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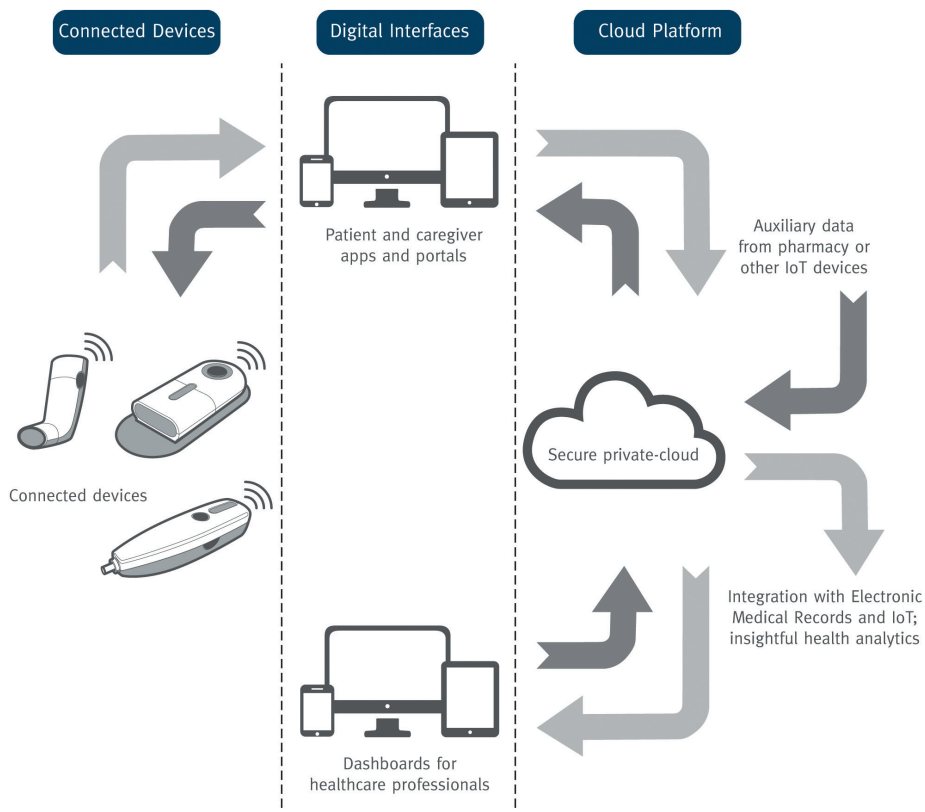
CONNECTIVITY OPENS THE DOOR TO INNOVATION AND OPPORTUNITY

In this article, Neil Williams, Director of Front-End Innovation and Connected Health, Phillips-Medisize, outlines the need for connectivity in the future of healthcare and details Phillips-Medisize's third-generation Connected Health Platform technology.

Evidence is mounting that connectivity is going to play an increasingly powerful and pervasive role in medicine moving forward. For pharmaceutical companies and drug delivery device developers, integrating connectivity into innovative health solutions offers promising opportunities to improve

the experience for both patient and provider, whilst supporting increased medication adherence and therefore facilitating improved therapeutic outcomes.

To optimise their potential, these connected health solutions should be built on three foundational pillars (Figure 1):



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Figure 1: A flexible and low-cost platform, based on the InterSystems HealthShare Health Insights platform that supports enterprise-wide clinical data handling.

1. Patient-centric drug delivery devices
2. Empathetic patient engagement, including regulated “Software as Medical Device” (SaMD) and Mobile Medical Applications (MMA) and portals
3. A robust health information-sharing and analytics platform that enables actionable insights.

Not surprisingly, the three pillars are closely intertwined. By integrating connectivity into innovatively designed, patient-centric drug delivery devices, such as injectors and inhalers, pharmaceutical companies can make it easier and simpler for people to take their medication on-time and monitor their condition. These connected smart devices can track medication administration, collect patient data and instruct and support patients with

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reminders, incentives, educational content and access to peer communities. The goal is to help patients, caregivers and healthcare professionals (HCPs) improve not only medication adherence but also disease management and, ideally, outcomes.

At the same time, a robust information-sharing and analytics platform enables pharma companies to connect and aggregate medication and diagnostic information across their medicines and therapy areas on a single-enterprise private cloud platform. Such a platform also allows them to integrate data from multiple other sources, such as diagnostic devices, biometric sensors and electronic medical records. HCPs can review patient medication adherence, biomarkers and patient-reported outcomes to

help manage the patient’s condition, boost adherence and improve outcomes (Figure 2).

TACKLING THE MEDICATION ADHERENCE CHALLENGE

Poor adherence to medication is a costly challenge worldwide, most importantly in terms of unnecessary human suffering and significantly reduced patient health, but also financially. An estimated 50% of medications for chronic diseases are not taken as prescribed, resulting in up to 70% of emergency department admissions. A review in the 2017 Annals of Internal Medicine reports that an estimated 125,000 deaths in the US alone are linked to patient non-adherence to prescribed medications. In turn, this accounts for an estimated cost of approximately US\$290 billion (£224 billion) to the US healthcare system.

While there are no easy answers to boosting medication adherence, improving the user experience can play a crucial role. The opportunity to build drug delivery devices and patient apps on an advanced connected health platform drives innovative design that, in turn, creates solutions for patients, caregivers, providers and payers.

To help its customers bring better drug delivery devices and connected health solutions to market quickly and confidently, Phillips-Medisize combines its experience in electronics integration and connected health with its expertise in electronics hardware, software engineering and printed circuit board manufacturing and assembly. Its innovative third-generation Connected Health Platform (CHP) provides a unique opportunity for pharma companies and drug delivery device developers to reduce the risk and cost of developing connected health solutions and accelerate time to market.

