Medicom
Innovation Partner
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THE DRUG DELIVERY DEVICE AND CONNECTIVITY CHALLENGE

Pharma organisations seeking to ensure a premium patient experience are leveraging smart, connected medicine delivery technologies and connected health solutions that enable patients to adhere to their prescribed medicines and to evidence outcomes. In this article, Neil Williams, Head of Connected Health at Medicom Innovation Partner, offers insights into the challenges and experiences of developing a complete connected system including injection device, app, cloud storage, integration engine and dashboarding tool, and what to look for in a partner, to help deliver connected health devices, apps and a strategic platform.

Patients are engaging in digital transactions with their healthcare providers, payers and social community. There are many opportunities and challenges, which need to be considered by Pharma, as the health industry refocuses towards revenue models based on results rather than activity.

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THE FINANCIAL POTENTIAL OF DIGITAL HEALTH SOLUTIONS

It is reported that improving digital health products and services could liberate US$300-450 billion (£206-309 billion) in the US. Pharma can play its part here and directly benefit. Increasingly healthcare payers and providers are focusing on outcomes measures and linking outcomes to costs. Pharma can leverage "real world" data to prove adherence delivers enhanced results; this data can be leveraged to help change prescribing behaviours, improve positioning within formularies, retain patients and bring new patients.

Connected services can also bring significant insight to Pharma. For example, if a disease-specific app was launched it would be possible to know where your medicine is densely used and where it is lightly used. You would be able to know which patients might be interested in study participation and be able to cohort patient groups. Of the top performing health apps, 68% include social networking; this is a rich source of data that can help pharma better understand patients' daily challenges and likes.

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Number of apps across Apple AppStore and Google Play	Percentage of apps with medication reminders	Percentage of apps with data sharing	Percentage of apps with data export	Percentage of top performing apps with social media
~ 90,000	2%	2%	9%	68%

Table 1: Some mHealth app statistics.

Without question, the patient should always be in control of how their data is utilised even if it were to be anonymised. Complying with standards such as HIPAA, information security and governance are mission-critical requirements of any connected health service.

MEETING STAKEHOLDER REQUIREMENTS

There are over 90,000 health apps across the Google Play and Apple App Store; many of these are simple health diaries, dieting aids and connected wellness apps that link to activity trackers, blood pressure, scales etc. All too often these apps are poorly aligned to patient cohort and market requirements. For example, only 2% of published health apps have a medicine reminder and or a data export function despite these features being commonly requested within focus groups (Table 1). For an app and connected health solution to stand out and deliver real-world benefit

regulatory authorities. Different markets have variable privacy standards, hosting requirements, treatment protocols etc and it is vital that the selected partner understands how to address these.

Understanding the regulatory processes and being accountable for both device and software compliance as the registered manufacturer of on-market products brings a burden of responsibility that challenges most software designers.

While it is necessary to be vigilant regarding privacy, it is also important to be aware that these challenges have been addressed in the healthcare IT industry for many years. The development partner must understand how to ensure patient data is safe, how to put patients in control of their data and data sharing, and how to do this in a regulated medical device environment.

It is also important to consider the medico-legal issues surrounding patient data and what implications this can have for a pharma company hosting or processing data on behalf of a patient.

correlate this to clinical outcomes and other lifestyle factors.

OUTCOME IS THE NEW INCOME

Insights about adherence are already being requested by pharmacy benefits managers, and the market is increasingly being driven to an outcomes-based revenue model. Proving the value of a medicine and having an engaged patient population could not only help patients achieve optimal outcomes but could also drive discussions about formulary position improvements.

Apps need to work seamlessly and securely even when the mobile device isn't connected to the internet, images a patient takes should not be accessible in their devices photos app, and if the patient wants to remove the app, all the associated data needs to also be removed from the mobile device. From the patient's perspective, the app needs to "just work" at any time and any place. A significant amount of upfront work and prototyping the user experience, design, workflows and consideration of human factors needs to be undertaken early in a project, to ensure that patients receive a solution that is valued and where necessary regulated.

