



SIMPLIFYING COMPLEXITY IN CLINICAL RESEARCH

How CytoSorbents uses Marvin EDC to streamline their COSMOS Registry.

CytoSorbents_{...}

The Client

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.

The Challenge

Implementing an advanced EDC system is often a daunting task for organizations running complex clinical trials.

CytoSorbents faced the challenge of finding a solution provider who could not only deliver a reliable system but also guide their team throughout the entire process.

Background

With a growing pipeline of clinical trials, the company needed a robust and flexible Electronic Data Capture (EDC) system to manage complex data requirements effectively.

Our Solution Marvin

We partnered with CytoSorbents on their COSMOS Registry, implementing our EDC solution Marvin to simplify and strengthen clinical trial data management. From the beginning, we provided comprehensive guidance throughout the implementation process, ensuring a seamless transition. Together, we developed a system fully tailored to their operational requirements and objectives. What stood out in this collaboration was not only the technical expertise we contributed, but also the way we worked alongside the CytoSorbents team. We consistently focused on reliability, professionalism, and a customer-oriented approach, aiming to build both an effective system and a strong partnership.

Requirements and Challenges

The COSMOS registry presented us at EvidentIQ with significant technical challenges. Most notably, the extensive and dynamic calculations embedded within the eCRFs, ranging from automated score computations to precise control of data collection time windows, were crucial to the study's success.

Alongside these advanced calculations, managing patient data that cannot be deleted for regulatory reasons but must be made invisible to certain users required **a flexible and secure data model** to ensure data integrity and full auditability at all times.

We want to sincerely thank the CytoSorbents team for their impressive patience, expertise, and collaborative spirit throughout the project. Their open, professional, and solution-oriented approach elevated this partnership to a whole new level. **We are proud of what we've achieved together.**

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We developed a set of interactive reports in Marvin EDC that allow CytoSorbents to track form completeness, patient status, and therapy metrics across multiple parameters with both graphical and tabular views. These tools give them a clear, exportable overview of data entry progress and study outcomes, which they now use regularly in their presentations and monitoring.

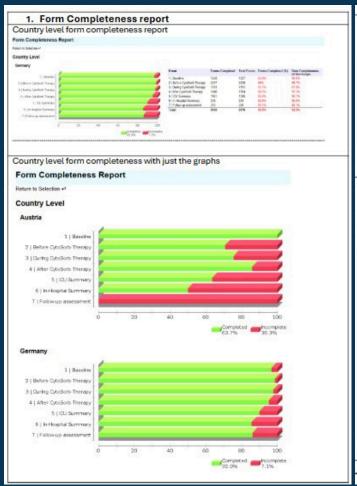


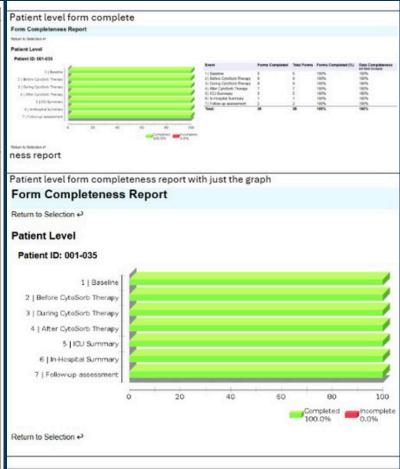
Tom Brain, Project Data Manager at EvidentIQ

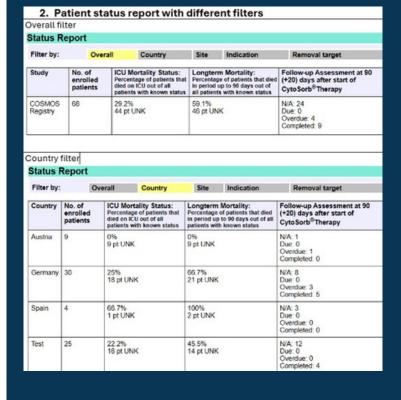
KEY CHALLENGES INCLUDED:

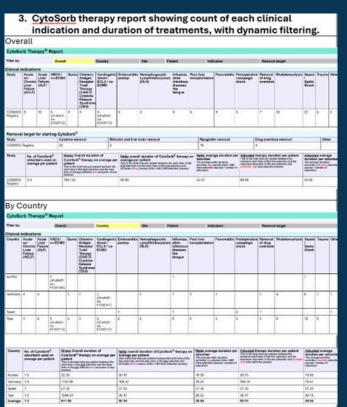
- GCP Requirements
- Integrated eTMF
- Customized reports
- Complex questionnaires: Calculated within the system, including range visualizations
- Different entry forms: Configured according to protocol requirements (e.g., for sites without informed consent)
- Data import/export: Managed via SAS
- Inclusion and exclusion criteria: Individually customized at the study level
- Patients without informed consent: 15 patients remain invisible in the system but are not deleted
- Study definitions: Tailored to meet specific requirements

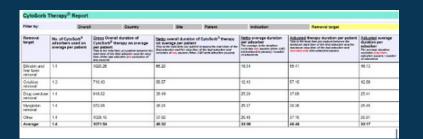
Interactive Reports

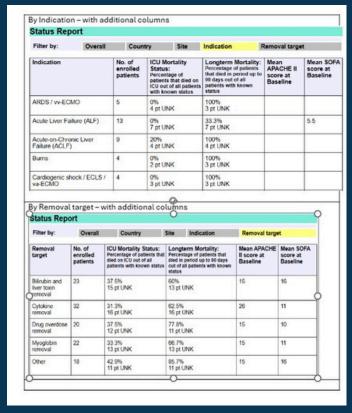












For organizations facing the challenge of implementing a complex EDC system, we can wholeheartedly recommend the services of EvidentIQ. From the very beginning, we were guided through the process and provided with a product that fully met our expectations and requirements. The EvidentIQ team is consistently friendly, reliable, and highly competent. Thanks to this excellent collaboration, our project is running smoothly and successfully.



Robert Wilke
Clinical Study Manager
CytoSorbents, Germany



EvidentIQ is a leading provider of modern eClinical solutions designed specifically for experts in clinical research.

Our eClinical software, Marvin, is an effective **CDISC-certified** EDC system that includes numerous modules such as randomization, patient-reported outcomes (ePRO), IWRS, CDISC tabulation, reporting, medical coding, and more.