CASE STUDY

GlucoModicum

Phillips Medisize
a molex company

GLUCOMODICUM TEAMS WITH PHILLIPS-MEDISIZE TO DEVELOP INNOVATIVE NEEDLE-FREE CONTINUOUS GLUCOSE MONITORING SOLUTION

SEAMLESS COLLABORATION SOLVES MYRIAD HUMAN-CENTERED DESIGN, RISK MANAGEMENT AND COMMERCIALIZATION CHALLENGES TO FULFILL VISION FOR INNOVATIVE DEVICE

CHALLENGES

- Extensive medtech product planning, design, development and manufacturing expertise required to drive commercialization efforts for first-of-its-kind continuous glucose monitoring (CGM) solution
- Devising the device demanded heightened usability, testing and quality assurance to ensure patient safety, comfort and compliance

SOLUTION

- Phillips-Medisize's human-centered design approach—examining product usefulness, usability, desirability and manufacturability—proved invaluable in streamlining product design
- Seamless collaboration between GlucoModicum and Phillips-Medisize accelerated innovation and expedited development of 10 product iterations over 2 years

BENEFITS

- Phillips-Medisize's support for rapid product iterations saved GlucoModicum several years in product planning and development
- Shared sense of commitment drove successful completion of usability studies and continual product refinement
- Experience in front-end innovation, human-centered design and usability testing proved crucial to the product development process

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Alejandro García, PhD
Chief Technology Officer, GlucoModicum

With the incidence of diabetes predicted to grow to 1.31 billion people by 2025*, the need to address the high cost and inconvenience of current diabetes monitoring and management methods and inequities in patient care is growing exponentially along with it.

GlucoModicum, a medtech startup based in Finland, set out to close the gaps in diabetes care by devising a simpler, more convenient and cost-effective testing method. "No one wants to stick a needle into their body unless they have to," explains Jokke Mäki, Managing Director of GlucoModicum. "We wanted to create a solution that is needle free, accurate and more affordable so people would actually monitor their glucose."

And they did just that. The GlucoModicum wearable device, called Talisman, leverages innovative magnetohydrodynamic (MHD) technology, which applies a small amount of energy directly to interstitial fluid—the body fluid between blood vessels and cells—for fast extraction of a glucose sample. (Currently, the device is not FDA approved and does not have the CE Mark.) Among the biggest design obstacles was integrating the proprietary MHD technology with ultra-sensitive glucose biosensors and advanced algorithms.

To fulfill their vision for this innovative continuous glucose monitoring (CGM) solution, GlucoModicum sought a world-class contract development and manufacturing organization (CDMO) with deep medtech expertise to address a complex list of user experience and technical engineering challenges. GlucoModicum required a collaborator with special expertise in electronics, human-centered design, connectivity and software, plus proven regulatory experience and strengths in miniaturization and manufacturing.

REVOLUTIONIZING CONTINUOUS GLUCOSE MONITORING

Phillips-Medisize, a Molex company, and a global leader in the design, engineering and manufacturing of pharmaceutical drug delivery, invitro diagnostic and medtech devices, was selected in September 2021. Together, the team of Phillips-Medisize and GlucoModicum accelerated both the design and development of a precise, affordable and convenient CGM solution.

"Bringing new technologies to market poses significant product design challenges," says Homer Fairley, Business Development Manager for Phillips-Medisize. "Our expertise in product usability and design, as well as skills in turning those ideas into a manufacturable product, are competitive advantages for Phillips-Medisize."

"From day one, we wanted to ensure we were developing a product that met very demanding requirements regarding usability and manufacturability," says Alejandro García, CTO of GlucoModicum. "We also wanted to make sure, starting with the first iteration, that we had a strong focus on human-centered design."

