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Monitor and Support Patient Medication Adherence through Connected Health

Healthcare is increasingly digital, from wearable medical devices to remote patient monitoring to telemedicine. Yet most big drug makers have been slow to join the m-health revolution. In fact, medication is one glaring example of the critical health data components that remain outside the digital environment or struggle to integrate effectively into electronic health records.

The High Cost of Poor Adherence

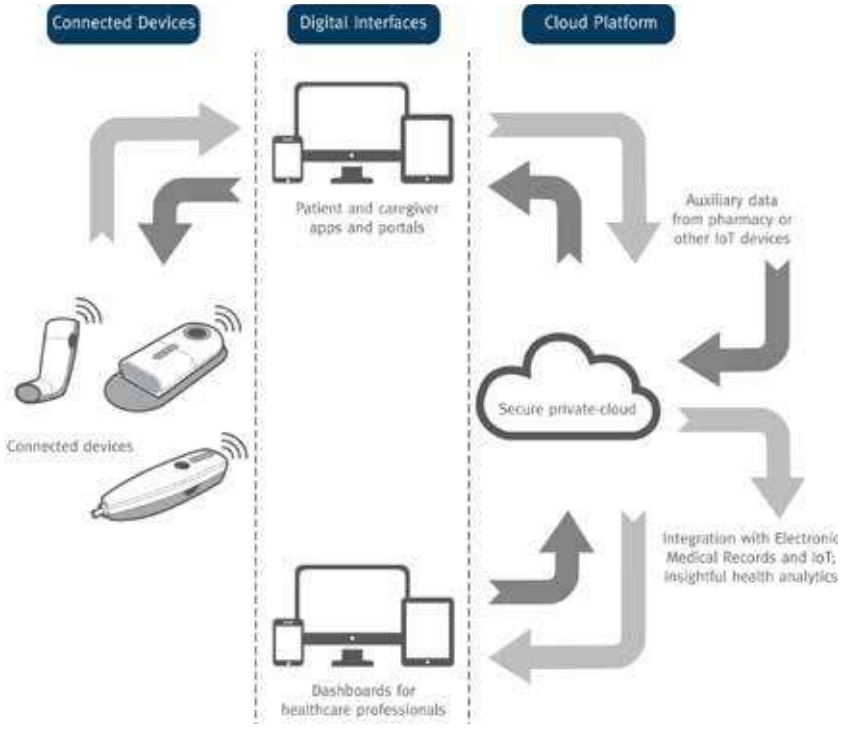
Medicine is vital to our understanding of disease management and progression. The ability to measure medication effectiveness – and patient adherence – plays an important role in managing and improving patient health, especially as healthcare systems in the United States and globally start to implement outcome-based reimbursement. However, little actual data exists that pinpoints when, or even if, patients take their medication. A range of research has demonstrated, though, that nearly 50 per cent of all medicines are not taken as prescribed.[1] Even for patients with chronic conditions, adherence is only 50 to 60 per cent.[2] It is estimated that this poor medication adherence is responsible for $290 billion in avoidable healthcare costs in the United States – approximately 13% of total US healthcare spending.[3]

In addition to their negative impact on patients, desired outcomes, emergency department admissions and healthcare costs, the poor adherence rates also reduce the potential income of pharmaceutical companies, accounting for approximately $188 billion in lost revenue.[4] Adherence rates ranging from 31 to 66 per cent for popular respiratory, diabetes and autoimmune drugs can leave between $1 billion and $10 billion dollars "on the table" in any given year.[5] However, even as little as a three per cent increase in adherence can generate more than $1 to $3 billion in additional revenue for these popular drugs over a five-year period, according to our estimates. This is significant, especially given the cost of new prescription drug development can be as high as $2.6 billion.[6] But despite this investment, when patients walk out of the pharmacy after filling their prescription, whether or not they actually take the medication as prescribed is anybody's guess. Connected health solutions can help fill that void.

