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 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.**

> *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 Marvin EDC

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

1. Form Completeness report

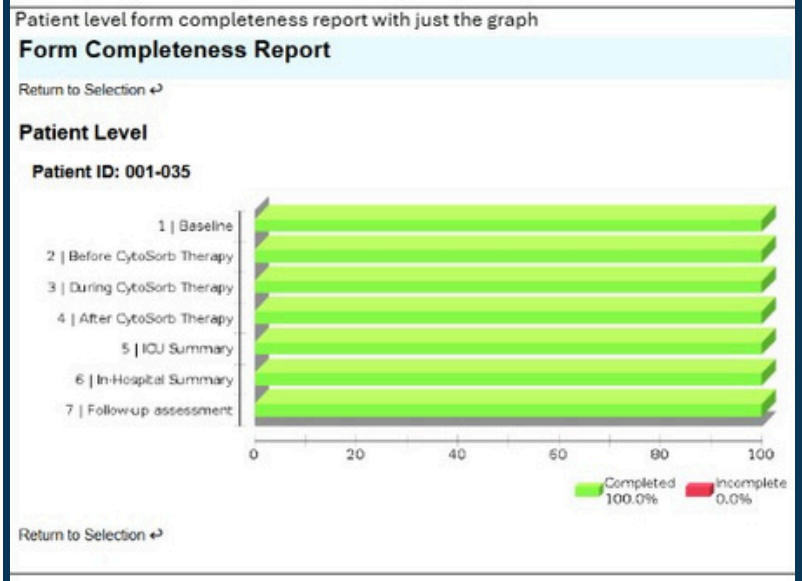
Country level form completeness report

Country level form completeness with just the graphs

Patient level form complete

ness report

Patient level form completeness report with just the graph



2. Patient status report with different filters

Overall filter

Status Report

Filter by: Overall | Country | Site | Indication | Removal target

Study	No. of enrolled patients	ICU Mortality Status: Percentage of patients that died on ICU out of all patients with known status	Longterm Mortality: Percentage of patients that died in period up to 90 days out of all patients with known status	Follow-up Assessment at 90 (+20) days after start of CytoSorb® Therapy
COSMOS Registry	68	29.2% 44 pt UNK	59.1% 46 pt UNK	N/A: 24 Due: 0 Overdue: 4 Completed: 9