THE CONNECTED HEALTH PLATFORM

To realise the value of patient self-generated data fully, it needs to be appropriately managed and shared. A simple medicine diary will only create insights about adherence for the patient to look at and perhaps share at an occasional consultation. The opportunity to integrate and share data across stakeholders brings significant insights about behaviours and outcomes. Data needs to be liberated and should not be contained in a silo. This is a challenge that pharma can help address while also addressing internal needs of on-boarding new patients, adherence and creating engagement between health professionals, patients, payers and pharma.

A true connected health platform needs to support the requirements of all stakeholders fully, and it needs to be extensible such that a pharma company can add multiple disease specific apps and services to a common infrastructure and clinical database. A platform should also be engineered to ensure that privacy and regulatory requirements are implemented. Note that these vary from market to

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to a patient, the entire connected health strategy needs to be developed and aligned to stakeholder requirements.

It is necessary to work closely with patients and clinicians to really understand their needs, and use proven processes to test concepts and define and produce an optimal solution. It's also important to consider the caregivers, case managers and wider support systems around the patient to ensure that the delivered device and software is purposeful and valued.

THE REGULATORY AND PRIVACY CHALLENGE

There are significant privacy challenges in the development of a connected health solution. The development needs to be mindful of the likely regulatory scenario and the possibility that the app and cloud platform may be considered to be part of a system/combination product by the

CREATING A TRULY-CONNECTED HEALTH APP

A truly connected app needs to be built on a connected health platform that allows integration and, with the patient's permission, sharing of health data so that powerful insights can be gained, outcomes optimised and all stakeholders able to derive value from patient and device data.

An app needs to deliver valuable services and insights to patients so that it becomes a trusted part of their daily life, and facilitate gathering of data which can be insightful to patients, providers, payers and pharma. For example, medication expiration and usage tracking and re-ordering adds convenience for the patient and also helps pharma understand use patterns, track and trace, geographical prescribing variations and much more. Such data also helps clinicians and case managers understand patient adherence and
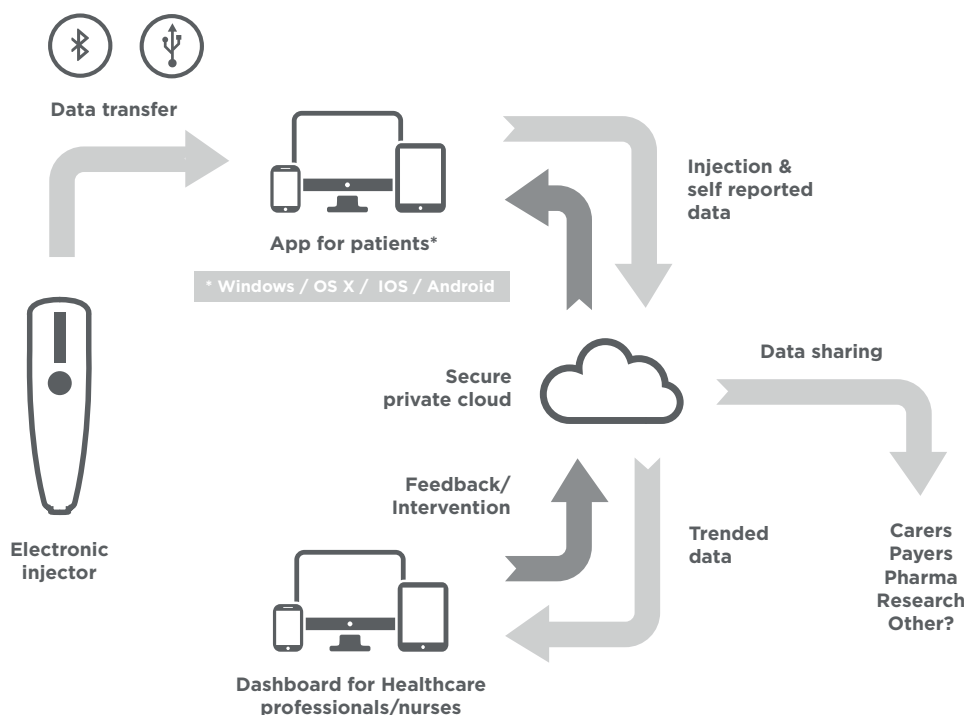
Figure 1: The complete connected system architecture.

market, which requires global experience of health data and privacy requirements. Additionally, the incorporation of clinical coding (ICD10, for example) allows a platform to be leveraged for global comparators, scientific research and integration to health provider and payer systems.

