# When compliance is about patients' lives

## Preventing organ failure with the power of AI

Cibiltech's AI-based medical device software is intended to provide decision support for healthcare professionals, and remote monitoring support for kidney transplant patients and patients with chronic diseases.

We spoke to Head of Quality and Regulatory Management, Manon Marault, to find out more about this extraordinary technology and how Compliance Navigator helps the company achieve its goals.

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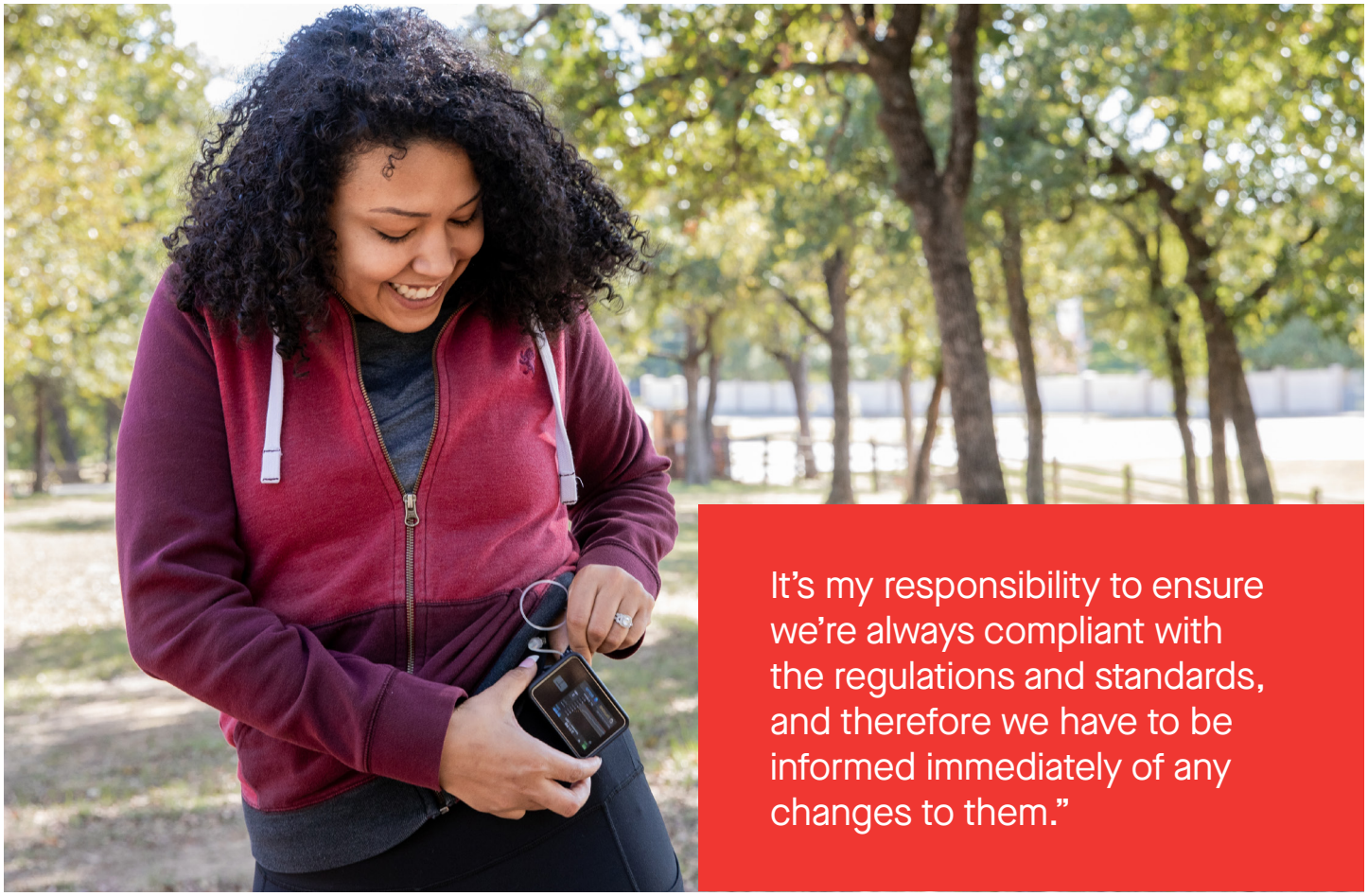
## Background

Created in 2019 in partnership with INSERM and the Paris Transplant Group, Cibiltech is a French medical tech start-up pioneering the development of artificial intelligence-based software medical devices. Its ambition is to build the distribution platform for algorithms to prevent organ failure.

Cibiltech has developed its first product, Predigraft, integrating the first universal predictive algorithm for transplantation. This technology is based on the Paris Transplant Group's recognized scientific excellence and decades of experience in treating transplant patients. The Predigraft platform helps healthcare professionals monitor transplant patients by providing allograft survival prognosis. It can also be used to design clinical trials.

Additionally, Cibiltech offers the Apilife Medical telemonitoring platform, which acts as a medical hub for chronic patients and their medical teams.

Manon Marault joined Cibiltech at its inception and is Head of Quality and Regulatory Management.



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## Customer need

Clinical software products with high patient benefits are now considered as medical devices, just like any other medical equipment.

Cibiltech was one of the first companies to embrace this new outlook. In 2021, the Predigraft platform received CE-marking as a Class IIa medical device under the Medical Device Regulation for kidney transplant patients.

This certification reflects Cibiltech's determination to apply high standards in everything they do, from development to delivery – just like any medical device manufacturer.

As a consequence, Cibiltech has to ensure that it is compliant with existing, new, and updated standards. Manon's first challenge was to create a Quality Management System. This included listing all the applicable regulations and standards.

"It's my responsibility to ensure we're always compliant with the regulations and standards, and therefore we have to be informed immediately of any changes to them", explains Manon.

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## The solution

Before Manon came across Compliance Navigator, her team was spending valuable time and money trying to manage their standards manually.

"I think there were two main challenges," says Manon. "One was the price, because our small company just had to buy every standard and regulation, and the majority of them were nominative/single use. That was very constraining for a team. The other challenge was trying to keep track of regulation/standard changes. Every time there's an amendment or modification, and every time a standard is replaced by another, it's essential for us to know about it. But when we were buying standards, there was not always a change tracking system that kept customers informed about any modifications to a standard or a regulation, or about a new release of guidelines. So that motivated us to come up with a specific tool for managing regulations and standards in one place."

What happened when Manon and her team saw a demonstration of Compliance Navigator?
"We were very enthusiastic. We did not know that such a tool existed."

She found the implementation easy. "The usability of the software is very good. We just needed to adjust each user's permission level, then add the standards and regulations we need to comply with. So we started using the tool right away." Manon herself trained the clinical team and the product team, who found it very user-friendly and easy to use.

## Customer benefits

A very important benefit is the monitoring of standards/regulatory changes as well as the expert commentary and guidance. "This helps us interpret some of the requirements of the new MDR 2017/745. For example, the notion of installation for cloud software does not have the same meaning as that for software that needs to be installed on the user's device."

"So Compliance Navigator gives us a kind of confidence that we're accurate and compliant. When a standard is reviewed, we get notifications on the status of the update, so we can anticipate."

Regarding the changes tracking system, Manon explains: "It is crucial for us to be aware of changes, as we have to incorporate the changes into our system and/or product. So Compliance Navigator gives us a kind of confidence that we're accurate and compliant. When a standard is reviewed, we get notifications on the status of the update, so we can anticipate."

Manon concludes, "The use of this software is important. I would like to keep it not only for my team, but also for the company."

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