Country filter

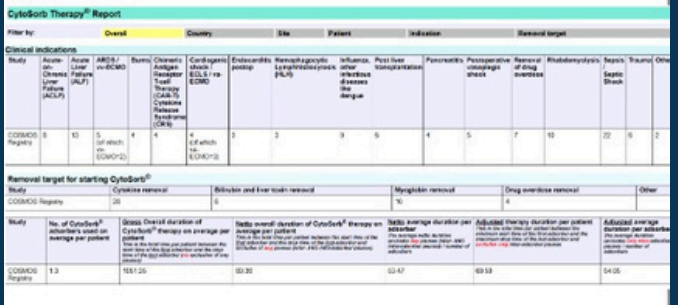
Status Report

Filter by: Overall | Country | Site | Indication | Removal target

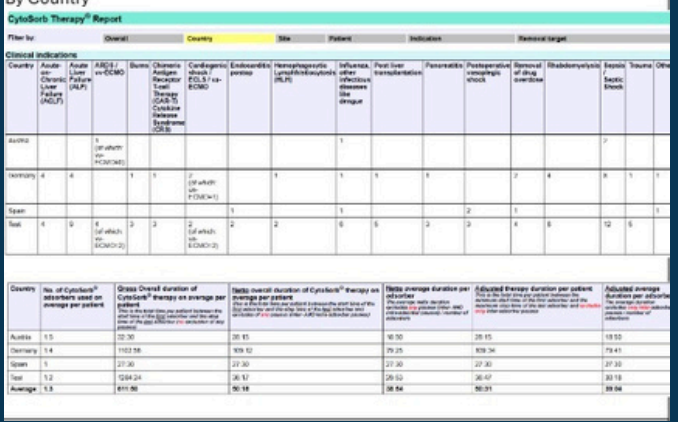
Country	No. of enrolled patients	ICU Mortality Status: Percentage of patients that died on ICU out of all patients with known status	Longterm Mortality: Percentage of patients that died in period up to 90 days out of all patients with known status	Follow-up Assessment at 90 (+20) days after start of CytoSorb® Therapy
Austria	9	0% 9 pt UNK	0% 9 pt UNK	N/A: 1 Due: 0 Overdue: 1 Completed: 0
Germany	30	25% 18 pt UNK	66.7% 21 pt UNK	N/A: 8 Due: 0 Overdue: 3 Completed: 5
Spain	4	66.7% 1 pt UNK	100% 2 pt UNK	N/A: 3 Due: 0 Overdue: 0 Completed: 0
Test	25	22.2% 16 pt UNK	45.5% 14 pt UNK	N/A: 12 Due: 0 Overdue: 0 Completed: 4

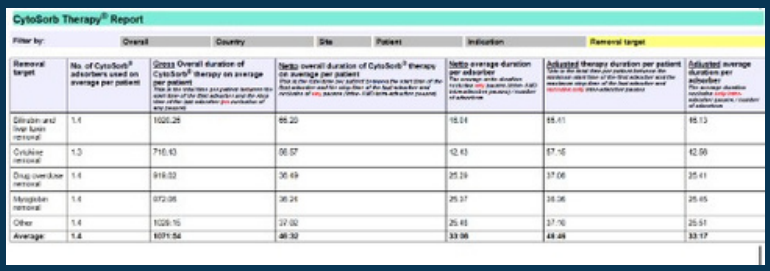
3. CytoSorb therapy report showing count of each clinical indication and duration of treatments, with dynamic filtering.

Overall



By Country





By Indication – with additional columns

Status Report

Filter by: Overall | Country | Site | Indication | Removal target

Indication	No. of enrolled patients	ICU Mortality Status: Percentage of patients that died on ICU out of all patients with known status	Longterm Mortality: Percentage of patients that died in period up to 90 days out of all patients with known status	Mean APACHE II score at Baseline	Mean SOFA score at Baseline
ARDS / vv-ECMO	5	0% 4 pt UNK	100% 3 pt UNK		
Acute Liver Failure (ALF)	13	0% 7 pt UNK	33.3% 7 pt UNK		5.5
Acute-on-Chronic Liver Failure (ACLF)	9	20% 4 pt UNK	100% 4 pt UNK		
Burns	4	0% 2 pt UNK	100% 3 pt UNK		
Cardiogenic shock / ECLS / va-ECMO	4	0% 3 pt UNK	100% 3 pt UNK		

By Removal target – with additional columns

Status Report

Filter by: Overall | Country | Site | Indication | Removal target

Removal target	No. of enrolled patients	ICU Mortality Status: Percentage of patients that died on ICU out of all patients with known status	Longterm Mortality: Percentage of patients that died in period up to 90 days out of all patients with known status	Mean APACHE II score at Baseline	Mean SOFA score at Baseline
Bilirubin and liver toxin removal	23	37.5% 15 pt UNK	60% 13 pt UNK	15	16
Cytokine removal	32	31.3% 16 pt UNK	62.5% 16 pt UNK	26	11
Drug overdose removal	20	37.5% 12 pt UNK	77.8% 11 pt UNK	15	10
Myoglobin removal	22	33.3% 13 pt UNK	66.7% 13 pt UNK	15	11
Other	18	42.9% 11 pt UNK	85.7% 11 pt UNK	15	16

For organizations facing the challenge of implementing a complex EDC system, we can wholeheartedly recommend the services of the whole Marvin Team. From the very beginning, we were guided through the process and provided with a product that fully met our 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.

Robert Wilke
Clinical Study Manager
CytoSorbents, Germany

marvin

We are 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.

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