

Medical Device Sponsor Deploys Medrio EDC and Yields a Multitude of Immediate Benefits



Highlights

- ✔ Conducted vendor selection using a five-step process
- ✔ Increased monitoring efficiency reduces delays, and accelerates overall progress of the trial
- ✔ Linear reduced their paper usage in one study by about 95%

Background

Perth, Australia-based Linear Clinical Research wanted to upgrade from capturing clinical trial data on paper at their Phase I site. They selected Medrio's integrated Electronic Data Capture (EDC) and direct data capture (DDC) platform. This is the story of their vendor evaluation – and their success with Medrio.

Challenges:

- ⦿ Conducted vendor selection using a five-step process
- ⦿ Established five essential qualities of EDC and DDC solutions
- ⦿ Used a collaborative process to make the final selection

Results:

- ⦿ Enhanced site operations: Improved data quality, strengthened patient engagement and accelerated workflow
- ⦿ Increased efficiency: Reduced paper usage by approximately 95%, and monitoring visits by 50%
- ⦿ Provides near-real-time visibility into data, for faster and better decisions

Linear aimed to maximize their reduction in paper usage, and so in addition to EDC, they were interested in implementing a tablet-based Direct Data Capture (DDC) application, which allows researchers to capture data electronically at clinical trial sites and sync it to the EDC with no paper involved.

Paper-based Trials Were Holding Back Rapid Growth

Linear Clinical Research, a 32-bed facility in Perth, Australia, was using paper-based data capture and management for all its clinical trials. But the rapidly-growing company realized that if they continued with paper, they would not be able to realize the efficiencies they needed to continue their growth and continue delivering outstanding service to patients and study sponsors.

Linear also knew it wanted a solution with a short implementation timeframe. “We did not want to take 12 months to implement something, because that’s a lot of effort and a lot of time,” says Knab. She acknowledges, however, that there was some skepticism among the staff about the decision to implement an EDC system. The Linear staff had only ever used paper, so she knew part of her responsibility would be to manage the change, which she did successfully by involving everyone right from the beginning of the process.

Before Linear sent out its Request For Information to potential vendors, it spelled out some 50 requirements that an EDC and DDC solution should meet, and identified five of those as top priorities. “If a vendor didn’t meet our standards for any one of those five, we wouldn’t consider them,” says Knab. “That made shortlisting the candidates very easy.”

The five top-level assessment criteria were:

- ⦿ **Change Control** – The ability to store multiple versions of the same form, thus lessening the burden of data migration.
- ⦿ **Data Migration** – The ability to export data in a variety of file formats, including different SAS versions.
- ⦿ **System Configuration** – The ability to configure the system back end using CDISC and HL7 standard guidelines.
- ⦿ **Built-in Auto Check Alerts** – The ability to compare adverse events to determine if grading has increased or decreased.
- ⦿ **Offline Capabilities** – The ability to capture data without an internet connection.

According to Knab, identifying the final preferred vendor was a team exercise. Each team member ranked the vendors, discussed their rankings and reached a collaborative decision on a final ranking. The final adjudicators of the decision were Knab and Linear CEO Michael Winlo, M.D.

“We wanted to gain efficiency in the back end, dealing with what we call ‘administration paper. We wanted to focus on our staff’s strengths, which are taking care of patients and facilitating a clinical trial, and not on copying forms and managing paper.”

– Simone Knabb, Enterprise Data Architect,
Linear Clinical Research

Why Medrio?

“That one-click navigation to the next participant is fundamental and a big time-saver.” Simone Knab, Enterprise Data Architect, Linear Clinical Research

After receiving trial versions of the products and assessing them, several products had very similar rankings. The company then did a “sandbox assessment,” whereby it rented tablets and set up the sandboxes with trial data.

Linear staff members used an assessment sheet with clearly defined criteria to evaluate the solutions. The sheet included such questions as: How quickly can we navigate from one participant to another? and How many keystrokes are required to open the next form for a participant?

