

CHOSING THE RIGHT EDC FOR THE COSMOS REGISTRY

AN INTERVIEW WITH ROBERT WILKE, CLINICAL STUDY MANAGER AT CYTOSORBENTS ON MANAGING COMPLEXITY AND ENSURING USABILITY IN AN INTERNATIONAL CLINICAL STUDY.



CytoSorbents is pioneering in addressing critical health challenges in the intensive care unit (ICU) and cardiac surgery. CytoSorbents innovative blood purification devices reduce potentially harmful substances in the blood, helping to restore balance to the body and improving patient outcomes. For patients in the ICU and undergoing cardiac surgery, time is of the essence. Having access to the right treatments at the right time can be life-saving, and help patients get better, faster.

Q What was the complexity of the Cosmos study?

The COSMOS Registry is a data collection initiative focused on the use of CytoSorb® in critically ill patients. Our goal is to gain a deeper understanding of how CytoSorb® is applied in everyday clinical practice, providing a foundation for the development of new therapeutic approaches.

The registry is designed to be international, multicenter, and prospective. **A key challenge lies in the diverse application areas of the adsorber, which require the collection of a wide range of parameters.** The complexity of the project is further increased by the need to document certain data only at specific time points.

Q What were your objectives in setting up the EDC system?

Despite the complexity of the documentation, a key objective was to make handling as simple as possible for the participating study sites and data entry personnel. **The focus was on intuitive usability and a clear, well-structured user interface to ensure that data entry is always straightforward and comprehensible.**

This way, data entry staff always know where and how data needs to be entered and what actions are required at each step.

Q How did Marvin EDC help to address the complex requirements?

The EDC system is highly flexible. **During the development of our eCRF, we particularly appreciated its dynamic structure: forms are only displayed when they are actually needed, helping to maintain clarity and ease of use.**

This also applies to repetitive forms, which can be easily added by the user, allowing recurring events to be documented quickly and efficiently.

Since certain parameters are to be collected only within predefined timeframes, the automatic calculation and display of these periods provide valuable support during data entry.

Q Has the EDC system met or even exceeded your expectations?

The project spans approximately ten years. We are well aware that during this time, many study sites and personnel will change. Therefore, it is especially important to us to make it as easy as possible for new team members to get started with the project – particularly with data entry. A self-explanatory and user-friendly EDC system is key to achieving this.

Given the long duration, we also place great value on a robust system that runs reliably and produces minimal errors. **Marvin has proven to be highly stable, both in terms of system performance and programming. Small but impactful features – such as integrated score calculations, automatic display of timeframes, and the dynamic structure of the system – make handling easy for all users while ensuring the collection of a wide range of data.** This is essential for generating meaningful analyses and achieving the best possible outcomes

Q Which features or customized solutions were especially helpful to you?

In critically ill patients, the collection of scores that reflect the patient's condition is essential – and equally important for our registry. While these scores are not always calculated directly by the study sites, patient records often contain sufficient information to allow retrospective calculation.

We were particularly impressed that a corresponding calculation matrix could be integrated into the eCRF. This matrix pulls data from various forms within the eCRF to automatically compute the scores. As a result, the workload for the study sites is significantly reduced, and the essential data for the registry could be reliably generated.

We continuously analyze the data - on the one hand to identify implausible entries or typing errors, and on the other hand to generate scientific publications. **For this purpose, various reports have been programmed in Marvin, which can be generated and downloaded at any time, depending on the planned focus of analysis.**

Q How did you experience the collaboration with Marvin and our team?

Implementing the complex requirements for an electronic data collection form was a demanding task. The Marvin team quickly identified our challenges and presented practical and feasible solution options. Throughout the process, we were supported with great competence and dedication.

Particularly valuable was the wide range of proposed solutions, which enabled us to successfully address various requirements. The team quickly understands our needs and offers flexible approaches to implementing a broad spectrum of topics.

The Marvin team is an extremely reliable partner, and we are always happy to collaborate with them.



Q When did the flexibility of the system prove most critical?

In the past, we had to make several adjustments to our eCRF. **The system proved to be highly flexible, allowing both minor changes and more extensive modifications to be implemented without any issues.**

Q What would you say to other companies facing a similarly complex EDC implementation?

For organizations facing the challenge of implementing a complex EDC system, we can wholeheartedly recommend the services of the Marvin team. From the very beginning, you are guided through the process and provided with a product that fully meets your expectations and requirements.

The Marvin team is consistently friendly, reliable, and highly competent. Thanks to this excellent collaboration, our project is running smoothly and successfully.

Q Three terms with which you would describe our solution and collaboration?

**Competent
Pragmatic
Customer- and solution-oriented**

We sincerely thank Robert Wilke and CytoSorbents for sharing their insights and experiences. Their perspective offers a valuable look at the considerations behind choosing the right EDC System and how it supports their work.