PRIORITIZING HUMAN-CENTERED DESIGN

Phillips-Medisize's experience in front-end innovation, human-centered design and usability testing of leading-edge medical products proved crucial to the product development process. A series of workshops and design iterations were driven by a team of experts from the company's Global Innovation and Development team. This included Phillips-Medisize specialists in industrial design, mechanical and electrical engineering, material science, miniaturization, supply chain management, software development, manufacturing, testing, quality assurance and regulatory compliance.

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** The Lancet, "Diabetes: a defining disease of the 21st century," published June 24, 2023; DOI: https://doi.org/10.1016/S0140-6736(23)01296-5*

Putting the user front and center is critical to patient adoption, regulatory compliance and ultimately, market momentum. Working closely with GlucoModicum, Phillips-Medisize addressed vital product success factors, encompassing device usefulness, usability, desirability and manufacturability. Each product attribute was examined closely to ensure the highest levels of safety, quality, performance and accuracy. An in-depth analysis of market dynamics included reviews of other CGMs on the market, as well as recommended blood glucose and diabetes management techniques. The latest trends in consumer wearables were also examined in conjunction with user research to assess how patients would interact with the device to better understand reasonable use and foreseeable patient misuse scenarios.

This research helped determine user expectations and inform product design recommendations regarding device synchronization and integration, as well as compact device sizes and commercial product design styles. "The usability studies proved instrumental in our selection of the most useful, user-friendly and secure form factor for our biosensor," recalls Zhanna Boeva, PhD, Sensor Lead for GlucoModicum.

Usability feedback leveraged during the product design phase helped to enhance safety and efficacy while identifying potentially confusing signals, the omission of certain instructions or unexpected user interface touchpoints. Various material options were evaluated, along with various methods for integrating those materials. Additionally, the choice of adhesive was investigated carefully, as close contact with the skin was critical for biosensor accuracy.

ASSESSING AND REDUCING RISK

Biosensor manufacturability and risk assessment strategies were also prioritized as each biosensor consists of multiple layers that require highly specialized manufacturing processes and converting equipment. "Phillips-Medisize helped alleviate manufacturability and risk assessment challenges," adds Boeva. "Everything needs to be bio-compatible, safe and user friendly."

Over 2 years, the collective team fine-tuned product designs with 10 rapid iterations of different product prototypes. With GlucoModicum, Phillips-Medisize helped reduce the complexity of biosensor manufacturing while improving the robustness of the electromechanical connections.

"Phillips-Medisize brings a lot of collaborative spirit," Boeva says. "Our values are very much in line with Phillips-Medisize. Their expertise has saved a couple of years in product planning, design and risk assessment. Ultimately, we expect to manufacture hundreds of millions of sensors."

PREPARING FOR MASS PRODUCTION AND COMMERCIAL-IZATION

Phillips-Medisize's ability to support GlucoModicum through critical commercialization and regulatory compliance steps will play a pivotal role in preparing for volume manufacturing. Since a CGM informs treatment decisions, the clinical efficacy and documentation required by notified bodies, such as Food and Drug Administration (FDA) and Pharmaceutical and Medical Device Agency (PMDA), are critical to planning a successful launch.

The Phillips-Medisize Design and Development team offers its medical customers regulatory capabilities customized to each company's needs—from regulatory documentation to guidance on device classification, risk assessments and device-specific submission requirements for notified bodies. In this case, Phillips-Medisize counseled GlucoModicum on what will be required for submissions to notified bodies in the markets where the company plans to launch this device. The GlucoModicum team found the advice and regulatory knowledge insightful and beneficial to their commercial launch plans.

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Sensor Lead for GlucoModicum

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In late 2022, GlucoModicum announced publication of the first-in-human data assessing the safety and effectiveness of its MHD technology in Scientific Reports, part of the Nature Research portfolio. The study on five healthy volunteers supported earlier results of Talisman's effectiveness. The integrated MHD technology and biosensor solution was 13 times more effective than other needle-free approaches tested, in extracting interstitial fluid from the skin. Additional testing of the five healthy volunteers revealed that Talisman's biosensor is 8 times more sensitive to glucose molecules than comparative biosensors on the market.

