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BEYOND TREATMENT

DEVELOPING CONNECTED DEVICES TO IMPROVE THE INTEGRATED STANDARD OF CARE

Here, Eric Dessertenne, Head of Commercial Operations and Business Development, and Edouard Poisson, Business Developer, both of Biocorp, introduce mHealth – the growing field of devices and apps that use mobile communications for healthcare – describe the importance of integrating medical devices with software in order to achieve the best results, and present their mHealth product, DataPen, a subcutaneous injection device that is connected with a mobile app using Bluetooth. The authors outline the various advantages that such a system brings, describe how they ensure security is maintained, and update us on the development status of the project.

INTRODUCTION

During the last decade, numerous studies on health information technology have underlined the positive impact of *eHealth* and *mHealth* on the healthcare system and patients' health. *eHealth* is the transfer of health resources and health care by electronic means. The term *mHealth* covers all devices and/or apps using mobile communications for health services. A review of the recent literature on the benefits of health information technology shows predominantly positive results with 92% of 154 included studies being positive or mixed-positive.[1]

These innovations are fuelled by healthcare sector needs and smartphone industry growth. Globally, there is a strong demand for new solutions to treat the rising number of people with chronic conditions and manage efficiently the growing healthcare expenses. Meanwhile, the booming smartphone industry is helping the spread of *mHealth* technologies, with more than one billion smartphone users worldwide in 2014.

Mobile health applications offer several opportunities such as lower healthcare costs, improved treatment outcomes and enhanced point-of-care delivery. Stakeholders from the entire healthcare industry have strong expectations concerning *mHealth* technologies:

1. Physicians strongly believe mobile health systems can help them give more informed clinical decisions and increase their patients' engagement
2. Patients favour medical treatments aligned more closely with the fluidity of their daily life
3. Payers face growing hospitalisation costs and need new processes to lower expenses
4. Pharmaceutical companies expect improved point-of-care delivery can bring new added value to their treatments.

THE IMPORTANCE OF MEDICAL DEVICE-SOFTWARE INTEGRATION

The rapid expansion and broad applicability of health-oriented software products have made it more complex to differentiate applications in one category, dedicated to mobile integrated therapies, from those in another, the lifestyle and information apps. The largest share of mobile health apps available today for download belong to the second category with apps that aim to inform users or help them improve their general health but do not target specific therapeutic areas (e.g. fitness, medical reference and wellness). These *mHealth* applications may be combined with wearable technology but are not integrated to a treatment. The

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Figure 1: Biocorp's DataPen, a reusable injection pen connected to a smartphone app.

mHealth apps from the first category help patients suffering from particular conditions in different possible ways (e.g. medical condition management, remote consultation and monitoring, compliance, etc). The *mHealth* apps belonging to this category, which are the focus of our study and also the focus of the US FDA's regulatory oversight, may have a significant impact on treatments and on the overall healthcare system.

However, these mobile applications often encounter the same obstacle: patients do not use them enough. Their retention rates are too low, mainly due to convenience issues for patients who already put a lot of effort into their treatments. Even mobile health apps recommended or prescribed by healthcare professionals meet moderate success, with 20% of patients using them and only 9.5% on a regular basis.[2] This issue greatly limits the benefits associated with *mHealth* technologies and their impact on patients' treatments.

Passive monitoring provides the solution to this hurdle. Once the medical mobile software is directly integrated with the drug delivery device, the monitoring process becomes fully automated. This device-software integration improves greatly point-of-care delivery and ensures the patient uses the mobile health app to its full extent. Furthermore, in order for this integrated system to be effective, it is necessary to keep both the device and the software easy-to-use and intuitive for the patient.

INTRODUCTION TO THE DATAPEN

The DataPen is a system composed of a reusable injection pen and a mobile app, connected by Bluetooth 4.0 (see Figure 1). This fully integrated system aims to help patients administer their medication, manage their treatment and share essential data with their physicians or relatives. The DataPen is used for subcutaneous delivery. The proof-of-concept has been developed for insulin therapy in diabetes mellitus, as real-time management is extremely important for this chronic condition.

