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Resolutum Global Leverages Medrio to Succeed in a Complex Phase 1 Oncology Study

In a recent rescue study, Resolutum Global, a contract research organization, faced the challenge of building a hybrid paper/EDC solution for an ongoing study that the previous provider had conducted on paper over 4 years. By leveraging Medrio, they were able to succeed in this task and deliver satisfaction to the study sponsor.

Challenges

- Rescue an ongoing oncology study for a sponsor with a limited budget
- Get trained and onboarded in a new system without delaying the ongoing study timeline
- Adapt a 3-site paper study into a paper/EDC model with minimal delay and no cost overrun
- Complete data collection and cleaning without duplicating previously completed tasks

Solutions

- Implemented Medrio EDC after an easy and affordable sales process
- Completed smooth onboarding with hands-on training using a dedicated sandbox area
- Leveraged intuitive features including skip logic, edit checks, form rules, data import, and more

Results

- Completed study setup in 3 weeks and locked the database in 4 months
- Provided final study data analysis (TLFs) 1 month after DB lock
- Leveraged a cost-effective pricing model to deliver the best deal to the client
- Received positive feedback from sponsor, sites, and CRAs

Challenges

Resolutum Global was tasked with completing a Phase 1 oncology study. Each of the study's 28 patients had repeating alternate treatment cycles, with an average of 5 cycles per patient at a duration of 21 days per cycle. This design enabled the researchers to make modifications based on how the patients reacted to the oncology treatment. But as Moses Mwangi, Managing Director at Resolutum, notes, "the alternation of the treatment cycles brought a significant degree of complexity to this oncology study."

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That complexity was not the only challenge that Resolutum faced, as this was a rescue study that was already in progress over four years at three sites. There was significant pressure from the sponsor to Resolutum not to duplicate the completed tasks such as setup, data collection, and cleaning, as the sponsor had already made a large investment in getting the study up and running with the first provider. Rapid onboarding, then, was the name of the game – Resolutum would need to get a handle on the study, and on their eClinical technology resources, without costing the sponsor more time and budget.

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Top Medrio features for Resolutum Global:

- Skip logic
- Edit checks
- Data import
- Form rules

Solutions

Resolutum implemented Medrio's electronic data capture software as their data management resource for the oncology study. Mr. Mwangi notes that the process of working with the Medrio team during negotiations was simple and easy: "The pricing was great, and it was really easy to get a quote provided promptly."

He also found the training and onboarding process perfectly suited to getting his team up and running in the Medrio system quickly and easily, enabling them to transition from the previous provider as seamlessly as the rescue study demanded. "Training and onboarding were excellent," says Mr. Mwangi. "It was a really sensible process. We got a sandbox to play around in, and someone to help us set up the first study."

Resolutum quickly found the Medrio system to be easy and user-friendly, with Mr. Mwangi noting that "if you understand data management, it's very easy to set up a study and adapt the system to different types of studies." There were numerous features of the Medrio software that Resolutum leveraged. In particular, the team found Medrio's skip logic, edit checks, data import, and form rule functionality to be well suited to their needs. With these features and others at their disposal, they were able to build a hybrid paper/EDC database and manage the complexity of the oncology study.

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Results

After a smooth training and onboarding process, the team at Resolutum was able to get their study set up in just three weeks – a notable achievement for most studies, but especially for a complex oncology study like the one at hand. Once the team was up and running, they were able to arrive at database lock in 4 months. Mr. Mwangi also notes the cost-effectiveness of working with Medrio: "The cost-effective monthly subscription fees, without a minimum study duration, was great for the sponsor."

This end-to-end efficiency was crucial. The sponsor needed to neutralize any delays and sunk costs stemming from their investment in the initial provider, and Resolutum delivered. As Mr. Mwangi notes: "The sponsor appreciated the rapid three-week study build, as well as the ability to import study data from the previous vendor's system instead of having to re-enter the data ourselves." Apart from the sponsor, Resolutum received positive feedback from site staff, who noted that Medrio enabled an easy transition from paper to EDC, as well as from CRAs, who were able to accelerate monitoring and query resolution.

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Resolutum is now building upon this success by incorporating Medrio into their bids for new business with new sponsors. In these talks, Mr. Mwangi has found that "Medrio EDC is gaining traction as the preferred early phase system based on rapid deployment, ease of use, and a cost-effective pricing model."

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About Resolutum Global

Resolutum Global is a biometrics CRO that focuses on clinical study data collection, analysis, and reporting. We specialize in early phase clinical trials and provide support from protocol development to clinical study report (CSR) writing using purpose-built systems and processes. Our team has international and local clinical trials experience gained through working in CROs, pharmaceutical, and biotechnology companies. Individually, each team member has at least 15 years' experience and collectively the company has over 60 years' experience to serve our customers. Our specialties are Data Management, Biostatistics and Medical Writing. Using a leading EDC solution, we optimize the data collection process and support risk-based monitoring for efficient data collection with reduced study monitoring load on the site(s) and sponsor. The Resolutum Global Biostatistics team provides sample size calculations, generates study randomization, and prepares statistical analysis plans, data analysis, and CDISC–compliant SDTM and ADaM data packages. Our medical writers support our customers from protocol development to CSR writing. Resolutum Global implements tailored solutions for our customers to successfully complete their studies time & cost effectively. For more info, visit **www.rgcro.com**.

About Medrio

Medrio is the leading provider of eClinical technology for early-phase pharma, device, and diagnostics clinical trials. Founded in 2005, the company's cloud-based EDC, Direct Data Capture, eConsent, and ePRO solutions 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 in clinical trials across a wide array of therapeutic areas, with notable success in oncology, infectious disease, and more. Medrio has extensive experience in all study phases and leads the market in early-phase trials. The company serves over 600 customers globally, with headquarters in San Francisco and offices in numerous domestic and international locations. For more information, please visit **medrio.com**.