INNOVATIVE SOLUTIONS:
DIGITAL DEVICES, DRUG DELIVERY AND SERVICES IN HEALTHCARE

In this article, the Medical Devices & Services team of Merck Group based in Coinsins, Switzerland, discuss the value of capturing "life data" using a connected device for improving patient adherence and therapeutic outcomes, using Merck's easypod™ device as an example of how digital technology can be successfully employed in a healthcare environment.

INTRODUCTION

Over the past 20 years, the healthcare landscape has changed significantly. While major advances in many therapeutic areas have been made, new challenges have arisen. For example, while life expectancy is increasing in many countries, the prevalence of chronic disease is also rising, which is coupled with the use of biological medicines. In 2015, EU member states' healthcare costs were >€1 trillion (£926 billion), equivalent to 7.2% of the EU's gross domestic product (GDP).[1] Healthcare has the potential to drive towards unsustainable higher speciality care costs. As such, there is an increasing need to go beyond the molecule and look at innovative ways to demonstrate and offer value to healthcare professionals and patients.

In parallel with the changing healthcare landscape, recent years have seen the advent of the digital age, with widespread use of the internet, smartphones and wearable technology in many markets. This has led to new and innovative ways to connect people with information and each other, and also offers opportunities to capture data at a patient population and individual patient level that can help inform current and future management approaches.

CURRENT PICTURE OF DIGITAL SOLUTIONS IN HEALTHCARE

The digital era has brought both advances in medical understanding and new technologies that have revolutionised healthcare. The use of eHealth records across medical services and centres, for example, can offer rapid access to patient information across different specialities supporting holistic care. While in 2007 only 9% of hospitals used eHealth records, a decade later 90% of hospitals employ and use them routinely.[2]

The digital revolution in healthcare shows no signs of stopping and presents many opportunities for patients to explore their health. The internet is often a source of health information, with one in five people in a UK survey reporting that they self-diagnose online.[3] More than 165,000 apps currently available for the Apple iPhone and Android phones are health-related. They offer medical information on conditions, symptoms and treatments, monitoring of health factors related to the user's condition, advanced medical consultation and appointment booking.[4-6] But how accurate are these apps in reality?

Whilst these tools may be useful for people who can't decide whether or not they ought to see a doctor, this method of obtaining information does not replace a

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face-to-face medical consultation and users should exercise caution when receiving the information.[7] In a study, funded by the US National Institutes of Health, software algorithms identified the correct diagnosis first only 34% of the time and symptom checkers tended to be overly cautious, encouraging users to seek medical attention when it was not needed – actions which could have serious implications for healthcare spending.[7] Despite their poor level of accuracy, digital medical apps continue to be used by patients and practitioners for a range of healthcare tasks and their use is not predicted to decline.[7]

WHAT DOES THE FUTURE HOLD?

Despite advances, there remains a significant need in chronic diseases for healthcare professionals (HCPs) and patients to be connected, by harnessing wider data points

the quality of conversations between patient and HCP can be significantly improved. Currently, healthcare insights are primarily driven by clinic appointments and evaluations performed in association with healthcare visits. This provides very limited knowledge as to the treatment behaviour on a day-to-day basis. It is during these "non-connected" periods that a patient can face challenges that impact their medication adherence and ultimately their clinical outcome.

The ability to capture "life data" beyond the clinic (e.g. patient attitudes and preferences, diet, exercise, sleep patterns and adherence) has evolved rapidly, but its use in healthcare is limited and under-utilised, leading patient insight between clinic visits to be lost. Adherence, for example, is a major consideration in patients with chronic diseases. Approximately 50% of patients do not take medications for chronic illnesses as prescribed and only a quarter of ongoing medication users are completely adherent, which can have a major impact on outcomes. For individuals with growth hormone disorder (GHD), for example, high adherence (≥78%) in the first two years was associated with significantly increased height gains compared with low/medium adherence (<78%), with a mean height standard deviation score (HSDS) gain of +1.16 in high adherence groups versus +0.88 in low/medium adherence groups (p= 0.01).[8]

With limited ongoing monitoring in most diseases, information about an individual's disease progression and treatment behaviour is missed and their appointments may only provide a snapshot in time. As a result, the patient's care team use an incomplete picture to inform treatment management decisions.

Digital solutions, including smart devices, can help complete the picture of the patient beyond the clinic and provide additional support to healthcare professionals. Data about an individual's condition, disease perception and adherence to medication can help enhance disease and treatment understanding, thereby informing and optimising medical practices. By leveraging digital technology and this "life data", a more complete picture of the patient journey can be achieved, giving a more holistic view to the HCP (Figure 1).

