SUCCESS STORY

The Right EDC Gives Paragonix Technologies Ultimate Autonomy with a Lean Team

Highlights

- Medrio helped Paragonix expand quickly without external support
- Medrio EDC allows for easy mid-study changes
- EDC allows cloning of previous studies to save valuable time

Overview

Paragonix Technologies selected Medrio EDC for their GUARDIAN-HEART clinical study. Electronic Data Capture (EDC) technology is being used to collect and manage registry data, examining the effect of controlled hypothermic preservation in heart transplantation. The registry analysis currently spans 23 transplant centers, five sites, and over 900 patients. Due to the EDC platform ease of use, agile workflows, and unparalleled technical support, the Paragonix team was able to build their study infrastructure within one week and achieve first-patient-in (FPI) within three weeks. Medrio's intuitive platform empowered their lean study team to expand to three large registries quickly and without the need for additional external support.

Challenges:

- Lean study team
- Finding a user-friendly platform for both sites AND study teams
- Setting up studies, maintaining, and making mid-study changes without 3rd party support

Results:

- Single source of truth for site and study teams
- Quick mid-study changes without vendor support or downtime
- Increased site efficiency
- Easy expansion to three large registries

medrio

"Since Medrio EDC is intuitive in its use and maintenance, we are able to execute on three large registries using a small, yet highly effective team," shares Anderson. "And we do it without the need for additional, costly external support."

The Details

Paragonix Technologies needed an agile solution to build the largest data repository uniquely tailored to study heart preservation issues in transplantation. To be successful, they would need an EDC (Electronic Data Capture) platform that was intuitive not only for their clinical sites, but also for their study team members. Paragonix identified that Medrio's flexible and easy-to-use platform, paired with a responsive support team, was the best way for their team to achieve big results.

Getting Set Up

Paragonix's novel registry leveraged a small, robust team of researchers. They needed a solution capable of empowering their team to get onboarded quickly and have autonomy over their study builds so they could maximize trial efficiencies.

"We built the initial study infrastructure within one week," says Anderson, "using a mixture of Medrio's user-friendly interface, tailored onboarding, and technical support. Thanks to the flexible platform and support, our team is now able to make mid-study changes very rapidly and on our own."
The Paragonix team was able to configure the database to meet their unique study needs by implementing range checks and customized queries. On-demand training made onboarding their internal staff, clinical sites, and data entry teams easy and standardized, saving valuable time for their lean team. Within three weeks, they had achieved database lock and were ready for patient enrollment.

Why Medrio EDC

Medrio EDC has the functionality that novel Medical Device registries need without the complexity.
Due to the unique nature of their patient cohorts, Paragonix needed a solution that allowed them full control and configurability over their study builds. Medrio EDC empowers Paragonix to set-up studies in days using a mixture of pre-set and flexible workflows. As mid-study changes are needed, such as when a COVID-19-related question had to be added to a form, Paragonix was able to implement the change quickly and with no disturbance to their sites or patients. Since initiation of their first registry in April 2020, Paragonix has enrolled over 900 patients and added two additional registries. As each study gets implemented, Paragonix is able to clone and configure the previous study to save valuable time for their team and reduce redundancies in study set-up. This has allowed Paragonix to reduce their study build time even further from three weeks to a matter of days.

"Since Medrio EDC is intuitive in its use and maintenance, we are able to execute on three large registries using a small, yet highly effective team," shares Anderson. "And we do it without the need for additional, costly external support."

> **"We were up and running in three weeks. Right away we felt that we could do what no other company had done before – build the largest data repository for heart transplantation.**
>
> *—Lisa Anderson, CEO of Paragonix Technologies.*

Results

Paragonix Technologies creates and maintains live registries to improve clinical outcomes for transplantation, regardless of donor or recipient characteristics. By investing in technology that their study teams and sites prefer, they are able to put that mission into practice.

The GUARDIAN-HEART clinical registry reduced study build times so Paragonix had the bandwidth to build and maintain two additional registries, without additional staff or IT support. Sites and data entry teams reported ease of use and benefited from a standardized EDC to create a single source of truth. In tandem with a responsive customer support team, on-demand training, and technical support, Paragonix was able to empower their small team to build registries quickly and autonomously using Medrio.

"We are excited to continue building upon the existing registries in our database," shares Anderson.

> **"Identifying the right eClinical vendor that balances intuitive technology with customer support is key for any Medical Device company doing registry work.**
>
> *— Lisa Anderson, CEO of Paragonix Technologies.*

ABOUT PARAGONIX TECHNOLOGIES

Paragonix Technologies designs, produces, and sells FDA cleared and CE marked organ preservation and transportation devices that safeguard organs during the journey between donor and recipient patients. Our mission is to create a new standard for organ preservation and transport that improves patient outcomes worldwide. Our devices incorporate clinically proven and medically trusted hypothermic preservation techniques combined with real-time monitoring and digital solutions to provide unprecedented physical and thermal protection for donor organs. For more information visit **paragonixtechnologies.com.**

ABOUT MEDRIO

At Medrio, we know that it takes a global village to achieve a healthier world. Our leading eClinical Data solutions have helped sponsors, CROs, and sites from all trial phases and therapeutic areas secure over 770 regulatory approvals. Whether conducting traditional, hybrid, or fully-virtual trials—our adaptive platform of EDC, DDC, eConsent, RTSM, and ePRO/eCOA help streamline your studies, without compromising data quality. And our experts are on-call 24/7 to help you solve your most pressing needs. Discover the Medrio difference and learn more at **medrio.com**.