



What Successful eClinical Vendor Selection Looks Like: Linear Clinical Research Finds a Crucial Asset in Medrio EDC and eSource

Perth, Australia-based Linear Clinical Research evaluated 74 EDC vendors before selecting Medrio for its first departure from paper-only clinical trials. Months later, they're almost completely paperless.

Vendor Selection

- Conducted vendor selection using a five-step process
- Established five essential qualities for all EDC solutions under consideration
- Used a collaborative process to make final selection

Why Medrio?

- Outstanding service and support
- Time- and cost-saving eSource tablet application
- Simple, intuitive interface; superior ease of use

Result: Success for Linear

- Enables greater focus on staff strengths
- Increases efficiency: Reduced paper usage by approximately 95%; yielded 50% reduction in monitoring visits
- Provides near-real-time visibility into data

Background

Linear were well aware of the benefits of EDC and were ready to eliminate paper.

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.

"We wanted to gain efficiency in the back end, dealing with what we call 'administration paper,'" says Simone Knab, Digital Strategy Lead at Linear Clinical Research. "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."

Even before starting their search for an EDC solution, Knab and Linear were well aware of the benefits of EDC and were ready to eliminate paper. Those benefits include the ability to capture, clean and review data in real time, and to allow study monitors to remotely access and query data. 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. Soon the staff came to understand the benefits of the new approach, and the skepticism disappeared.

Vendor Selection Criteria

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– Simone Knab, Digital Strategy Lead,
Linear Clinical Research

In early 2017, Linear initiated a structured five-step process for selecting an EDC vendor. The steps were: requirements analysis, request for information (RFI), request for proposal (RFP), sandbox testing, and final selection.

Before Linear sent out its RFI, it spelled out some 50 requirements that an EDC 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. Final adjudicators of the decision were Knab and Linear CEO Michael Winlo, M.D.

Why Medrio?

“Medrio provided a mobile data capture application that was accessible and usable by clinic staff.”

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

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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. “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.”

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 afterwards was unanimous. Across the board, we all agreed that Medrio was the one.” Between its EDC and eSource 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: “Among all the vendors, 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 application programming interfaces (APIs), which will enable Linear to seamlessly integrate their source data securely with study CROs and/or sponsors. Making data available via APIs 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.

Result: Success for Linear

Linear has accelerated their processes, improved data accuracy, and provided quicker alerts to adverse events.

Linear proceeded to implement the Medrio EDC and eSource 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 studies, and ultimately plan to scale up to 40 studies in Medrio. Winlo says moving from paper to EDC has enabled his team to accelerate their processes, 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.

“The clinic team loved using the tablets for mobile data capture during that first study,” says Knab. “They loved having to sign in only once, and then being able to simply click and save a result without having to sign their name and enter a date over and over. They also loved not having to initial and supply a reason for every update or change. The staff immediately saw the benefit of mobile, electronic data capture and how it enabled them to complete their work more quickly.”

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.

EDC also increases efficiency for external teams that work on 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. Cancelling 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.”

In addition, now that Linear can capture data directly in the eSource tablet application, they have reduced the need for CRAs to be onsite for paper-based source data verification (SDV). CRAs can now perform remote SDV online. Knab reports that all involved find this to be a much simpler and more efficient approach.

Positioning Linear for the Future

“Our EDC implementation has created interest within the CRO community.”

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Linear Clinical Research

Linear implemented Medrio 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 data results quicker so we can get them to the FDA quicker and drugs can reach the market quicker. Everyone has those same goals.

“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 Medrio

Medrio offers an integrated eClinical SaaS platform providing speed and ease of use to clinical trials. Medrio’s affordable, cloud-based EDC and eSource products allow data managers to build studies in days instead of months with no IT or programming required, offering unprecedented control in database build and data management. Medrio is also the EDC industry’s momentum leader, outgrowing the industry by a factor of 4, and has served over 3,000 clinical trials of all phases and therapeutic areas. The company’s software has been used in clinical trials conducted across the globe.

For more information, or to schedule an online demonstration or request a free trial, please visit <http://www.medrio.com>.

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 into world-first clinical trials.

To learn more, visit www.linear.org.au.