



EVIDENTIQ



CytoSorbentsTM

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.

SIMPLIFYING COMPLEXITY IN CLINICAL RESEARCH

How CytoSorbents uses Marvin EDC to streamline their COSMOS Registry.

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.

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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

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

Overall

CytoSorb Therapy® Report

Filter by:	Overall	Country	Site	Patient	Indication	Removal target											
Clinical indications																	
Study	Acute Liver Failure (ALF)	Acute Liver Failure (ALF)	ARDS / ex-ECD	Burns	Chemical Antigen Release (CAR) Toxicokinetic Release Induction (CRI)	Cardiogenic shock (CLL) ex-ECD	Endotoxaemic sepsis	Hemophagocytosis (HLH)	Influenza, other infectious diseases	Post liver transplantation	Peritonitis	Postoperative shock	Removal of drug overload	Rhabdomyolysis	Sepsis	Trauma	Other
COBACS Registry	3	10	5 (of which ex-ECD=2)	4	4	4 (of which ex-ECD=2)	3	3	3	6	4	5	7	15	22	3	2
Removal target for starting CytoSorb®																	
Study	Cytokine removal						Bilirubin and liver-tissue removal				Megalinium removal		Drug excretion removal				Other
COBACS Registry	26										5		4				
Dynamic filtering																	
Study	No. of CytoSorb® treatments used as average per patient	Gross overall duration of CytoSorb® therapy as average per patient			Netto overall duration of CytoSorb® therapy as average per patient			Netto average duration per patient			Adjusted therapy duration per patient			Adjusted average duration per patient			
COBACS Registry	1.3	1051:26			30:30			32:47			69:13			54:05			

By Country

CytoSorb Therapy® Report

Filter by:	Overall	Country	Site	Patient	Indication	Removal target											
Clinical indications																	
Country	Acute Liver Failure (ALF)	Acute Liver Failure (ALF)	ARDS / ex-ECD	Burns	Chemical Antigen Release (CAR) Toxicokinetic Release Induction (CRI)	Cardiogenic shock (CLL) ex-ECD	Endotoxaemic sepsis	Hemophagocytosis (HLH)	Influenza, other infectious diseases	Post liver transplantation	Peritonitis	Postoperative shock	Removal of drug overload	Rhabdomyolysis	Sepsis	Trauma	Other
Austria	1	1 (of which ex-ECD=1)													2		
Germany	4	4		1	1			1	1	1			2	4			
Spain												2					
Italy	4	4	2 (of which ex-ECD=2)	3	2			2	2	3		3	4	6		12	5

Dynamic filtering

Country	No. of CytoSorb® treatments used as average per patient	Gross overall duration of CytoSorb® therapy as average per patient	Netto overall duration of CytoSorb® therapy as average per patient	Netto average duration per patient	Adjusted therapy duration per patient	Adjusted average duration per patient
Austria	1.0	32:30	38:15	40:50	28:15	18:55
Germany	1.4	1932:56	939:12	79:25	839:34	79:41
Spain	1	27:40	27:40	27:40		27:40
Italy	1.0	526:24	26:57	26:57	26:47	26:18
Average	1.3	611:06	30:18	32:46	69:31	59:04

