medrio

Case Study

During an Observational Oncology Study, Sciformix Finds an eClinical Ally in Medrio

A sponsor wanted to switch from their CRO's in-house EDC to a state-of-the-art EDC. They approached Sciformix for the study, who used Medrio to enhance their data management and study design.

Challenges

- In-house EDC used by the sponsor's original provider couldn't accommodate large late-phase study volumes
- Researchers needed more robust EDC functionality around edit checks, monitoring, and more
- Lack of stability and functionality put data at risk

Solution

- Sponsor switched to Sciformix and Medrio EDC
- Cloud functionality made it possible to share information seamlessly
- Drag-and-drop interface made study build easy and fast

Results

- Accommodated a large quantity of data smoothly
- Minimized costs and timelines
- Maximized ability to protect sponsor data

Background

Sciformix, an SPO (Scientific Process Organization) serving a diverse variety of clinical trials across all phases, has built substantial experience in Medrio in a short span of time. They began using Medrio's EDC solution for a number of studies, in various therapeutic areas and encompassing thousands of patients, with investigators based throughout India and the US. One of these studies, an observational oncology study with high recruitment, provides a strong example of Sciformix's ability not only to optimize their study build and data management, but also to enhance their data sharing and monitoring capabilities.

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Challenges

The post-marketing oncology study required an EDC capable of managing its large volume of data and performing data reports and cuts for tracking and trial optimization.

Sciformix was hired by a pharmaceutical company to conduct an observational trial for one of their oncology products in the market. They were responsible for collecting data to help in the assessment of its efficacy relative to other market-approved drugs and capture any adverse events.

The sponsor initially employed a CRO who used an in-house EDC solution for their studies. However, it soon became clear that this EDC was not the right match for the oncology study at hand because post-marketing studies are often among the largest clinical trial types, entailing the collection and analysis of data from thousands of participants. To avoid issues such as system overload and delays in project timelines, the EDC used for these studies needed to be exceptionally stable and robust in order to accommodate the sheer quantity of data involved.

In addition to the issue of data quantity, there were other aspects of the in-house EDC that left the researchers looking for more. The system offered a rudimentary edit check design that could lead to data errors being overlooked. The monitoring functionality fell short of meeting the researchers' needs as well. For some studies an in-house EDC with this kind of basic functionality may suffice; however, for this post-marketing oncology study, it put the sponsor's data at risk.

Read on to see how Sciformix and Medrio empowered the sponsor to overcome these challenges.

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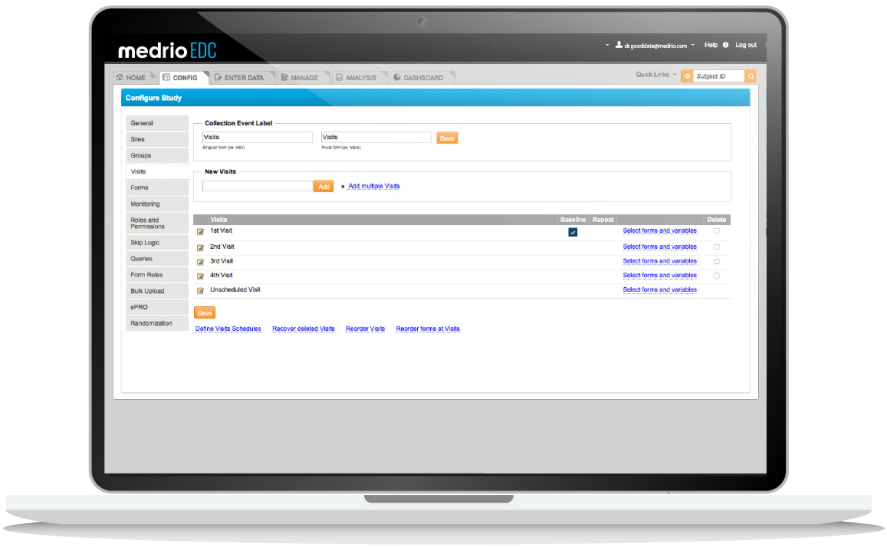
Solution

Sciformix selects Medrio's cloud-based EDC and utilizes its robust features and functionality.

While the project manager at the sponsor wasn't familiar with Medrio, after viewing the product's capabilities the team was convinced that Medrio was the right choice to meet the study requirements, tolerate large amounts of data, and enable researchers to navigate the software with ease and efficiency.

This decision paid off. Medrio's edit checks, which ensure data accuracy by raising queries when a form contains missing or erroneous data, were well-designed and executed within the expected timelines. It was simple and easy to resolve queries and manage discrepancies related to the data. In addition, Medrio was fully cloud-based, making data sharing easier, which was key for a study with a large numbers of subjects, sites and monitors.

In addition to these features, the data managers at Sciformix found value in Medrio's ability to build studies with a simple drag-and-drop interface. Other EDC solutions they previously used required programming to build studies; in Medrio, the team could build studies more independently, without being reliant on external programming or IT staff. This allowed them to work more efficiently.



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Results

"We've had a great experience with Medrio. The platform is extremely user friendly and I am very happy with the customer support provided by Medrio and team."

- Practice Head Clinical Development at Sciformix

Both the sponsor and Sciformix quickly found Medrio to be an ideal fit for the study they had undertaken. The system proved capable of handling the vast quantity of data inherent in post-marketing studies, and provided the simplicity and intuitiveness necessary for the team to move quickly through their research. Perhaps most importantly, it helped to reduce the cost and timeline of the study and offered the monitoring functionality to minimize risk to the data, all important deliverables to the study sponsor.

About Medrio

Medrio is a leading healthcare technology company providing eClinical solutions including EDC, eSource, and ePRO for clinical research. Founded in 2005, the company's cloud-based software platform and mobile suite of products deliver fast, flexible, and easy-to-use tools for the collection and management of clinical data and patient reported outcome responses. Study sponsors and contract research organizations have used Medrio extensively across drug, device, diagnostic, and animal health trials. Medrio has extensive experience in all study phases and leads the market in early-phase trials. The company serves over 500 customers globally, with headquarters in San Francisco and offices in numerous domestic and international locations. For more information, please visit www.medrio.com.

About Sciformix

Sciformix Corporation is a leading scientific process organization (SPO) that provides process, technology and consulting services to the life sciences industry. We collaborate with our clients through the entire product development lifecycle to provide a full range of services from study design to post marketing surveillance and commercialization support. Our areas of specialization include Safety & Risk Management, Clinical Research & Post-Approval Support Services, Regulatory Affairs & Regulatory Operations, Real World Evidence & Market Access, and Technology Services. Our mission is to become a strategic partner to global life science companies providing high quality scientific knowledge-based expertise with the ultimate objective of improving quality of healthcare for patients worldwide. Our corporate headquarters are located in Massachusetts with operations in North America, Europe, India and the Philippines.

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