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MALLYA: ENLIGHTENING PAST, EXCITING PRESENT, PROMISING FUTURE

Arnaud Guillet, Vice-President Business Development at Biocorp, reviews the Mallya connected device platform, from the origins of the project to the current success in diabetes and deployment in other fields, and introduces the promising next-generation Mallya.

Looking back at the Mallya journey, which began in 2014, gives some perspective on the evolution of the drug delivery device and the pharma industry during the last few years. Following the path of other sectors – with a noticeable delay due to regulatory, technical and mental barriers – the rise of digital health and connected solutions has been spectacular in this field, and we are now at the dawn of a new era of value-based care, supported by objective data. This wave has been specifically spectacular in the field of diabetes, initiated by disease management mobile apps, the adoption of continuous glucose meters, digital therapeutics – and now, smart solutions to monitor insulin delivery.

In this context, after six years of intense development, testing and regulatory work, the first version of Mallya – dedicated to insulin pen injectors – has been launched in the fourth quarter of 2020, in a few geographies in Europe and Asia, and is preparing for large-scale distribution in 2021, with orders already secured. But smart delivery devices require continuous improvements and sustained innovation towards an ever-better patient experience and Biocorp is now unveiling the next

version of its Mallya platform to be launched within two years. It is time to look back at the origins of the Mallya project and contemplate present and future challenges.

THE UNMET NEEDS BEHIND THE SOLUTION

When launching its connected initiative in the early 2010s, Biocorp quickly decided to focus on diabetes, as it was the therapeutic area with the most urgent needs for treatment delivery monitoring solutions, and decided to go for the add-on option, considering the characteristics of this area.

From the perspective of both the patients/healthcare professionals (HCPs) and the health industries, investing in connected solutions to support the management of diabetes seems like an evident necessity. Managing diabetes is a complex endeavour and relies on multiple pillars: careful lifestyle management, carbohydrate counting, glucose monitoring, titration, medicine intake, frequent adjustments and interactions with referring doctors. Plus, the structure of the market calls for differentiating factors. Diabetes is a highly concentrated market, specifically for the insulin segment, with a limited number of companies competing for commercial advantage and looking to differentiate through their service offering.

This context explains the spectacular penetration of connected solutions in the field during the past few years, covering almost all parts of the patient journey, with very advanced solutions for glucose monitoring (continuous glucose



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monitoring systems such as Dexcom G6 (Dexcom, Camberley, UK) or Abbot Freestyle Libre 2), successful digital therapeutics (Livongo (CA, US), Omada (Copenhagen, Denmark)) and US FDA-approved insulin titration software (Amalgam RX (DE, US)).

Connectivity emerged as a market standard. But there was one missing piece in this picture: a reliable solution to monitor insulin delivery, for which pen injectors are by far the widely dominant option. Providing reliable smart pen options has emerged as a new frontier for diabetes management, and the only option to provide a truly comprehensive disease management product.

In that context, Biocorp decided to go for the add-on option, as disposable pens are by far the most commonly used option by patients. Integrating electronic components and communication sets into a disposable system was neither economically viable nor environmentally acceptable. Users' habits are hard to break and, to this day, there is no evidence of a significant switch from disposable to reusable pens. This is why Biocorp worked on developing a smart clip-on device, collecting the dose selected and enabling automatic transfer to companion software that can be easily installed on existing pens and removed once they are out of drug, which will also last for a significant time.

Although Mallya was initially developed for diabetes, pen injectors are a common drug delivery system in many other fields, including fertility, growth hormone deficiency, osteoporosis and parathyroid hormone. Engagement factors might be different in those different therapeutic areas but Mallya can provide several benefits – from injection guidance and reassurance to compliance tracking and patient reward initiatives.

THE SOLUTION

Based on these foundations, Biocorp has developed Mallya, a Bluetooth-enabled add-on module composed of two parts – a body, containing an electronic board that is clipped to the pen; and a button, attaching to the dose button of the pen. It turns any conventional injection pen into a connected device and automatically records treatment information (selected dose, date and time of injection). Data is sent in real time to companion software, using Bluetooth technology.



Figure 1: The Mallya device.

"Mallya turns any conventional injection pen into a connected device and automatically records treatment information."

This device was developed following some core principles to ease user adoption and trust, and simplify implementation for pharma companies.

