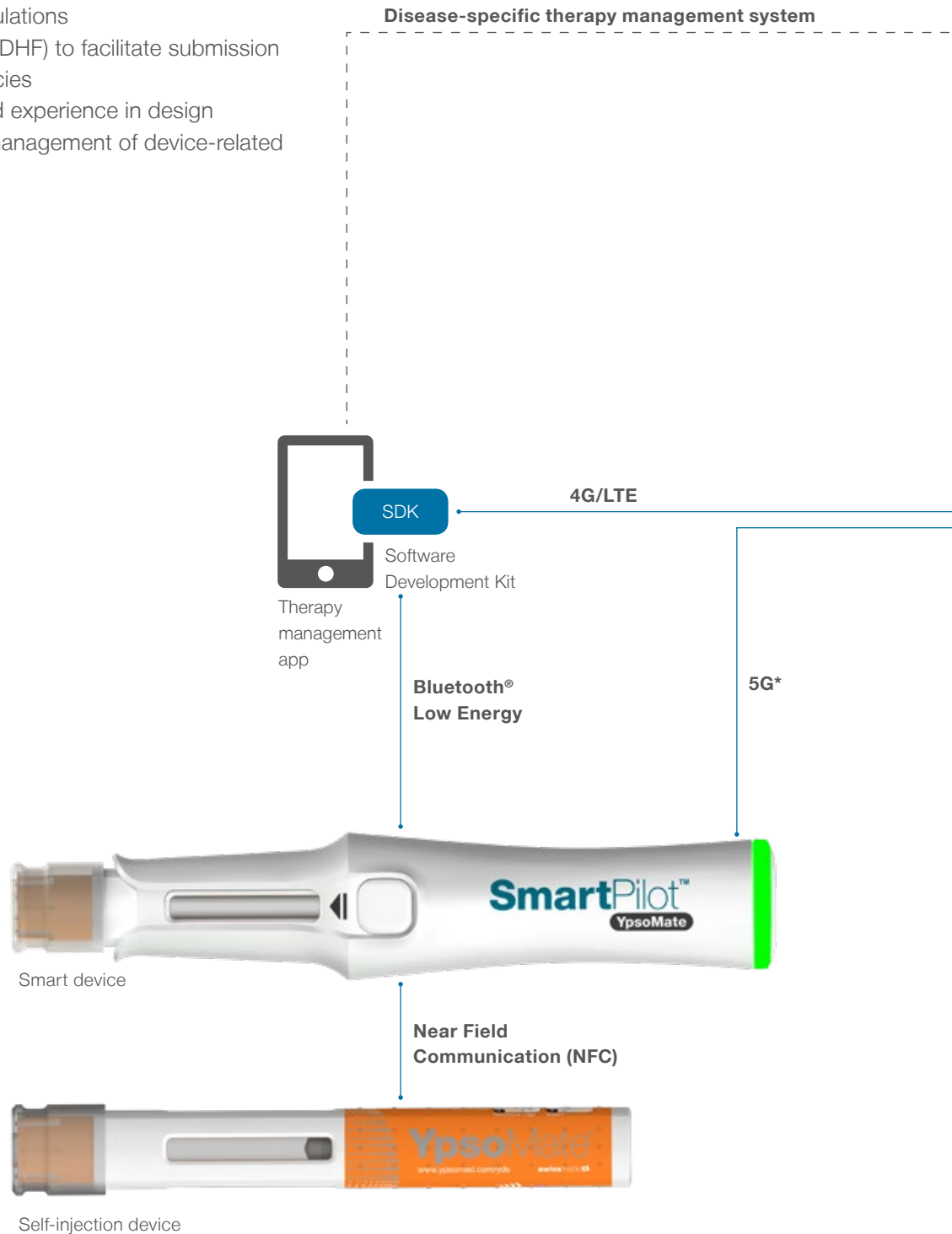
- Configuration of application A
- Configuration of application B
- YDS SmartServices™ capabilities