"Passive monitoring provides the solution to this hurdle. Once the medical mobile software is directly integrated with the drug delivery device, the monitoring process becomes fully automated"

The device itself is easy to use and allows patients to deliver their treatment accurately and comfortably. There are only two steps prior to injection, to input the blood glucose level measured beforehand and to input the insulin dose to inject. The user can then proceed to the insulin delivery by attaching a new needle to the pen, priming and injecting the drug. All the different steps are indicated by colour LEDs to ensure patient follows the right process (Figure 2). The data is then sent automatically to the mobile app and stored in a secure database.

The device is compatible with standard 3 ml cartridges and with standard pen needles. The design and user interface of the DataPen are similar to those of existing pens in order to allow patients to switch easily from their traditional insulin delivery device to Biocorp's connected pen. Its weight (55 g without cartridge) and its size (16.8 cm) are also close to other reusable pens available. The device is fully independent during the injection process. Its internal memory can store up to three weeks of data (for insulin treatment, 3-4 injections per day), if it is not close to the smartphone or if the mobile phone does not have internet connection.

The mobile app associated with the device brings additional functionalities to help the patient, including reminders and

Figure 2: The DataPen uses a colour LED to help the patient go through the injection process.

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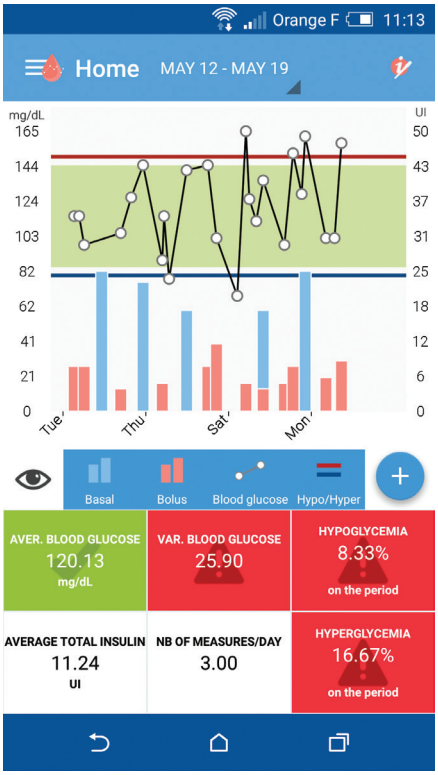

Figure 3: The patients can review quickly all their data thanks to a customisable dashboard. (demo version shown here)

alerts. Biocorp has focused its software development on three aspects:

- An intuitive user interface: patients prefer easy-to-use applications that require very little training
- Comprehensive visualisation dashboard (shown in Figure 3): physicians and patients need easy and quick access to the recorded data

"The DataPen is composed of a reusable injection pen and a mobile app, connected by Bluetooth 4.0. This fully integrated system aims to help patients administer their medication, manage their treatment and share essential data with their physicians or relatives"

- Data security: as detailed further below, health data security is crucial to develop patient-wise and even pharmaceutical lab-wise applications.

A DEVICE TO IMPROVE THERAPEUTIC COMPLIANCE

Therapeutic compliance can diminish complication risks and improve treatment outcome. A recent study estimated the effect of 100% treatment compliance in diabetes mellitus treatment with positive results: direct risk for diabetes-related kidney disease, stroke, heart disease and amputation were reduced by 13.6% for fully compliant patients.[3]

However, lack of therapeutic compliance is common, especially for patients suffering from chronic conditions. These diseases require burdensome treatments for a long period – often life-long, after the initial diagnosis – that patients have trouble following. For instance, the average compliance rate for Type 1 diabetes patients in the US is 70%.[4] It is even lower for other conditions such as multiple sclerosis with an average compliance rate of only 40% worldwide.[5]

These low rates impact treatment outcome and patients' health on the short- and long-term, and also have financial consequences for both healthcare systems and pharmaceutical companies. In the US, associated avoidable healthcare costs are estimated to amount to US$100-300 billion (£65-195 billion) per year.[6] Globally, associated annual pharmaceutical revenue loss is estimated to be $564 billion.

There are several factors explaining general lack of compliance: [6]

- Patient-centred factors: patient-prescriber relationship, forgetfulness, demographic and psychosocial factors, etc.
- Therapy-related factors: treatment complexity, medication side effects, etc.
- Healthcare system factors: lack of accessibility, long waiting time, difficulty in getting prescriptions filled, etc.
- Social and economic factors: inability to take time off work, cost and income, etc.
- Disease factors: disease symptoms, severity of the disease.

