BIOCORP
BEYOND TREATMENT

THE MULTIPLE VALUES OF INTEGRATED SOLUTIONS

In this article, Arnaud Guillet, Business Development Associate, and Eric Dessertenne, Head of Commercial Operations & Business Development, both of Biocorp outline the potential value of the data that can be collected from integrated devices, not only for pharma companies but also for patients and payers.

Switching to connected devices is a much debated topic but what is the real value behind these new solutions?

The shift from product-centered and cost-based medicine to patient-centric and value-based medicine is already in motion. In this new context, Biocorp does not perceive devices as instrumental to the treatment, but as part of the treatment. Thus, a connecting device does not mean adding new functionalities, it means providing integrated treatment solutions, which incorporate:

- A drug delivery system, to meet the primary function of such devices
- A treatment management tool, to embrace this new patient centric era
- Automatic generation of treatment data, to demonstrate treatment efficacy and prove value.

These new treatment solutions must deliver drugs in the most convenient and user-friendly way, support patients in monitoring and managing their treatments (including supporting their relationships with healthcare providers (HCPs) and relatives), and generate reliable treatment data to demonstrate their efficacy, for example, to payers.

When it comes to connected health solutions, there are two key questions to be addressed. Firstly, who should pay? Patients, pharma or payers?

It goes without saying that moving to connected devices generates an extra upfront cost that needs to be supported most of the time by pharma companies. This extra cost can be allocated to the marketing budget and be part of a financial effort to monetise a key product, even though the impact of this shift will go way beyond.

"Pharma companies are neither data-hosting centres nor data encryption specialists, but they need access to compliant, secure, reliable health data to enhance their operational and strategic capacities. Providing them such access is one challenge that Biocorp is ready to meet."

This extra cost will eventually impact on pricing, which can imply a higher cost for patients. However, if these solutions bring actual added value to the patients in terms of comfort and treatment management, their willingness to pay will go up.

Finally, payers are most likely to be involved if these solutions are proved to be medico-economically efficient. Higher reimbursement by public payers or inclusion in private insurance coverage plans are to be expected. In this context, data generated by connected devices will have a key role to play.

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The second key question to be addressed is, who owns the data generated by connected devices?

This question has provoked a lot of debate among both the healthcare and the big data communities. However, the simple answer to this is that patients own their data.

> "Biocorp has built software capacities to provide its partners with secured, anonymised, consistent and reliable data."

Thus, the first step is to obtain patient consent before considering any possible use of the data. To obtain such consent, healthcare companies must follow strict guidelines, which ensure they are not only compliant with regulation, but also meet patients' expectations and are extremely protective of their privacy. Then, the question of ownership is open and depends on various criteria that are beyond the scope of this article.

However, the real question is not data ownership – it is data access and right to use. Pharma companies are neither data-hosting centres nor data encryption specialists, but they need access to compliant, secure, reliable health data to enhance their operational and strategic capacities. Providing them such access is one challenge that Biocorp is ready to meet.

ADDED VALUE TO HEALTHCARE KEY STAKEHOLDERS

Connected devices can improve patient experience, provide pharma with a decisive competitive advantage and support payers in their effort to contain costs related to treatment.

Patients
Patients have requested evolution of devices – initially only to focus on risks (data safety, privacy issues etc) – but they have gradually integrated the potential benefits. Now it is estimated that 75% will sign up for a mobile app to a help them adhere to their treatment and track their health goals.[1]

Patient engagement emerged as a top priority for healthcare organisations. 72% of US healthcare organisation leaders indicate that consumer and patient considerations, such as patient engagement, satisfaction and quality of care would be the business issue that would most impact on their organisation over the course of the next two years.[2]

Connected solutions bring comfort to the patients in managing their treatment and improve care efficacy, thanks to:

- Personalised health: tailored solutions to adapt to each patient
- Simplified treatment management: automatic collection of data, reminders, easy stock management (info on stock of consumables), solutions adapted to their habits (mobility, speed, instantaneity) and tools (tablets, smartphones, applications)
- Treatment accuracy and safety: facilitate reporting, eliminate human errors, prevent patients from missing their shots, avoid double dosing
- Treatment understanding: patients have access to accurate treatment data in real time on their smartphone
- Easy relationship with HCPs and relatives involved in their treatment: options to share reports, simplified and faster communication routes.