Merck has significant experience in the development and commercialisation of smart injection devices. The easypod™ electromechanical autoinjector administers a pre-set dose of Saizen®, a growth hormone for individuals with GHD. Over 40,000 of these devices were used worldwide in 2017 alone. easypod™ stores the date, time and status (complete, partial, missed) of each injection. easypod™ also has an eHealth component called easypod Connect, which uploads data wirelessly from the patient's home to a cloud-based platform and allows different stakeholders (healthcare

Patient smart devices and wearables capture 'life data' which are currently missed by healthcare. By leveraging the digital world, we can achieve transparency along a patient journey. This is an exciting opportunity to understand patients like never before, identifying hidden aspects of their chronic disease and treatment experience.
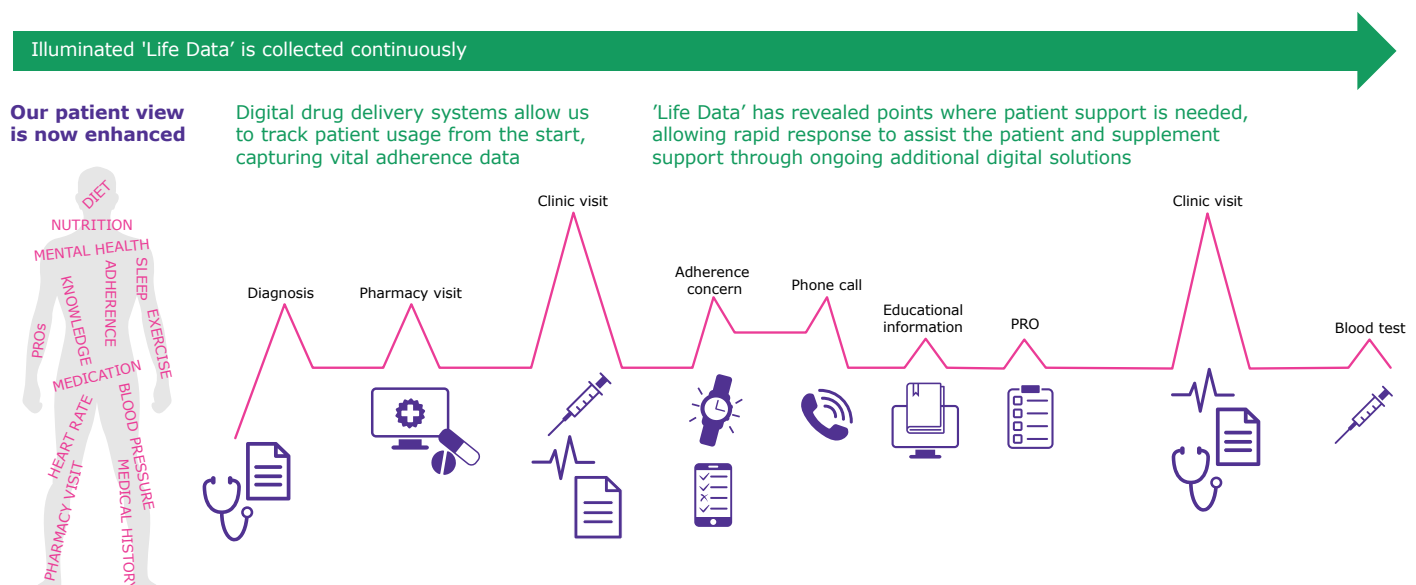

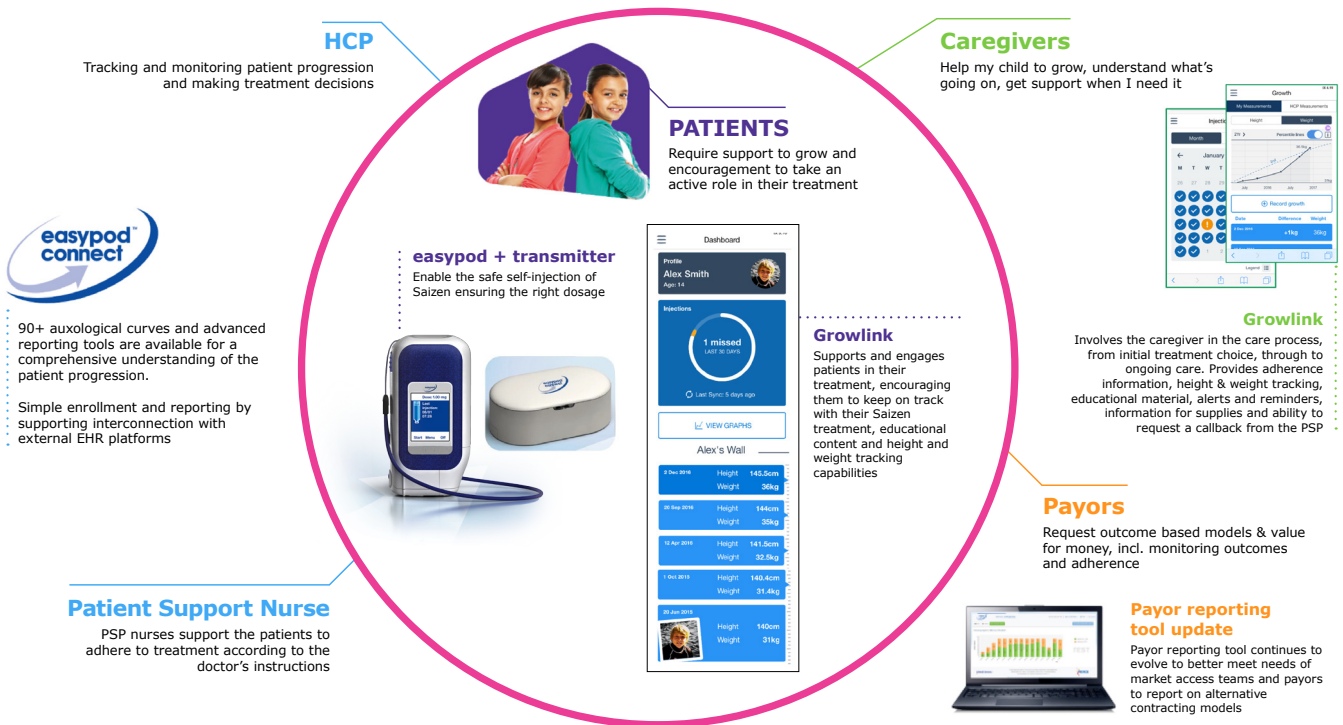Figure 1: An enhanced patient view.