Moreover, Talisman is effective at measuring Time in Range (TIR), which is becoming preferred over the more common A1C glucose measurement because it can determine when and for how long patients' glucose levels are within, and outside of, acceptable ranges. This makes TIR a precise and convenient way to monitor the effects of medication, diet, exercise and other variables on glucose levels.

The Talisman has the potential to be the first major technology introduction in the CGM space in the past 25 years. "Our goal is to bring a non-invasive, wearable, medical-grade device to market that ultimately reduces the patient burden associated with diabetes," says Mäki.

As the company moves closer to final phases of development, Phillips-Medisize is supporting additional manufacturing for clinical builds, along with regulatory submissions for review and approval in Europe and the United States.

Preparations are also underway to leverage Phillips-Medisize's global manufacturing footprint, extensive supply chain network and advanced assembly automation capabilities once in-depth clinical studies and regulatory approval are completed. To assure a trouble-free production ramp, 20 members of Phillips-Medisize's global team convened at GlucoModicum's headquarters in Finland to strategize for the future. In total, over the past four years of collaboration, over 20 experts from Phillips-Medisize have contributed to the Talisman program to optimize various aspects of the solution. "One of our competitive advantages is the ability to scale manufacturing to produce hundreds of millions of units on time and in a cost-effective manner," says Fairley. "That's a big benefit to this project."

ADVANCING NON-INVASIVE HEALTH MONITORING

"For me, this collaboration with Phillips-Medisize has been an extraordinary learning experience," says Dr. García. "We have created something we are proud of, and I'm very excited to continue working together."

GlucoModicum and Phillips-Medisize are exploring other potential uses of this innovative technology to support the monitoring and management of other diseases. GlucoModicum has identified more than 100 biomarkers that could be monitored from interstitial fluid and have high degrees of clinical relevance in addressing other medical conditions.

"Working with Phillips-Medisize, we applied compelling science to develop a world-class product that may help billions of people better manage their diabetes," concludes Mäki. "I have to say this has exceeded our expectations."

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>
> *Homer Fairley, Business Development Manager, Phillips-Medisize*

ABOUT GLUCOMODICUM

GlucoModicum is transforming how people monitor their glucose levels with precise, needle-free magnetohydrodynamic technology, empowering people to live healthier lives. GlucoModicum's leadership team has an exceptional track record building technology and MedTech businesses, featuring a multidisciplinary team with two senior professors and multiple PhDs with expertise in physics, bio-electronics, bio-sensors and medicine. Everything GlucoModicum does is backed with extensive scientific data. The company holds a global IPR portfolio concerning enabling technology and integrated solutions. For more information, visit www.glucomodicum.com.

PHILLIPS-MEDISIZE BRINGS POSSIBILITIES TO LIFE

Phillips-Medisize, a Molex company, collaborates with leading pharmaceutical, medical technology and invitro diagnostic companies to design, engineer and manufacture life-saving innovations. In addition, the company's specialty commercial business supports automotive, consumer and defense industries. A contract development and manufacturing organization (CDMO), Phillips-Medisize leverages its 60 years of expertise and globally renowned capabilities to collaborate with customers to deliver products and solutions that annually help millions of patients, healthcare professionals and individuals live healthier, more productive lives. For more information, visit www.phillipsmedisize.com.

ABOUT MOLEX

Molex is a global electronics leader committed to making the world a better, more-connected place. With presence in more than 40 countries, Molex enables transformative technology innovation in the automotive, data center, industrial automation, healthcare, 5G, cloud and consumer device industries. Through trusted customer and industry relationships, unrivaled engineering expertise, and product quality and reliability, Molex realizes the infinite potential of Creating Connections for Life. For more information, www.molex.com.

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The product in this case study has not obtained a CE marking applicable to the health, safety and environmental regulations of the European Union, and has not been reviewed or cleared for use by the U.S. Food and Drug Administration or comparable health regulatory authorities in other jurisdictions.

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