The requirements of pharma are different to those of provider organisations. A commercial case-management solution that looks at cohorts and risk stratification is a valuable tool. However, it doesn't specifically address the patient, healthcare professionals and pharma – "one size fits all" is not the most effective solution to patient cohort needs and stakeholder engagement.

MEDICOM'S APPROACH TO CONNECTED HEALTH SOLUTIONS.

Delivering a truly connected, potentially regulated, health solution is complex and requires expertise and experience (Figure 1). Medicom has extensive experience of smart, connected, medicine delivery devices and how best to leverage these technologies to create value-driven device and connected health strategies. Working for pharma clients, Medicom defines disease- and molecule-specific drug delivery strategies, tests concept feasibility, and designs and manufacture advanced connected medicine delivery devices, apps

and cloud platforms. Through ongoing internal development programs and access to intellectual property, Medicom has a portfolio of technologies that may be applied to accelerate time to market.

Medicom is bringing its third-generation connected health platform to market for its pharma clients to leverage in conjunction with connected health apps and regulated connected devices, enabling connectivity across the health ecosystem. This platform solution is tailored to each pharma client's requirements, and is typically hosted in a private cloud. Each pharma client can have a single, private cloud instantiation across the entire company portfolio, capable of being tailored to address multiple disease areas, multiple branded apps, portals and integrations while also providing a single source for advanced analytics and machine-based learning.

CONCLUSIONS

- Connected drug delivery devices and systems are entering the pharma landscape.
- Seek a platform approach that can be specifically tailored to your initial needs yet is extensible across your business as your connected health strategy and areas of disease focus evolve.
- Ensure that the designed user experience is fully oriented towards researched and evidenced patient, healthcare