Payers
Payers can achieve cost savings thanks to patients' better compliance and healthier behaviours:

- Monitoring tools contribute to improve treatment adherence (reminders, alerts, etc). An Oxford study published in the American Heart Association journal *Circulation* in January 2016[8] demonstrates that text message reminders can help reduce blood pressure by significantly improving treatment adherence.
- Direct cost of non-adherence in the US is estimated at US$100-289 billion (£69-200 billion) annually by the Center for Disease Control.[3] Non-adherence to cardio-protective medications increased risk of cardiovascular hospitalisations (from 10% to 40%) and mortality (from 50% to 80%). Improved self-management of chronic diseases results in an approximate cost-to-savings ratio of 1:10.
- Connected solutions make patients responsible for their treatment, creating value-conscious and empowered healthcare consumers. This shift to "behavioural economics" has already been embraced by some payers.

As an illustration of this new trend, South African insurer Discovery has implemented the Vitality programme. This initiative uses financial incentives to encourage members to make healthy lifestyle choices, such as awarding points for physical exercise, discounts on healthy foods and points-based rewards ranging from reduced insurance premiums to travel options and shopping discounts.

As a result of these benefits, gym usage among Vitality members increased by 22% over a five-year period, and the proportion of healthy food being purchased increased by 3% in the first year. The use of benefit programmes to engage members in healthy behaviour change has also led

> "Major big data actors on the market have been developing innovative solutions to process data in the most effective way but they cannot succeed without partnering with healthcare providers, medical research institutes, pharmaceutical companies and device makers."

to significantly reduced costs. For chronic conditions, risk-adjusted hospital costs are as much as 30% lower for engaged Vitality members. A fitness study showed that hospital admission rates are 10% lower and length of stay in hospital is 25% lower for highly-engaged Vitality members.

Pharma
Connected solutions creates substantial value for pharma at various levels:

- Increase pharma revenues by boosting medication adherence. A 2012 Capgemini Consulting report[6] showed that the global pharmaceutical industry loses an estimated $564 billion annually due to medication non-adherence and

even a modest 10%-point increase in adherence could lead to a significant rise in pharmaceutical revenues

- Enhance patient engagement and experience
- Engage with HCPs: 85% of US doctors use smartphones and medical apps. 88% would like their patients to monitor their health at home, particularly their weight, blood sugar, and vital signs
- Provide competitive advantage: in a highly competitive market, the device is a key way to differentiate. Connected devices offer substantial benefits over regular devices
- Improve relationship with payers by offering value-based medicine, real-life evidence.

Figure 1: A wealth of data.

THE GOLD MINE BEHIND CONNECTED DEVICES: DATA

Biocorp's vision of connected solutions goes beyond the device itself and its various benefits for patients, payers and pharma. For Biocorp, connected devices means above all else – data. These brand new integrated solutions will generate a vast amount of health data on patient adherence, behaviours with treatment and satisfaction (Figure 1).

Making these data available, intelligible and usable for pharma partners is one key Biocorp objective. Over the past few years, beyond reinforcing Hardware R&D efforts, Biocorp has built software capacities to provide its partners with secured, anonymised, consistent and reliable data. This will fuel pharma business intelligence and bring multiple benefits.

Before describing Biocorp data capacities, let's look at what pharma can do with data.

THE BENEFITS OF QUALITY DATA

Real-World Proof of Value

A new era of healthcare is arising where monetary payments are based on *in-situ*, real-world evidence. It's a small step from direct impact to indirect impacts, such as population-based reductions of comorbidities. Ability to provide such evidence will become a key asset in the relationship with public and private payers.