1. Simplicity for Users and all Stakeholders

Providing connectivity to patients is key but it also important to take into consideration that patients are using a "simple" pen injector device already and we have to integrate connectivity into their daily routine without impacting their user experience. To make it seamless for patients, tremendous efforts were made on the mechanical side to work on the form factor and look and feel of the device. The evolution of the platform is testament to the level of commitment from the R&D and usability teams (Figure 1).

On the hardware, firmware and software side, Biocorp's R&D team made the system totally passive from the patient perspective – and the set-up and the onboarding sequence

have been streamlined using a proximity pairing system and a quick video sequence to guide patients through the process.

Making it simple for patients also implies a clear value proposal. Biocorp has explored many potential functionalities for the device but, through discussions with HCPs, patients and pharma partners, eventually realised the importance of focusing on a very limited number of key functionalities – type of insulin, dose selected, time and date.

On top of simplicity for users, ease of implementation for pharma partners was a key driver in the design and development of this solution: the implementation of Mallya does not imply any modification of the existing pen, whether internal or external. No mechanical adjustment is needed to make it fit and no addition of small components (magnets, electronics, etc) is required. Following this principle significantly limits the regulatory and industrial impact for Biocorp's partners.

2. Accuracy, Reliability and Robustness

Mallya was initially developed for diabetes and the monitoring of insulin delivery. In this area, accuracy and exhaustivity of information is paramount. Coming from this background, top priority was to work on a system reaching the highest level of accuracy, replicable on any pen platforms, in any therapeutic areas.

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level of accuracy. The model accuracy and the algorithm reliability were validated through robust testing, combining bench tests and user testing in real-life settings.

Beyond accuracy, the system provides further guarantee to the patient: exhaustivity of data, visual signals to warn the patient if wrong manipulations or misuses are detected, distinction between dose selected and unselected versus actual injection, and distinction between priming and actual injection.

Furthermore, Biocorp's R&D team worked on the robustness of the system and perfected the choice of materials and the resistance of components to make it compatible with the challenges of daily life. Drops and spills are to be expected, and the device has been developed and tested to face these situations. It can also adapt to different storage conditions, including storage in the fridge. Mallya should adapt to the ways of its users, not the other way round.

3. Agnostic and Replicable

Finally, Mallya has been designed as an agnostic platform, covering different pen platforms with the same solution, to leave the choice of treatment options entirely in the hands of patients and HCPs. For instance, in the field of diabetes, patients can use a specific pen for their basal insulin (e.g. Lantus (insulin glargine injection), delivered by Sanofi's Solostar pen) and a different one for their short-acting insulin (e.g. Novorapid (insulin aspart), delivered

by Novo Nordisk's Flexpen). In this configuration, the patient is not tied to a specific brand or pen platform, as Biocorp can offer the same solution for both options.

This agnostic principle has led the Biocorp team to work on different pen platforms – making the Mallya technology easily replicable and expandable to any therapeutic areas.

WHERE WE ARE NOW – DIABETES AND BEYOND

Five years after the start of the project, Biocorp has a fully developed and industrialised Mallya range for disposable insulin pens, with a CE mark Class IIb granted in June 2019, significant distribution and development contracts with major players in the diabetes industry, and active programmes to adapt the technology to further pen platforms in other therapeutic areas such as fertility or growth hormone.

Given the potential of the insulin market for this technology, Biocorp decided to support on its own the development of a complete range of Mallya for disposable insulin pens, covering the most important platforms. Three different variants are now fully developed and industrialised – Mallya for Sanofi's Solostar (carrying insulins such as Lantus, Toujeo (insulin glargine injection) and Apidra (insuline glargine injection)), Mallya for Eli Lilly's Kwikpen (Basaglar (insulin glargine) and Humalog (insulin lispro injection))

and Mallya for Novo Nordisk's Flexpen (Levemir (insulin detemir) and Novorapid (insulin aspart)). From the same technology base, specific stock keeping units (SKUs) for each platform have been developed, with slight mechanical variations on the Mallya cap and the size of the body part. However, overall form factor, look and feel, performance, functionalities and user experience remain exactly the same from one platform to another.

This initiative was the foundation of multiple commercial successes. In July 2019, Biocorp signed a major partnership agreement with Sanofi, including global distribution of Mallya and specific development activities. The scope of the agreement and the level of investment from Sanofi – around €20 million (£18 million) in total – acknowledged the quality and potential of the Mallya technology. This partnership has now reached a new, exciting phase with imminent launches scheduled between the fourth quarter of 2020 and the second quarter of 2021 in various geographies in Europe, the Middle East and Asia, with the US not far behind.