Getting Connected to Meet Growing Demand

Only a few connected health solutions tied directly to medication have made it to market so far. These pioneering systems indicate that connected health solutions are going to become more prevalent in monitoring, measuring and supporting patient adherence to prescribed medications. Integrating connectivity into innovatively designed, patient-centric drug delivery devices offers promising opportunities for pharmaceutical companies to improve the patient and provider experience. It also helps them to support increased adherence by making it easier and simpler for people to take their medication on-time and as prescribed. Connectivity provides an efficient way to monitor patients' adherence and condition, as well as to share both real-time and historical data with patients, clinical researchers, healthcare providers, caregivers and payers.

The connected health ecosystem includes three primary components: connected devices, such as inhalers and injectors; digital interfaces, including patient and caregiver apps, and dashboards for healthcare professionals; and a cloud platform, enabling data integration with multiple sources including diagnostic devices, IoT sensors and EHRs in order to generate insightful analytics. To be successful, a connected health solution needs to be built on the right technology, incorporate a deep understanding of key business drivers and focus on serving patient needs. In order to create a positive patient experience that supports improved adherence, a connected system should include simple, intuitive mobile apps and reminders that support and motivate users. It has to be easy for patients to load apps, connect to devices and record data. It should also enable pharmaceutical



companies to motivate and instruct patients on treatment information and medication administration, further supporting adherence.

Four years ago, the first connected health system was approved by the FDA for a specific drug. In the time since the product was released to the market, interest in connected health has flourished. The number and popularity of connected health pilots is growing, but pharmaceutical companies sometimes struggle with how to scale the model, and extract and quantify the value created, which can impede additional investment. While the cost of developing connected technology is significant, so is the potential for supporting increased adherence, facilitating improved outcomes, and potentially generating additional revenue for the drug manufacturers. Recognising the increased interest and demonstrable benefits connected systems provide, we decided to invest in developing a highly scalable platform to service the expanding market, rather than developing and maintaining one-off, application-specific solutions for each new project.

Best Practices and Benefits of a Connected Health Platform

The result was a connected health platform. This cloud-based connected health platform provides a scalable medical device data system (MDDS) for pharmaceutical companies and platform drug delivery device customers. The opportunity to build drug delivery devices on an existing connected health platform helps pharmaceutical companies and drug delivery device developers on several fronts. It reduces the risk, time and cost associated with developing connected health solutions. This, in turn, helps accelerate time to market. Additional benefits of building solutions on a connected health platform include:

- **Comprehensive information-sharing and analytics capabilities.** A connected health platform supplies the digital tools needed to extract powerful health and market insights. It provides a medical device data system (MDDS) that connects pharma companies, clinical researchers, providers, patients and payers, sharing and displaying information from connected drug delivery devices, biosensors and regulated mobile medical applications (SaMD/MMA). Advanced analytics capabilities that span the care continuum allow researchers and other users to quickly generate 360-degree views of data, and also to create a data presentation layer for use by the analytics engine, providing deep insight into how medication is taken. Dashboards can be changed or fine-tuned quickly and easily at any point – not only during the core software development phase, as has previously been the case. This capability saves time and money, adds high-value flexibility and streamlines connection with other supported external analytic systems. A connected health platform can also integrate medication, diagnostic and therapeutic data from multiple sources using an enterprise master patient index as well as support global comparisons by normalising data across geographies. As a result, American patients with asthma, for example, can be compared with patients in France or the United Kingdom. Data can easily be anonymised or pseudonymised to support clinical research. It can also be made actionable, enabling patients to be added to specific care pathways and monitored accordingly.