Another major issue facing pharma is getting pharmacy benefit management companies and insurers to include their products in formularies. Some formularies are being decided on outright cost alone, cutting out competing products. Real-life data can prove that your drug conferred a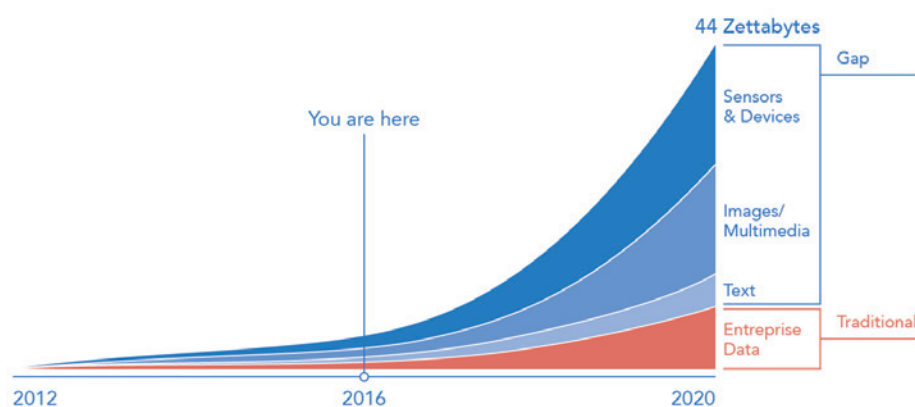 health advantage and long-term cost savings from a population standpoint over a cheaper competing product. Assessing treatments to enhance health-economic efficiency, data analytics are a key enabler for evidence-based medicine.

AstraZeneca recently implemented a relationship with the Anthem, Inc (Indianapolis, IN, US) data and analytics group. They plan to conduct real-world studies to determine best treatments, including some for chronic diseases, as well as to guide R&D investment decisions. AstraZeneca is working with payers to ensure it has the evidence to obtain coverage for its drugs.

Improves Safety Management

Safety monitoring is moving beyond traditional approaches to sophisticated methods that identify possible safety signals arising from rare adverse events. Furthermore, signals could be automatically detected thanks to connected solutions. This approach provides data on the reach and reputation of different medicines. Bayesian analytical methods, which can identify adverse events from incoming data, could highlight rare or ambiguous safety signals with greater accuracy and speed.

In the context of pharmacovigilance, an automatic collection of data could trigger the alarm instantly whenever an issue arises and allow an early response to physician and patient sentiments, which could prevent regulatory and public-relations backlashes.

Improves Clinical Trials

Data collected can help pharma improve the criteria for including patients in a trial. They could target specific populations, thereby enabling trials that are smaller, shorter, less expensive and more powerful.

Insights gathered in real time can allow rapid responses such as dynamic sample-size estimation (or re-estimation) and other protocol changes. Efficiency gains are achieved by enabling smaller trials for equivalent power or shortening the time necessary to expand a trial.

Real time means quick identification of safety or operational signals requiring action to avoid significant and potentially costly issues such as adverse events and unnecessary delays.

Increased use of electronic data capture could help in recording patient information in the provider's electronic medical records. Using electronic medical records as the primary source for clinical-trial data rather than having a separate system could accelerate trials and reduce the likelihood of data errors caused by manual or duplicate entry.

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Optimise R&D Investments

Data collected could lead to computational studies and advice on treatable populations, trials design, subject selection (e.g. best-responding patient groups), delivery method (e.g. oral *versus* injectable). It will provide key decision makers with valuable information to define R&D investments better, including drug development.

Early Identification & Better Targeting of At-Risk Subjects

Connecting data from health, genetic, ancestral and other databases, which support preventative lifestyle changes and treatments, and contain information on population-wide healthcare costs through integrated devices, can permit early identification of at-risk subjects. It will automatically improve subject targeting.

Data can help in designing more effective risk management programmes by segmenting patients and stratifying risks. Data analytics make it possible to assess deviations from protocols by region and individual provider. Drug effectiveness can then be improved by targeting programmes and actions at patients who deviate furthest from protocols or who are more likely to change behaviour.