Following this initial success, Biocorp signed another major distribution contract with Roche Diabetes Care France in June 2020. Roche plans to distribute Mallya through French pharmacies and integrate the data into its existing software ecosystem including connected glucometers (Accu-Chek Mobile, Accu-Chek Guide) and a companion app called Gluci-Check. Biocorp is therefore preparing for large-scale production and distribution of Mallya devices in France, starting from the first quarter of 2021.

To boost Mallya distribution and cover all potential geographic areas, Biocorp has also signed deals with local distributors

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in South Korea, South Africa and Eastern Europe. Finally, Biocorp has partnered with software players to integrate Mallya data into existing ecosystems providing broader services to patients, including glucose readings, carbohydrate counting (Health2Sync (Taipei, Taiwan)), basal insulin titration (Amalgam RX) or bolus calculator (SocialDiabetes (Barcelona, Spain)).

In parallel with this intense activity in the field of insulin, Biocorp has initiated partnerships with pharma companies to adapt Mallya technology to other pens in therapeutic areas such as Parkinson's disease, fertility treatment and growth hormone deficiency. Although treatment plans, injection frequency, variability of doses and expectations vary from one therapy to another, accurate capture of the dose dialled always remains the priority of stakeholders. In that regard, Biocorp's proprietary electromagnetic sensing technology, relying on strong intellectual property, can guarantee the highest level of accuracy, regardless of the existing pen platform. Pharma partners can rely on a strong technological basis and leverage Biocorp's expertise, know-how and previous R&D efforts, which reduces development timelines, costs and project risks.

THE NEXT GENERATION

These developments of different insulin pen platforms and customised programmes for pharma companies made Biocorp realise that Mallya had no specific restrictions in terms of form factor. Mallya is about a technology, based on a magnet evolving around the standard position of a magnetometer, and a guarantee of accuracy, robustness and usability.

Biocorp started working on the next generation of the product, not because the existing version was not satisfactory, but for the sake of continuous innovation for the benefit of patients, HCPs and its healthcare industry partners.

One of the reasons why digital, software solutions and connected devices have such difficulties penetrating the pharma industry is due to the pace of innovation. Pharma is used to working for 10 or 15 years before getting a drug approved, and then benefiting from a long patent protection and commercial life, without making any change. The same paradigm applies for traditional drug delivery devices. But the burst of digital health really changed the game. On the other hand, connected drug



Figure 2: The next-generation Mallya.

delivery devices face a difficult dilemma: relatively long development cycles but a short commercial life before they become obsolete, due to the extremely fast pace of innovation in this sector. When a request comes from a pharma partner, the time to design, develop, industrialise and approve such systems makes them already obsolete at the end of the journey.

Therefore, players like Biocorp need to anticipate future needs and initiate internal developments to de-risk projects and shorten development time to match the pace of digital health innovation and help pharma companies be successful in this field. To that end, Biocorp has been working – and continues to work – extensively on the next generation of Mallya.

The challenge was simple: making it one piece, with everything contained on the cap. The challenge sounded impossible, given the principles of Mallya technology and the different electronic features and components, but it was met by Biocorp's

R&D team by leveraging the very solid know-how the entire team has acquired on magnetic sensing technology – and also thanks to the fast pace at which electronic components are released, thus providing new solutions. Following years of intense design and development activities at Biocorp, the company has now introduced a new version of the Mallya platform, all in one piece (Figure 2).

ABOUT THE COMPANY

Recognised for its expertise in the development and manufacture of medical devices and delivery systems, Biocorp has today acquired a leading position in the connected medical device market, thanks to Mallya. This intelligent sensor for insulin injection pens allows reliable monitoring of injected doses and thus offers better compliance in the treatment of diabetics. Available for sale from 2020, Mallya spearheads Biocorp's product portfolio of innovative connected solutions.

ABOUT THE AUTHOR

Arnaud Guillet is Vice-President Business Development at Biocorp, in charge of finding partnerships and licence opportunities for Biocorp's range of connected devices. Previously, Mr Guillet worked for a healthcare consulting firm with a strong focus on connected health strategies for pharma and insurance companies and has additional past experience in the pharmaceutical industry with Sanofi and the insurance industry with AXA (Paris, France). He graduated from HEC Paris (France), a major European business school.



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