The DataPen contributes to an improved therapeutic compliance by influencing

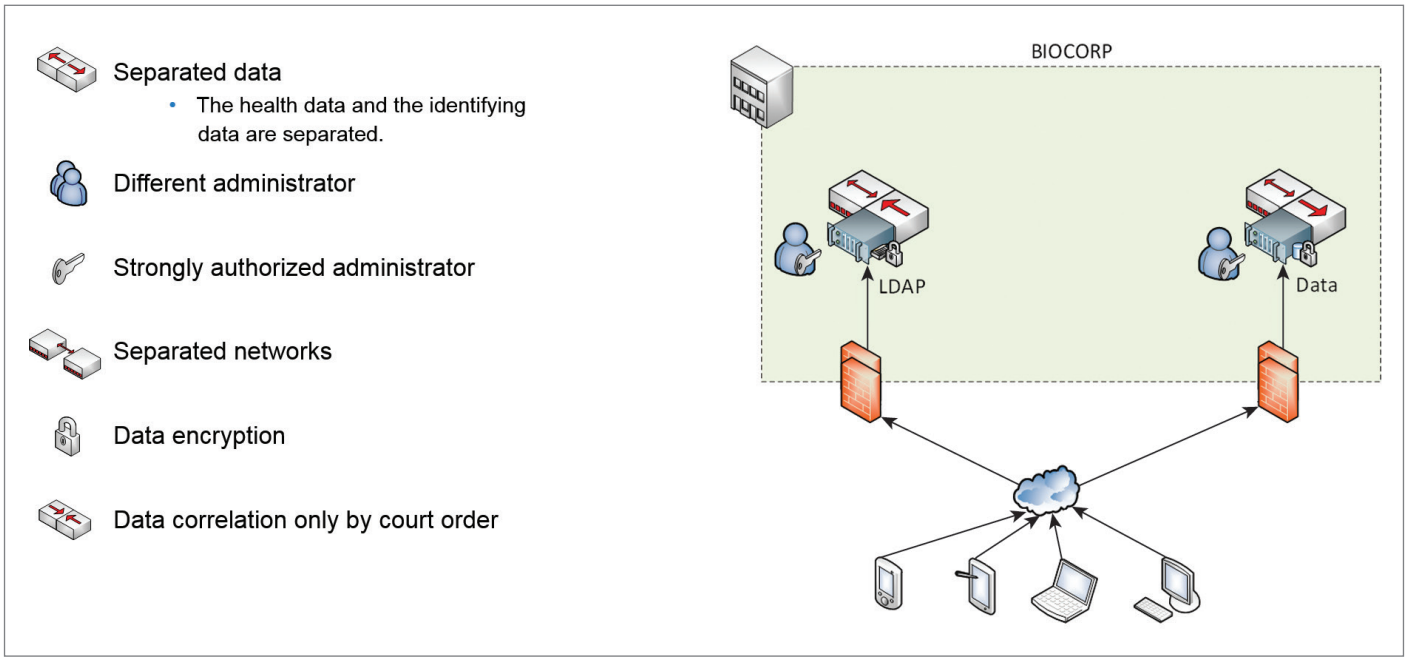

Figure 4: Data anonymisation: one of the security layers developed by Biocorp to protect patient data.

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patient-centred factors. First of all, patients have real-time access to information about their treatment and can better understand the benefits associated with good therapeutic compliance. Secondly, the DataPen helps create and maintain behavioural habits enhancing compliance. Both the device and the mobile application are extremely intuitive to ensure the patient uses the system regularly. Thirdly, the reminders and alerts avoid forgetfulness, especially if the patient's family is involved. This is particularly important for diseases such as diabetes for which non-taken medication can lead to major health issues and hospitalisation.

The connected device also improves the patient-prescriber relationship. The physician receives essential information about the patient's health and treatment, and can make more informed clinical decisions. Due to the integration of the software with the device, all of the data is recorded and managed automatically, making it much easier for physicians to provide accurate follow-up.