Data gathered in real-life conditions will help identify issues and appropriate actions to be taken in complex cases, including correct tests and properly selected, dosed and timed treatments. Better treatment selection and regimen will lead to better patient compliance

PARTNERSHIPS WITH PROVIDERS

Major big data actors on the market (such as IBM, OptumHealth, Oracle, Verisk Analytics and McKesson) have been developing innovative solutions to process data in the most effective way (IBM Watson Health solutions and Oracle Enterprise Healthcare Analytics, to provide just one example) but they cannot succeed without partnering with healthcare providers, medical research institutes, pharmaceutical companies and device makers.

In this context, Biocorp will help pharma to be a part of big data projects and capture some of this booming market value. The global healthcare data market is expected to reach $18.7 billion by 2020 from $5.8 billion in 2015, at a CAGR of 26.5% during the forecast period.[10]

IBM Watson Health wants to help drug and device companies make that shift from being a product maker to evolving into a company that offers its customers solutions. In line with that thinking, in 2016, IBM Watson Health and Medtronic announced a partnership aimed at improving care in diabetes. "They collect a lot of data through blood glucose monitors and insulin pumps," said Kathy McGroddy-Goetz, Watson Health's Vice-President of Partnerships

and Solutions, "but they didn't have the ability to generate cognitive insights that could transform easily into services and solutions." With Watson's help, the two companies are set to release an app by the end of 2016 that could feature a text-message service that tells the patient that a low blood sugar or hypoglycaemic event is likely to occur in the next hour.

Besides device makers, the company has also partnered with Novo Nordisk. This partnership is also centered around how to help patients manage chronic disease better. "In the past, a pharma company wouldn't necessarily know who their patients are. Now they're trying much more to engage patients and find ways to understand more about them. That's become really valuable to them," added McGroddy-Goetz.

Novo Nordisk is working with Watson Health to develop a type of virtual coach to help inform decisions about insulin dosage. Watson will also analyse health data from patients with diabetes to help them ultimately better manage the diseases. That data could end up informing a tool, like a mobile app, that could help take some of the guesswork out of diet, exercise and insulin.

BIOCORP CONNECTED DEVICES

Biocorp offers two options to integrate connected solutions into your portfolio:

- Launch a development programme to replace your device with a brand new connected device
- Equip your existing devices with an add-on, a smart sensor that turns regular devices into connected and communicating devices.

New development Program Approach, Illustrated by DataPen

Compatible with prefilled cartridges, the Datapen is a smart and innovative subcutaneous drug delivery system adapted to chronic disease treatments.

The electromechanical injection simplifies the product delivery and provides maximal user comfort. This system guarantees a high degree of accuracy for the injection and a high repeatability of injected doses. Data are automatically transferred to a treatment mobile app via Bluetooth. Biocorp complies with the highest standards of health data encryption to guarantee maximal data security.
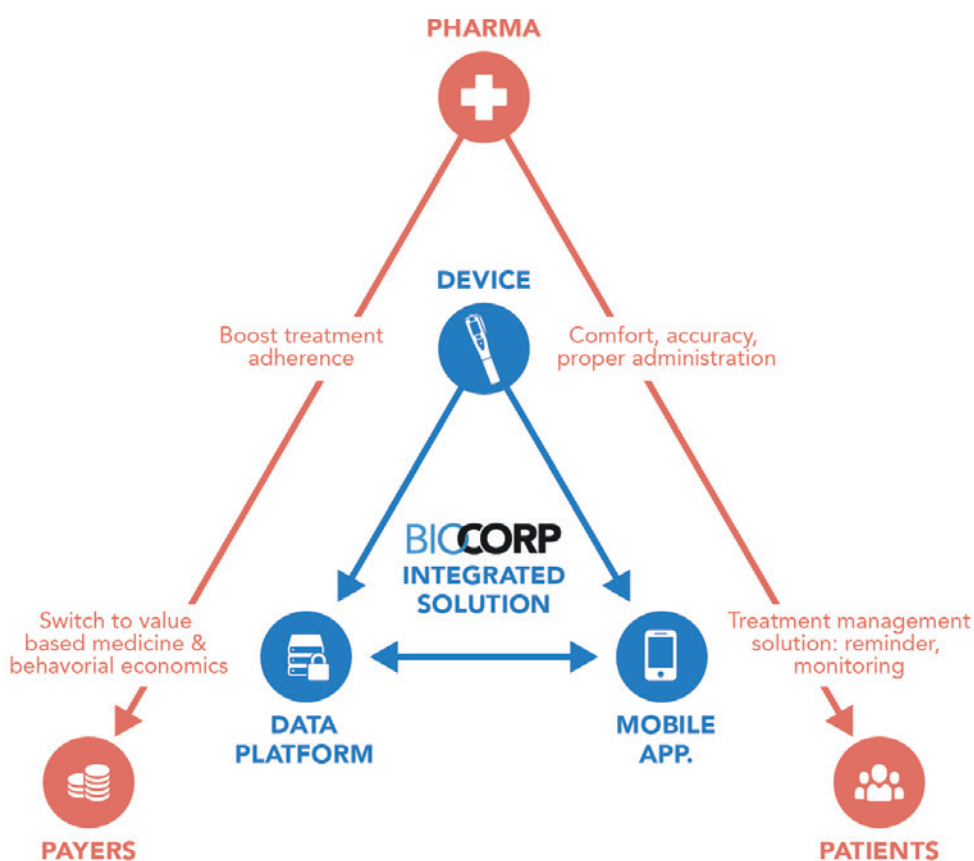