professional and other stakeholder needs for each disease area.
- Leverage partners with proven connected health experience in both drug delivery devices and software; in the case of combination products it is complex to separate solution components and manufacturer responsibilities.
- Consider that your app, platform and connected drug delivery device can be regulated.
- Begin with the end in mind; while your initial ventures into connected health may be modest, ensure that you choose a partner and platform technology that can support your longer-term vision and advancing market expectations.
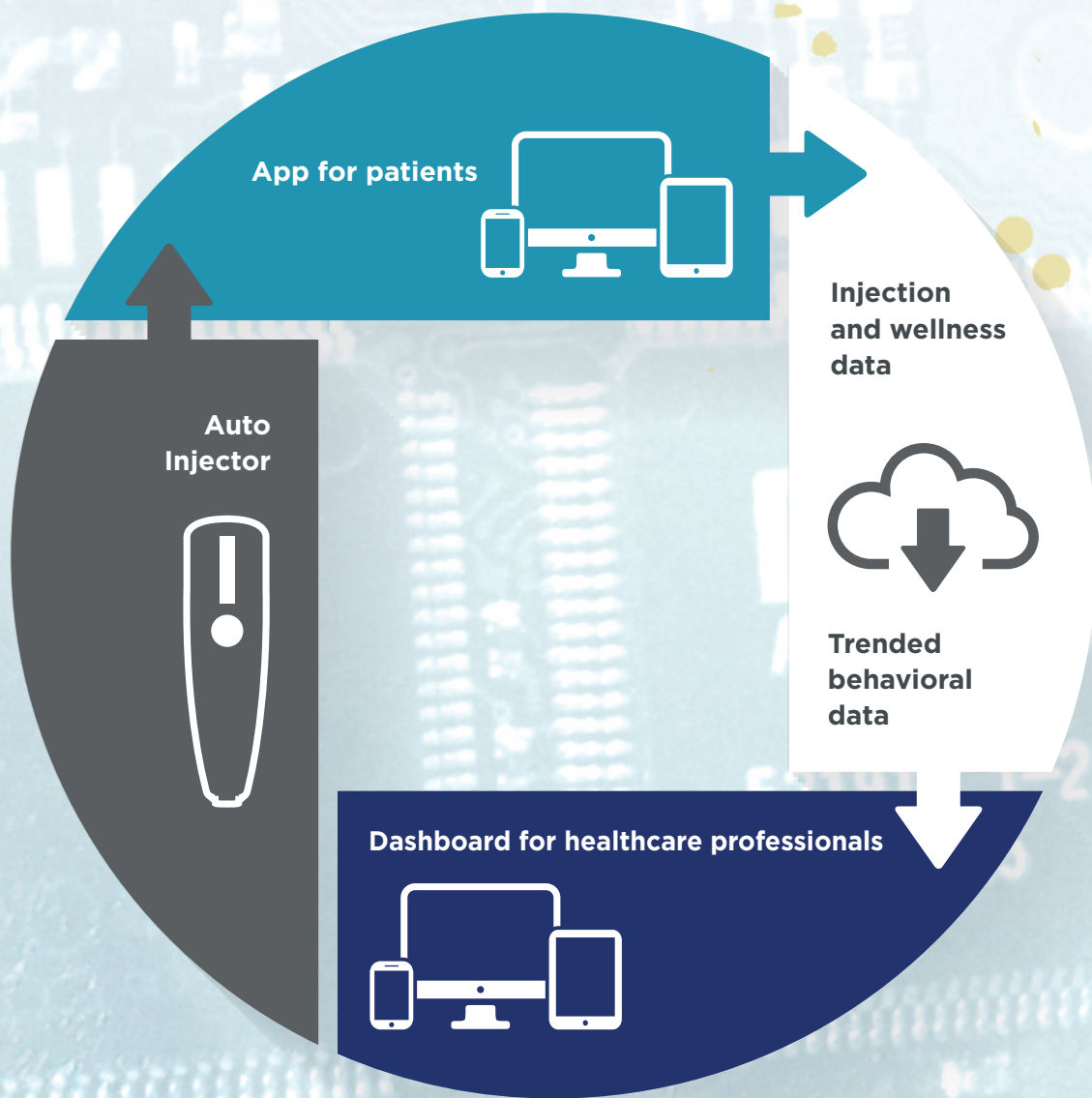
ABOUT THE COMPANY

Medicom Innovation Partner (a Phillips-Medisize Company) is a leading global innovation, development and low-volume production provider focused on Drug Delivery Devices and Connected Health solutions for the high-value rare disease and orphan drug market. Medicom Innovation Partner was established as a technology venture of Bang & Olufsen A/S back in 1989 and the company has been a dominant player within the Drug Device world for more than 25 years. Medicom holds a dedicated staff of more than 90 high-calibre innovation specialists, mechanical, hardware, software, quality assurance, regulatory and production engineers based in Struer, Denmark, and Cambridge, UK. Medicom has experienced considerable growth over the last five years.

As of May 31, 2016, Medicom is part of Phillips-Medisize Corporation. Phillips-Medisize is a leading global outsource provider of design and manufacturing services to the drug delivery and combination products, consumable diagnostics and medical device, and specialty commercial markets. The company has annual sales of over US$700 million with 80% of the total revenue coming from drug delivery, medical device, primary pharmaceutical packaging and diagnostic products such as: disposable insulin pens, glucose meters, specialty inhalation drug delivery devices, single use surgical devices and consumable diagnostic components.

Together Phillips-Medisize and Medicom will become one of the leading players within the growing drug delivery device and connected health market.

World leaders
in patient centric drug delivery systems

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App for patients

Injection and wellness data

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