SECURE CONNECTED HEALTH PLATFORM OFFERS MULTIPLE BENEFITS

This scalable cloud-based platform addresses key challenges our customers and their patients face:



Figure 2: Enabling patient data and service ecosystems.

“Despite the differences in American and European medical coding systems, it’s possible to compare patients with, for example, diabetes in the US with those in Germany or the UK.”

- **Information-sharing and analytics capabilities.** The Phillips-Medisize CHP is built on InterSystems HealthShare Health Insight. InterSystems is a global leader in healthcare software and integration. Designed for connected drug delivery devices, bio-sensors and regulated SaMD/MMA, and fully documented to support 510k and combination product submissions, the platform provides a medical device data system (MDDS) that connects pharma companies, providers, patients and payers through a unified healthcare record and powerful analytics spanning the care continuum.

The CHP is an advanced analytics tool that enables customers to quickly generate views of their data, as well as create a data presentation layer for exporting/exposing data to third-party reporting systems. The ability to change or fine-tune dashboards quickly and easily without the need for expensive, time-consuming software development efforts offers a big advantage.

Previously, dashboards had to be created as part of the core software development phase, after which changing them was time consuming. The ability to revise dashboards “on the fly” saves time and money, offers valuable flexibility and makes it easy to connect with other supported external analytic systems.

In addition, the CHP can integrate medication, diagnostic and therapy data from multiple sources, make it actionable and normalise it across geographies for global comparisons. For instance, despite the differences in American and European medical coding systems, it’s possible to compare patients with, for example, diabetes in the US with those in Germany or the UK. The CHP can also identify the

data or keep it anonymous, depending on the patient’s preferences.

- **Scalability.** Phillips-Medisize’s CHP is massively scalable enterprise-wide. Having a flexible, scalable platform in place eliminates the need to create a customised solution from scratch each time a new drug is introduced, as has traditionally been the approach. This typically results in creating multiple databases which then must be connected in some way to provide a common view of the data. With the CHP, all data can be connected to a single cloud platform per client, but data can be viewed discretely or collectively.

Once an initial project and infrastructure are developed for a customer on the CHP, adding additional infrastructure for future projects is highly cost-efficient. Also, as the patient population increases, the price per user declines, further minimising the cost barrier to integrating connectivity in health solutions for common chronic conditions.

In addition, whether drug device developers or pharma companies are collecting, storing and managing data for a thousand patients or hundreds of millions, they can count on the same level of safety and security.

- **Collaboration.** Clients typically are deployed in their own private cloud. However, clients sometimes have cross-industry partnerships and want the ability to share data. We can combine them into a cost-effective collaborative environment.

PROVEN EXPERIENCE FOSTERS INNOVATION

The innovative CHP from Phillips-Medisize incorporates more than a decade of experience developing connected health solutions, including one of the first wireless autoinjectors approved by the US FDA as a combination product for medication tracking. There’s still a steep learning curve when it comes to connected health solutions,

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given that most companies have not yet integrated connectivity into drug delivery devices. But that’s changing – Phillips-Medisize is currently working with partners who expect to bring products to market at an accelerated pace.

Phillips-Medisize’s experience has proven that innovation flourishes at the intersection of market needs and emerging technologies. Pharma companies and drug delivery device developers need to push the boundaries in the design, development and manufacturing of connected health solutions to continue to enhance the patient and provider experience – and sharpen their own competitive edge.

ABOUT THE COMPANY

Phillips-Medisize, LLC, a Molex company, is an end-to-end provider of innovation, development, manufacturing and post-launch services to the pharmaceutical, diagnostics, medical device and speciality commercial markets. Post-launch services include a connected health app and data services. Backed by the combined global resources of Molex and its parent company Koch Industries, Phillips-Medisize’s core advantage is the knowledge of its people to integrate design, moulding, electronics and automation, providing innovative high-quality manufacturing solutions.

ABOUT THE AUTHOR

Neil Williams is the Head of Connected Health and Director of Front-End Innovation at Phillips-Medisize, based in Cambridge (UK). Mr Williams consults for biopharma clients, innovating and executing strategies to enhance stakeholder engagement through connected drug delivery devices and software. He has over 23 years’ experience covering medical devices, telemetry, digital x-ray, clinical decision support, secure mobile working, patient engagement and health analytics for businesses including Philips Healthcare, Microsoft, Elsevier Health Sciences, Hospira, Hearst Health and ZOLL. Prior to Mr Williams’ commercial career he trained at Leicester University Hospitals in Operating Department Practice and was faculty for numerous post-graduate advanced life support programmes.

5 THINGS TO CONSIDER WHEN MANUFACTURING CONNECTED DRUG DELIVERY DEVICES

The estimated number of connected drug delivery devices continues to increase and the impact of this trend could be significant, explains Phillips-Medisize, a Molex Company



While digital connectivity or connected health can improve the coordination and delivery of patient care, original equipment managers need to keep these five things in mind when creating connected drug delivery devices:

- 1 Development strategy and design consideration**
- 2 Situation analysis and patient compliance**
- 3 Connectivity ecosystem**
- 4 Wireless subsystem**
- 5 Security of device and information**

As the Internet of Things continues to become an integral part of people's lives, the opportunity to use it within drug delivery device applications remains promising. The manufacturers and device designers must identify, investigate and overcome these challenges so that the implementation of wireless and other related smart technologies can be achieved. When done successfully, connected systems enable the patient and caregivers to have a 360° view of both the patient and the disease – not only to manage adherence, but to improve results by understanding the effect of the regimen.