Figure 2: The Biocorp integrated solution.

Add-On Approach,
Illustrated by EasyLog and Inspair

Integrating some electronic components into disposable medical devices proved to be cost inefficient due to the cost of technology. However, add-ons answer that unsolved business case. Through add-ons, Biocorp's ambition is to connect existing medical devices by adding smart sensors to regular drug delivery devices.

This new approach provides a shortcut towards integrated drug delivery systems because it fits in the lifecycle management strategy with no impact on industrial process. It also limits the investment needed to convert regular injection devices into connected devices.

In the field of injection devices, EasyLog is a smart sensor that converts all injection pens, reusable as well as disposable, into connected devices.

EasyLog automatically collects injection data (dose injected, time and date). The measure is 100% accurate and can differentiate doses selected and doses actually delivered. Data are transferred via Bluetooth to a treatment mobile app. Successful ergonomics tests in users have proven that the system is easy to understand and user friendly.

In the field of respiratory devices, Inspair is a smart sensor that turns pMDIs into connected devices, records inhalations and guarantees proper inhalation technique compliance.

Inspair features miniaturised sensors and electronic card, and fits on most MDI mouthpieces thanks to specific adaptors.

The system monitors inhalations and guarantees proper inhalation technique compliance. It automatically records daily inhalations, checks the right preparation of the canister (shake before usage), assesses the co-ordination of actuation with inhalation ("hand-mouth" co-ordination) and provides useful guidance throughout the inhalation steps.

BIOCORP MOBILE APPLICATIONS

All Biocorp smart drug delivery systems are connected to medication adherence mobile apps providing patients with real-time information on their treatment, reminders and alerts as well as a treatment calendar, graphics and analytics (Table 1).

Thanks to its software capacities, Biocorp can develop mobile applications specific to a designated pathology

BIOCORP Software Factory	BIOCORP Agile Method
• Automation: no human error for testing/deploying, continuous QC with automated tests and deployment • Standards: internal best practices compliant with the highest market standards • Control of lead times: calibrate to meet deadlines and project requirements • Constant quality check before release for better software quality	• Iteration: build and release new software using iterative processes • Build as you go: easy integration of new product requirements • Quick time to market: quick deployment of new functionalities
Efficiency: quick delivery of product functionalities with the highest standard of quality and control	

Table 1: Biocorp software development approach for apps providing patients with real-time information, reminders, alerts, calendar, graphics and analytics.

Figure 3: Appli home 7 days

Figure 4: Appli reports

(such as diabetes, growth hormone deficiency, asthma or cardiovascular issues) and adapt their content to specific treatment management issues (Figures 3 and 4).

