PHILIPS

CASE STUDY

Smart Devices Help Ypsomed Measure Medication Adherence for Clinical Trials

Managing devices and data on the cloud using Philips HealthSuite digital platform built on Amazon Web Services (AWS)

Ypsomed Delivery Systems is a manufacturer of injection devices used to dispense medication in clinical trials. The company, headquartered in Switzerland, is a leader in the field with 30 years of experience developing and manufacturing injection and infusion systems.

The company is keenly aware of the importance of medication adherence — measuring medicine intake and ensuring doses are given at the correct time. Poor medication adherence is an expensive problem, with non-adherence costing the US healthcare system nearly $300 billion annually[i]. In fact, 50-60% of patients with chronic illnesses don't take medication properly[ii]. This also has a direct impact on clinical trials; the consequences of poor adherence in clinical trials include failure to confirm efficacy, risk of harm due to misleading labels, impaired development of breakthrough drugs, and treatment failures[iii].

In trying to find a solution for non-adherence, Ypsomed faced a complex, two-tier problem. To tackle non-adherence, a contract research organization (CRO) needs the ability to remotely manage drug administration in real time, share information on drug intake within and beyond clinical trial teams, assess and enhance adherence, and to manage trials that are multi-center and/or in multiple regions. This leads to the need for a connected solution. Yet such a connected solution presents additional challenges, such as the burden to configure and remotely push updates to smart devices. CROs also need secure device-to cloud-communication and the ability to constantly monitor smart devices launched across regions. They also need to assure access control on smart devices. These challenges require the capabilities of a cloud platform to manage.

CHALLENGE

Ypsomed sought to create a digital solution for medication adherence monitoring and smart device management for contract research organizations' (CROs) use in clinical trials, including self-injection systems for trial participants to administer medications at home. Yet the company faced significant demands for remote device management, global scale, and privacy and security regulations such as HIPAA and GDPR.

SOLUTION

Ypsomed adopted Philips' HealthSuite digital platform (HSDP), a cloud platform built on Amazon Web Services (AWS), in order to address these challenges. HSDP allows Ypsomed to connect devices to the cloud and remotely manage them; store data; and manage and scale services in multiple geographies while providing for healthcare regulatory, privacy, and security requirements.

RESULTS

Ypsomed reports that they have:

- Created MVP of their solution from scratch in five months by developing with Philips HSDP on AWS
- Used HSDP to help enhance security, as Philips HSDP provides for HIPAA and GDPR requirements
- Realized cost savings by reducing operations, infrastructure, and staffing costs

The solution: Connected devices and remote device management

Ypsomed sought to create a digital solution that CROs could use to monitor medication delivery in clinical trials. "Connected devices hold great promise to improve clinical trials, to accelerate trials and improve adherence," says Andreas Schneider, PhD, Innovation & Business Development Manager for Ypsomed.

Ypsomed's goal was twofold. Their first goal was to provide connected self-injection systems for trial participants to administer medications at home. The second was to track usage of these connected self-injection devices and make that data available to stakeholders involved in clinical trials, such as CROs, investigators, and pharmaceutical companies. In addition, Ypsomed needed to ensure devices could be monitored across geographic regions, needed to store data at scale, and needed to adhere to privacy and security requirements such as HIPAA and GDPR.

The Ypsomed Connected Drug Delivery Solution is comprised of:

- **Smart Pilot:** connected medication injection device
- **Smart Services:** device management
- **Cockpit:** dashboard showing device data

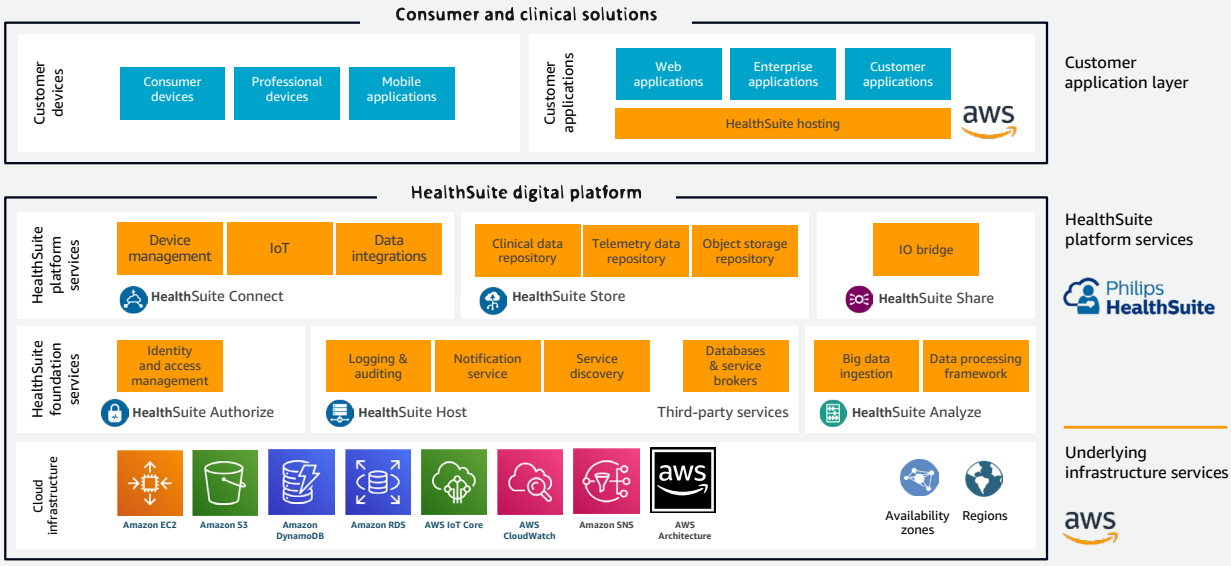
Using Philips HealthSuite digital platform, built on Amazon Web Services