Figure 2: easypod™ eHealth approach to treatment management: the Saizen® ecosystem.

> "Merck is proud that this broad eHealth approach is now benefiting over 14,000 patients worldwide. Recent studies also show that this approach is resulting in clinically significant levels of adherence improvement in the real world."

professionals, payers and patient support nurses) to view this comprehensive data (Figure 2). This remote monitoring capability allows the care team to act in a timely manner in order to manage their patients more effectively and offer tailor-made interventions depending on the issue at hand. This data can also be anonymised and aggregated to offer payers the opportunity to look at the effective use of medication in specific geographical areas.

easypod™ also has a patient smartphone application called Growlink, which was developed alongside growth hormone deficient patients and their carers. Growlink gives the patient and/or their carer the opportunity to track their injection progress, monitor their height improvement, as well as order ancillaries for their easypod™ device. The combined view of both adherence performance and clinical outcome (in this case growth improvement) aims to engage the patient and/or their carer in their treatment. Merck is proud that this broad eHealth approach is now benefiting over 14,000 patients worldwide. Recent studies also show that this approach is resulting

in clinically significant levels of adherence improvement in the real world.[9]

easypod™, in combination with the easypod Connect platform, was evaluated in a cohort of 9,314 patients across 33 countries, to assess adherence in real-world settings. The study reported that:

- The majority of patients using easypod™ had high adherence levels at each time point (1, 3, 6, 12, 24 and 36 months). This was defined as adherence at levels ≥85%, calculated as mg of growth hormone injected vs mg prescribed.
- At month 48, data were available for 665 patients, of which 67.8% of patients continued to achieve adherence levels ≥85%.
- Adherence was slightly better in girls than boys and showed a fall in levels with increasing age in both genders.
- These insights may help future inform strategies to target adherence in boys and older children.

easypod™ represents an important step in our ability to inform individual

management and, by pooling data, disease-level interventions. With the opportunities available as technology advances, a future goal is to collect the full range of "life data" from patients, revealing further insights and points where support is needed and identifying unmet needs for future development focus.

PIONEERING EXPERTISE IN MEDICAL DEVICES AND SERVICES

The increasing digitisation of our lives is currently producing a radical change in business models across several industries and the opportunity presented by connected devices in healthcare has been recognised. However, regulatory hurdles, country-specific challenges, the need to design and develop a device that is intuitive for patients and HCPs alike and addresses future needs can impede success or prevent a device coming to market. Further to this, the ability to leverage such devices and digital solutions in a manner which truly adds value to multiple stakeholders can be a challenge.

Merck's Medical Devices & Services (MD&S) arm understands these challenges and has developed specific device and digital solutions that address many complex issues and opportunities across therapeutic areas such as endocrinology, fertility and neurology. Merck's unique blend of professionals ensures a global presence and offers 10+ years of experience in deploying

these solutions in more than 50 regulated healthcare markets.

Merck's MD&S arm is focused on developing connected solutions, like easypod™, that gather meaningful and actionable insights into the behaviour of the patient when they are away from their healthcare team. These solutions look to engage and empower patients with complex long-term diseases, gather data to drive insights into the disease and give a deeper, transparent understanding of patient activity and insights between visits. This holistic view may help inform efficiencies within clinics, help to identify patients requiring greater support and aim to improve the patient experience and, ultimately, outcomes.

CONCLUSION

With the digital revolution, there is an opportunity to understand and support patients in new ways – gathering insights into aspects of their chronic disease and treatment experience, and supplementing support through ongoing digital solutions. By harnessing digital "life data", there exists

the potential to evolve healthcare insight, and deliver benefits to all stakeholders.

The expertise and experience within Merck's MD&S function allows Merck to operate with an ideation to commercialisation model. This includes insight gathering to identify the issue or opportunity, hardware and/or software development, regulatory approval and finally launch at scale that includes ongoing post-launch support. In this way, Merck can help bridge the gap to revolutionising healthcare.

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