BIOCORP DATA QUALITY

Having data that are consistent, reliable, and well linked is one of the biggest challenges facing pharmaceutical R&D. (See boxed text for details of the data processing platform.)

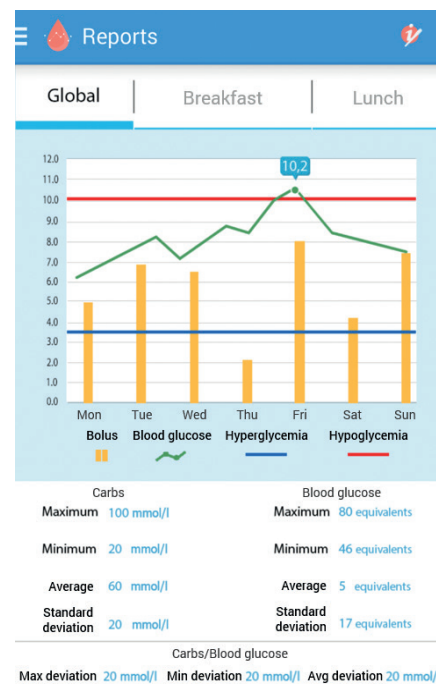• Secure data: secure connection process with individual code

• Security: TIER III Data Center, encryption of all flows, doubling of security equipment

• Compliant data: anonymised data, upgradeable privacy settings, formal patient consent required

• Reliable data: tested technologies, automatic collection (no human error), no selection biases

• Specific data: controlled cohorts, related to a specific pathology, related to specific device

• Comprehensive data: all data automatically captured and integrated, no information gaps.

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BIOCORP DATA PROCESSING PLATFORM

Data acquisition

- Data is collected from a unique user account
- Secure connection process is provided with strong factor authentication.

Storage

- Hosting: compatible with government-certified web hosts
- Security: TIER III DataCenter, encryption of all flows, doubling of security equipment
- High availability: fail-over, supervision 24/7, multi-site
- Performance: network connection fibre, high performance storage, servers clusters and application cluster.

Processing

- Designed for Big Data: several billions of transactions are possible
- Big Data management: high level of data quality and accessibility for BI
- Cryptographic anonymisation process, providing the highest level of protection for patients.

BIOCORP, YOUR TRUSTED PARTNER FOR INTEGRATED TREATMENT SOLUTIONS

Electromechnical injection: only a slight push, whatever the quantity of product injected

Visual signal to notify the end of injection

Home

114.4

42

DATAPEN,

A REUSABLE INJECTOR
PEN CONNECTED
TO A MOBILE APP.

Compatible with regular prefilled cartridges

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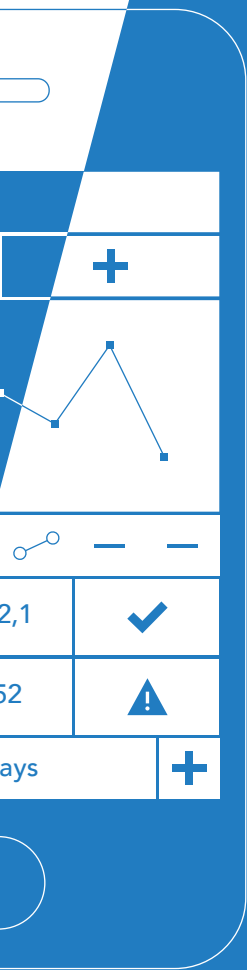**+33 (0)6 08 02 14 51**
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INJECTION DATA ARE S
ON SERVERS BELONGING
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HOST BEFORE BEING SA
TRANSFERRED TO A TREATM
MOBILE APP.

EASYLOG,
A SMART SENSOR FOR INJECTION DEVICES

Automatic collection of doses with time and date

Compatible with all injection pens, reusable as well as disposable

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ATTACH AN ADD-ON **TO YOUR EXISTING DEVICE**

Compact design, miniaturized sensors and electronic card

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WEB
AFELY
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Modular concept fits with the majority of MDIs available on the market

INSPAIR,
A SOLUTION TO MONITOR MDI USE