- **Robust cybersecurity.** Data security and privacy must always be a top priority. Connected health solutions can be deployed in a secure private cloud with a credible legacy of health data security, in a cloud hosting option selected by the pharmaceutical company, or in the company's own data centre. Those offered as Platform as a Service (PaaS) relieve customers from responsibility for data management and storage, whether they count patients in the thousands or hundreds of millions. They also free pharmaceutical companies and drug device developers to focus on their primary objective: connected health solutions that provide better patient experiences and facilitate improved patient outcomes. In addition, cost-effective and secure collaborative environments are available for situations where cross-industry partners want the ability to share data.

- **Streamlined regulatory documentation.** Connected health platforms that come complete with full regulatory documentation services to support premarket submissions for 510(K), combination products and CE mark help lower project costs and speed time to clinical trial, regulatory approval and market – ahead of the competition.

- **Modular approach.** Working with a manufacturing partner who can deliver connected health solutions that incorporate devices with electronics and sensors already embedded also speeds the development process and keeps costs low, for both reusable and disposable drug delivery devices. Connected health platforms that come with a software development toolkit and defined, extensible API, allow any device to be connected to the system. As a result, pharmaceutical companies can deploy a single solution across all therapy areas for each product and drug compound if desired, rather than having to utilise different companies' platforms for each product and device type. Pairing a configurable app with the connected health platform and deploying it across multiple products using a standard Bluetooth interface further supports a rapid, low-cost path to clinical trial and market.

- **Massive scalability.** Building infrastructure for a connected health solution on a flexible, scalable platform rather than

starting from scratch for each new drug makes it highly cost-efficient to add or refine infrastructure for future projects. Because the price per user declines as the patient population increases, the costs for integrating connectivity for medications used to treat common chronic conditions also decrease.

- **Post-market surveillance and updating.** Connected health solutions need to keep pace with the constantly changing mobile technology industry. Drug device developers and pharmaceutical companies not only need to invest in the service and support required to deploy and maintain the systems, but also need to proactively test new mobile operating system releases and smartphone models against the connected health platform and apps. A drug delivery device built on a platform that is continually updated and modified as needed ensures a seamless patient experience, which is always a primary focus.

Connected Health in Practice: A Case Study

This case study demonstrates the value a connected health solution can add for both patients and pharmaceutical companies. A leading pharmaceutical company recognised the need to update its current drug injection device in order to retain existing patients and attract new ones. The company's drug had established safety and efficacy, but its injection device lagged in user-friendliness. The company sought to use electronics to improve the injection experience but also wanted to help patients better manage their disease by offering seamless integration between the device and a patient app that could track injections and remind patients when and where to take them. An innovative electromechanical autoinjector connected to the cloud was launched in just two-and-a-half years, using customisable technology accelerator building blocks that eliminated the need for lengthy and costly R&D processes. The new connected autoinjector system featured:

- Ergonomic design with a button in the middle of the device, operated with one hand and light pressure, making for a gentle experience;
- Secondary control functions hidden on the inside, so they don't interfere with the day-to-day operation of the device;
- A dashboard for healthcare professionals to easily monitor patients and determine who needs support;
- Bluetooth connectivity that ensures data on injection time, volume and body location are synced with the patient app and dashboard;
- Personalised, localised messages and reminders for patients on their device and in the app.

The integrated system was introduced in countries worldwide after its initial launch in Europe. It has made injections more intuitive for patients, made it easier for caregivers and healthcare providers to coordinate and follow up on treatment and helped the company retain its market position.

Summary

The learning curve for connected health solutions remains steep, but the pace of development continues to accelerate as pharmaceutical companies and drug device developers seek to meet market needs by capitalising on emerging technologies. Unlocking the value in connected health offers promising potential for creating a more positive patient experience that can help improve adherence and facilitate better outcomes. The opportunity to develop innovative, connected health solutions using a secure, cloud-based platform that provides a safe and scalable medical device data system helps pharmaceutical companies and drug delivery device developers reduce risk, cost and time to market. At the same time, by demonstrating a clear pathway to value creation, these cost models can bridge the gap between pilot and programme and encourage additional investment in connected health by pharmaceutical companies.

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