

Sciformix Finds an eClinical Ally in Medrio



Highlights

- ✓ Medrio helped Sciformix reduce the cost and timeline of the study
- ✓ Fully cloud-based platform made sharing easier
- ✓ EDC allowed Sciformix to work independently and efficiently

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.

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

Results:

- Benefits from the flexible pricing model
- Rapid, easy staff training in Medrio EDC
- Planning five more studies in Medrio

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Challenges

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.

Solution

While the project manager at the sponsor wasn't familiar with Medrio, after viewing the product's capabilities the team was convinced that Medrio EDC 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 number 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.

Results

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.

“ 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

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 the quality of healthcare for patients worldwide. Our corporate headquarters are located in Massachusetts with operations in North America, Europe, India, and the Philippines.

ABOUT MEDRIO

At Medrio, we know it takes a global village to achieve a healthier world. Since 2005, we’ve developed a successful ecosystem of visionary people like you who want to change the world- employees, customers, and partners alike.

We’ve supported sponsors, CRO’s, and sites from across the life sciences industry spectrum. With our help, they have secured more than 375 approvals and reached critical breakthroughs. Our expertise spans all therapeutic areas and covers all phases of clinical trials. We aim to deliver the best customer experience possible because your success is our success. www.medrio.com.