In late 2018, Ypsomed turned to Philips and the HealthSuite digital platform (HSDP). Philips HSDP provides cloud services and platform as a service that allow users to connect devices, collect electronic health data, aggregate and store data, and analyze data—within healthcare regulatory, privacy, and security requirements. Philips HSDP is built on top of a breadth of AWS services including Amazon EC2 for compute, Amazon S3 for storage, and AWS IoT Core to enable connectivity services.

Using Philips HealthSuite digital platform (HSDP) on AWS in development can help users:

- **Accelerate** development: get development right the first time and scale faster and more systematically
- **Scale** to geographic, volume, and market demands
- **Secure** clinical data in a HITRUST-certified platform
- **Enhance** interoperability with hospital systems via native support for FHIR, HL7, DICOM, IHE profiles
- **Build and run** cloud-based solutions that help you administer faster, better clinical trials
- **Integrate** wearables and devices, clinical trial end user support, provisioning, patient support, and device creation

Philips HealthSuite digital platform and AWS native services



Components of the Ypsomed solution

Ypsomed built their Connected Drug Delivery Solution, a solution for medication adherence monitoring and smart device management for clinical trials, using HSDP's cloud services and platform as a service on AWS. The solution consists of Smart Pilot (connected medication injection device), Smart Services (device management) and Cockpit (dashboard showing device data).

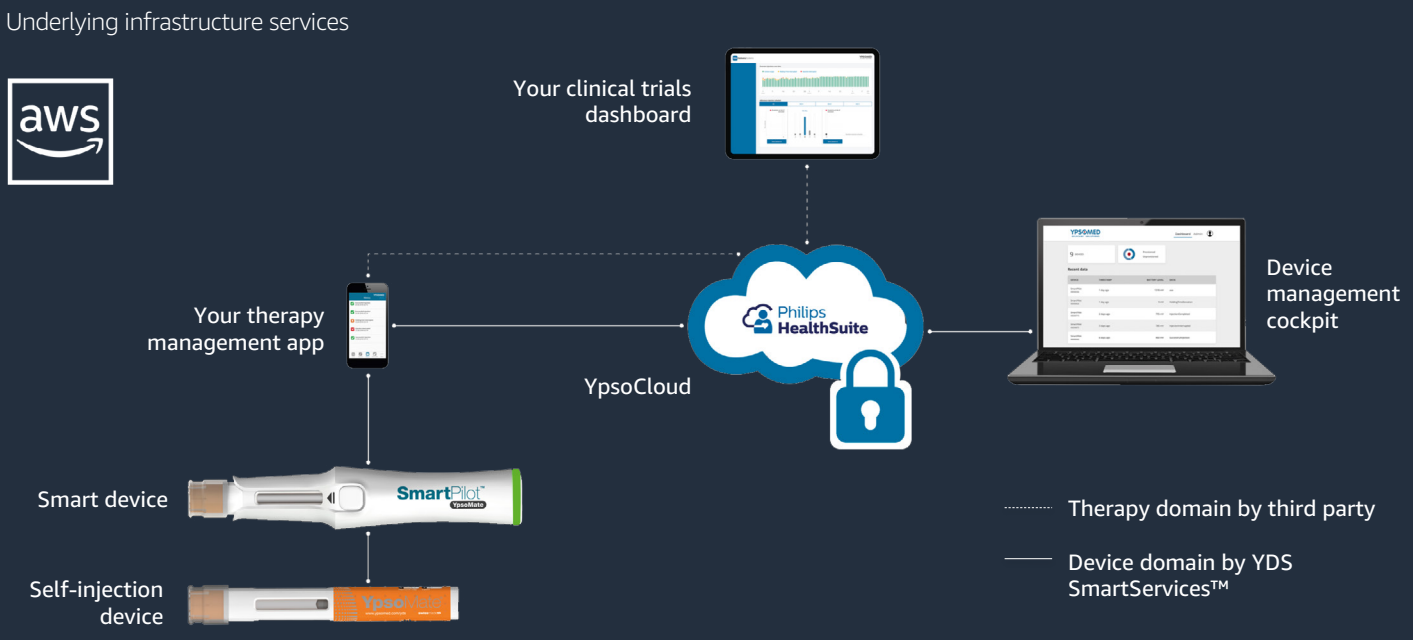
These components are powered by the YpsoCloud that leverages HSDP for device connectivity, remote device management, identity and access management and device/patient data storage and to provide for privacy, security, and medical device data system regulatory requirements and 24 x 7 operational support.

