Software of clairvoyance, structure and reliability

Current clinical trials require advanced software systems to get them up and running efficiently. The capability of those systems are not only about organisation, but is about foreseeing potential issues as well as troubleshooting them. Irena Seredina and Muriel Comblain, executive director and head of operations at **S-Clinica** respectively, discuss how their company's clinical trial management system is helping clients around the world anticipate and mitigate risks, while continuing to keep costs under control.

The planning, management and tracking of clinical trials are essential components within medical research. As studies become increasingly complex and expensive, it is more important than ever to have the correct tools in place to ensure they are as efficiently run as possible. A clinical trial management system (CTMS) is an umbrella term for software that makes use of the latest technological advances to help pharmaceutical and biotech companies consolidate their operational data and speed up study execution.

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Companies are increasingly turning to these management systems as solutions designed specifically to unify and manage data in clinical trials. They play a vital role in bringing all research components together.

"Communication between different departments is key to success," says Irena Seredina, executive director of S-Clinica. "At the beginning of a study, there isn't a lot of information, [but] a CTMS centralises [whatever there is] and allows it to be shared, so it can be analysed collectively."

This emphasis on collaboration is central to S-Clinica's own specific iteration of a CTMS tool. "We developed ClinVision

with a biotech company," explains Seredina. "They needed a forecasting tool to efficiently manage their portfolio and wanted to benefit from our unique drug supply algorithm. We managed to integrate a lot of functionalities into our system, based on feedback that came from the field. As a result, it really is a hands-on solution."

Own brand

ClinVision goes one step further than an average CTMS with its focus on preparation. "The whole idea was based on anticipatory management," says Seredina. "Real time is too late. Real time means you have faced your problems, they're in front of you. Instead, you need to be able to anticipate problems and issues. This is why we call ClinVision a CTAMS: a clinical trial anticipatory management system."

The tool can be used from the very first concept, before any protocol has even been drafted, and at every stage thereafter. "Right from the start, ClinVision can help make a rough estimate of supplies needed and prepare the production pre-order," explains Seredina. "Then, going further, information can be entered into the system

on a continuous basis, and the potential costs and risks can be analysed. You can really start figuring out your way and preparing for the next steps.

"It will start with a limited number of assumptions, but needs to be comprehensive enough to allow for the complexity and changes going forward."

This is particulary relevant because, from protocols to recruitment, the parameters of clinical studies are constantly changing and researchers face a lot of uncertainty.

Designed to be helpful

Crucially, the system is user-friendly and designed with its customers in mind. "Clinical trials operate under continuous pressure from constraints, such as time-to-market and the cost of drug development," Seredina says. "[And] the pressure keeps increasing.

"ClinVision improves communication between different departments," she continues. "For example, operations and supply chain management teams can both access the system and update their respective pieces of information. In collaboration, they can investigate different scenarios and identify the most suitable way to proceed."

Every parameter entered into the forecasting tool is used to generate the interactive response technology (IRT) system, which helps to increase efficiency and reduce the lead time to launch a study. "It's a great advantage to have both the IRT and forecasting combined into one single system," says S-Clinica's head of operations, Muriel Comblain. "If you use

different systems for each, you lose a lot of time as you have to explain the study to both teams."

Comblain also believes there is an exciting opportunity to make the software available to a significantly wider range of organisations in the near future. "At the moment, forecasting tools are very costly," she explains. "By integrating the forecasting and IRT systems, we are able to provide a cost-effective solution for smaller and midsize companies that, at the moment, are still trying to do their job with Microsoft Excel spreadsheets because they think they cannot afford the technology."

Uncertainty: forever the mother of invention

Times of crisis also bring uncertainty and have a significant impact on clinical trials. "Situations like the one we are currently facing with Covid-19 demonstrate how there is a real necessity for these tools," says Seredina. "The pandemic brought changes not only in the recruitment rate, but in the mode of functioning as people were in

lockdown. We need to be able to analyse the impact of unexpected events almost immediately and react promptly. We cannot avoid risk. What is really important is to anticipate the risk and mitigate it properly."

With increasing numbers of employees working remotely, the ClinVision program is able to connect teams around the world. "People working in different countries can

share information and analyse challenges together," explains Seredina. "This enables them to make proactive decisions and adapt the clinical supply chain."

This is a change that S-Clinica has found easier than most. "We are a paperless company, using only electronic

documentation and signature. It was not complicated for us to adapt."

Contemplating the future, Seredina and her colleagues are keen to continue building long-term partnerships with global pharmaceutical, biotech and contract research organisation companies, analysing their latest clinical trial challenges and providing innovative software solutions.

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This dedication to understanding their clients' needs has enabled S-Clinica to develop a unique, anticipatory CTMS that is able to meet the demands of today's challenging clinical trials. ●

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