“We did the assessment on the clinic floor,” says Knab, “because we really wanted feedback from staff members who would be using the system. The vote afterward was unanimous. Across the board, we all agreed that Medrio was the one.” Between its EDC and DDC functionality, Medrio easily met all five of the necessary criteria defined by Linear and rose above the competition in its ease of use from the site perspective. Among the features that stood out: “Medrio was the only one that provided a mobile data capture application during the sandbox assessment that was accessible and usable by clinic staff,” says Knab. “The key feature for us is that the application shows the participant list on the left with the associated data. When you select a form, the form stays on the page when you click on another participant. That one-click navigation to the next participant is fundamental and a big time-saver.”

The Medrio solution also came with built-in integration, which will enable Linear to share their source data seamlessly and securely with study CROs and/or sponsors. Making data available via integration supports faster and easier data transfer and improved data quality review. APIs can also provide greater flexibility in delivering data than can routine scheduled data exports.

“Medrio were one of the first to provide us a sandbox with easy access, and also support in setting it up,” says Knab. “The process of working with vendors on this sandbox phase quickly gave us a feel for what it would be like to work with each of them.”

— Simone Knab
Enterprise Data Architect,
Linear Clinical Research

Result: Success for Linear

“Eliminating those on-site visits increases efficiency, reduces delays, and accelerates the overall progress of the trial.” Simone Knab, Enterprise Data Architect, Linear Clinical Research

Linear proceeded to implement the Medrio EDC and Medrio DDC solutions—a five-week setup process, including training on the new system—and has already reduced their paper usage in one study by about 95%, with the adoption of electronic systems for the remaining processes in the pipeline for the near future. They will soon be starting two more, and ultimately plan to scale up to 40 studies in Medrio. Winlo says moving from paper to EDC has enabled his team to accelerate the drug-development process, improve data accuracy, and provide quicker alerts to any adverse events. It will also eventually improve patient engagement by enabling patients to track trial data themselves.

Knab says the built-in, pre-defined CDISC standard forms within Medrio were a bonus. They give Linear total control over study forms and design, which enhances Linear’s ability to deploy a study more

quickly than if they were to continue outsourcing form design to a third party. Having the ability to build EDC studies in-house, thereby avoiding time-consuming back-and-forth communications with a vendor, ensures all builds are implemented efficiently.

Linear has also gained near-real-time visibility into data. The facility often has multiple trials underway simultaneously, and managing the paper for all of them can be a major challenge. Adopting EDC enables the facility to log in, see the status of trial data, assess queries, and quickly fix issues with missing pages. They get a near-real-time overview of the data because the data is visible about a minute after it's captured, instead of a day or two later as it was with paper.

Positioning Linear for the Future

Linear implemented the Medrio platform to gain efficiencies in mobile data capture and perform real-time data analysis to quickly validate data quality. "Our EDC implementation has created interest within the CRO community," says Knab. "They understand we're trying to gain efficiencies, create a seamless data flow, and demonstrate to the industry how we can get high-quality data quicker so we can get them to the FDA quicker and drugs can reach the market quicker. Everyone has those same goals.

Medrio's integrated EDC and DDC platforms also increase monitoring efficiency in Linear trials. "For example," says Knab, "the sponsor-contracted CRA who normally visits us in person to monitor a study can now remotely log in to review our forms and data. On two occasions already, the CRA was able to cancel a visit to review data from our first study because she saw the data was clean and at a good standard. Canceling two of four scheduled visits means reducing the monitoring frequency by 50 percent. Eliminating those on-site visits increases efficiency, reduces delays, and accelerates the overall progress of the trial." And with the ability to sync the data directly from Medrio DDC to EDC, the burden of source data verification is significantly reduced.

"Our overall level of satisfaction with the Medrio EDC solution is very high," she continues. "Especially regarding their service, which is a big deal for us. Medrio has provided everything we've asked for, and done it within our timeframes. When you buy a product, you also buy into a vendor, and it's not until you start using the product that you really get to know the vendor's culture. Medrio's culture has been to communicate with Linear and to be transparent and open. The overall relationship has just been great."

ABOUT LINEAR CLINICAL RESEARCH

Based at the Harry Perkins Institute of Medical Research, Linear Clinical Research is a 32-bed facility with 24-hour medical emergency team coverage. Regulatory standards in Australia mean that clinical trials conducted at Linear are completed six months faster than in the U.S. and often at a third of the cost. Since it was established in 2010, there have been 170 clinical trials on general participants and over 180 oncology patients enrolled in world-first clinical trials. To learn more, visit www.linear.org.au.

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 across most 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.