Ypsomed's solutions enable clinical trial participants to self-administer medication using the SmartPilot connected medication injection device. Then CROs, and other users administering clinical trials, can use SmartServices and the Cockpit to monitor and manage those devices remotely, including tracking device performance and pushing firmware. Additionally, users can segregate the encrypted injection or patient data for third parties or CROs from device performance-oriented data. An Ypsomed customer can build its own clinical dashboard on top of this backbone or integrate with an existing clinical dashboard through a standard interface that provides ease of integration and standardized APIs.

Philips HSDP, built on AWS

- Remotely manage devices and ingest, store and integrate device data
- Ingest data from multiple healthcare and consumer sources (HL7, DICOM, IoT)
- Store patient reported outcomes and other clinical trial data centrally
- Share data and electronic records among healthcare organizations, pharmaceutical companies, contract research organizations (CROs), patients, and professionals
- Ingest, process, and visualize analysis of data and use the compute environment to run algorithms, machine learning, and real world evidence (RWE) analysis
- Provide an audit trail on data elements
- Provide for privacy, security, and regulatory requirements
- Get more information on HSDP at hsdp.io

YDS SmartServices™ building blocks for your solution



How Ypsomed, HSDP, and AWS work together

Ypsomed Requirements for SmartPilot	HSDP Capabilities	AWS Capabilities
• De-risk and accelerate the development of the full system • Fully secured device-to-cloud connectivity • Integrated medical-grade device management solution • Flexible Application Development Environment	• Healthcare Internet of Things services via HSDP Connect Services • HSDP's Cloud foundry application hosting/build environment • HSDP Platform Services • Cloud expertise demonstrated in solutions by customers	• Scalable and elastic storage and compute that can be configured to meet regulatory requirements • Born in the cloud databases which combine the performance, security, and availability of traditional enterprise databases with the simplicity and cost-effectiveness of open source databases • Comprehensive security features baked into AWS IoT give healthcare customers the ability to securely scale as their device fleet grows and requirements evolve.
Global/multi-site deployments to support clinical trials world-wide.	• Global 24x7 support • Regional deployments to address data residency requirements • Continuous monitoring of the performance and availability of the platform	• AWS builds its data centers in geographic Regions across the globe as well as across multiple Availability Zones, which gives customers the ability to go global in minutes while maintaining high availability and security of their applications. • AWS data centers are monitored 24/7 to help ensure the confidentiality, integrity, and availability of our customers' data.
Data storage and exchange to provide for privacy, security, and regulatory requirements	• HSDP Managed Platform Services with certifications and attestations to provide for privacy, security, and medical device data systems requirements • Robust Identity and access management services • Data encryption in transit and at rest	• AWS provides cloud security tools, security, compliance, and governance services and key features. • AWS supports security standards and compliance certifications.
• Allow integrated real-time views of adherence data in dashboards • Access to the details of patient adherence per treatment arm	• HSDP Managed Platform Data Storage Services • HSDP Managed Platform Interoperability Services	• Numerous database and data storage options give customers the flexibility to use the right data storage service for their use case.

Results for Ypsomed and a look to the future

Ypsomed reports that they accelerated their development and created the MVP of their solution from scratch in five months by building on Philips HSDP on AWS. Ypsomed also used HSDP to help enhance security, as Philips HSDP provides for HIPAA and GDPR requirements, and for technical flexibility through HSDP's toolbox of ready-to-use cloud services that the company can lean on for future development, such as analytics. By using HSDP's platform as a service and 24 x 7 operations support, Ypsomed also realized cost savings by reducing operations, infrastructure, and staffing costs.

Together, Ypsomed, Philips, and AWS support CROs in addressing poor medication adherence and enhancing clinical trials through providing tools to connect and manage devices and data on the cloud.

[i] "Patients who skip medications cost healthcare $300 billion annually," Healthcare Finance, May 2018 https://www.healthcarefinancenews.com/news/patients-who-skip-medications-cost-healthcare-300-billion-annually

[ii] "Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review." Annals of Internal Medicine, December 2012 https://www.ncbi.nlm.nih.gov/pubmed/22964778

[iii] Alasdair Breckenridge, et al, "Poor medication adherence in clinical trials: consequences and solutions," Nature Reviews Drug Discovery, 2017

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