Finally, the DataPen contributes to the development of a "personalised medicine". Monitoring extended Phase IV trials can help define specific groups of patients. These patient pools can then be treated more accurately.

THE IMPORTANCE OF DATA SECURITY

Mobile health is still a fresh and emerging field and all the stakes and opportunities are not clearly identified yet. The literature available on the subject has, however, underlined the importance of data security. In the 2015 Data Breach Investigations Report, Verizon reported 234 incidents concerning health data security and 141 of data theft amongst them. Health data security requires greater efforts in order to protect patient confidentiality. The purpose of implementing high data security is two-fold:

- Push cautious patients to use *mHealth* systems without restraint
- Use anonymous data more freely.

Bluetooth 4.0, used by the DataPen to transmit data to the associated app, is low energy consuming but brings moderate protection. The software R&D division at Biocorp, expert in data encryption and security, has added several layers of protection (see Figure 4).

First of all, each DataPen is associated with an app with an individual code that the patient enters before first-use. After this code has been successfully entered, the DataPen is linked to the patient's user account, meaning he can access his treatment information on any mobile device provided it is connected to the internet. In consequence, the data is not stored directly on the smartphone but on a database that the user account has access to. The database is a certified tier III with very high security, optimal availability and performance.

Secondly, the data is encrypted at the beginning of the data transfer process. Biocorp has patented an encryption system that adds more security to the Bluetooth 4.0 communication process.

Finally, the data is fully anonymised. Even though the data is encrypted and kept secure, this last layer of protection ensures that the patient data is kept confidential. User personal information and health data are two separate flows of information, kept into two different networks. Only the patient concerned can choose to de-anonymise his personal data, a process which requires two separate authorised administrators.

Most companies in the *mHealth* industry do not develop this complex infrastructure to support their software products. However, such systems are necessary today to implement mobile integrated treatments and provide comprehensive solutions. The structure developed by Biocorp grants optimal data security and has the capacity to process several billions of transaction.

DEVELOPMENT STATUS

The DataPen was presented for the first time at Pharmapack Europe 2015 in Paris, France in February, and was awarded in the "Exhibitor Innovation" category. The device has not yet been approved by the regulatory authorities. Discussions with pharmaceutical companies for various therapeutic areas are ongoing. Biocorp continues to strengthen its position as the pioneer in connected drug delivery and will announce new products over the next few months.

ABOUT BIOCORP

Biocorp is a company specialised in the development and manufacturing of medical devices. Biocorp develops innovative primary packaging for the pharmaceutical industry such as reconstitution sets and alternative to crimp caps. Biocorp also develops leading-edge passive safety systems for syringes and drug delivery devices. Biocorp has a unique double-expertise, making it a pioneer in digital health: a device R&D team and a software R&D team work hand-in-hand to develop highly integrated devices that help patients manage their treatment and improve their therapeutic compliance.

"The connected device also improves the patient-prescriber relationship"

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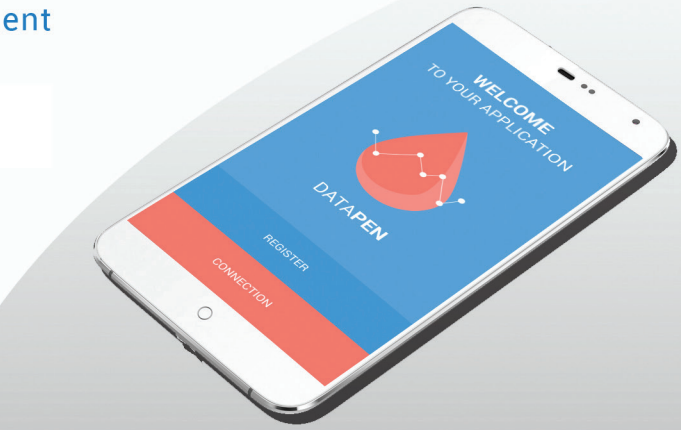
PIONEER IN CONNECTED HEALTH

The **DataPen**: be smart about your injection

- Improve therapeutic compliance
- Increase treatment efficiency
- Inject with high precision



Analytical insights

Data sharing

Treatment history

Stock management

The DataPen has not yet been approved by regulatory authorities

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DEVELOPING AND MANUFACTURING INNOVATIVE MEDICAL DEVICES

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