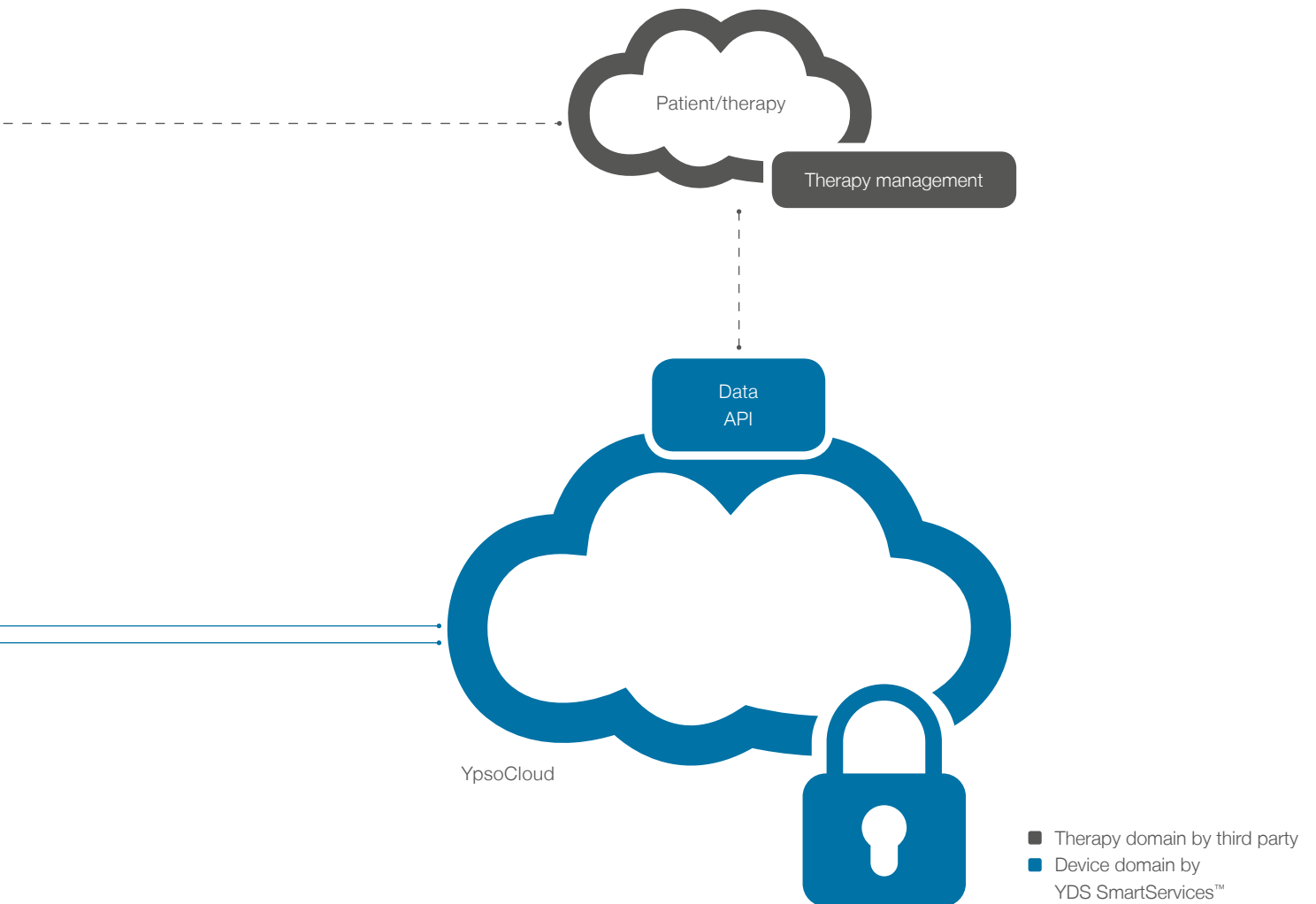
## Introducing a turnkey integrated connected health system

Linking the device to the therapy domain

- Compliant with relevant industry standards e.g. HIPAA, GDPR, 21 CFR Part 11
- ISO13485 certified meeting medical device quality system regulations
- Design history file (DHF) to facilitate submission to regulatory agencies
- Leverage Ypsomed experience in design control and DHF management of device-related aspects



\* Subject to country-specific roll-out



YDS SmartServices™ are an end-to-end secured turnkey solution to simplify adherence monitoring and provide secure smart device integration. Pharmaceutical partners may access therapy-relevant data via standard web-based data API. YDS SmartServices™ address key device domain challenges by focusing on: ease-of-integration, digital life cycle management and end-to-end security.

Leveraging Ypsomed's experience in the global marketing of diabetes management systems, YDS SmartServices™ establish an industry-leading reference architecture for embedding smart devices into digital ecosystems.

More **confidence.**  
More **success.**  
With **Ypsomed Delivery Systems.**



Pen systems



Autoinjector systems



Patch injector systems



Smart services

Ypsomed Delivery Systems provides a complete range of drug delivery products and services to biopharmaceutical companies. We offer everything from development and design to manufacturing and packaging, giving patients and customers more confidence and leading to more market success.