

**medrio**

## Case Study



# Biotech and Research Consultants Clear Path to Success with Flawless Study Startup Switch to Medrio

After the research consultants at Study Builders encountered many challenges while building a recent early-phase study, the study sponsor realized that a difficult change was in order.

### Challenges

- Short, rigorous Phase 0 study
- Cheaper eClinical tool lacked necessary functionality
- Danger of missing study timeline

### Solutions

- Evaluated replacement EDC vendors
- Switched to Medrio and restarted study build
- Benefitted from Medrio's flexibility, efficiency, intuitiveness, and affordability

### Results

- Completed intricate study build in 3 days
- Neutralized threat to study timeline
- Sponsor, consultants, and EDC all contributed to resolution

### Background

Over the years, electronic data capture (EDC) has provided an array of innovations to enhance clinical trials. In an industry as time-sensitive as clinical research, these innovations have become indispensable to sponsors and CROs.

The research consultants at Study Builders were contracted for a Phase 0 exploratory biomarker study, with a Medrio competitor's solution originally selected by the sponsor for their study build and data management. For their study build and data management, the sponsor originally selected a basic, lower-cost eClinical solution provided by a Medrio competitor. However, upon finding themselves in need of greater efficiency to meet their timeline and data management needs, the sponsor made a significant mid-development decision to migrate their development activity to a solution that they could rapidly deploy without compromising the overall study timeline or exceeding their budget. They chose Medrio as this solution, viewing the state-of-the-art innovations of Medrio's EDC as ideal for the on-time activation of their study. As a result, they were able to get the study onto a clear, unobstructed path to success.

# Challenges

The study required a more flexible EDC in order to meet its timeline.

This exploratory biomarker study presented the team with a short but intense study period, requiring them to develop the EDC solution in a very short timeframe while allowing for sophisticated use of features such as dynamic form design. As such, it was essential that the chosen EDC be seamless, efficient, and easy to use. The short timelines of hypothesis-generating studies are incompatible with EDC solutions whose implementation and functionality require extensive time and effort from data managers. The head of clinical operations at the sponsor company recognized that the study required a straightforward, no-nonsense approach to EDC, and was depending on the Medrio competitor to offer high quality and a robust feature-functionality.

## In need of a better fit

Against this backdrop, it quickly became clear that the originally selected solution simply wasn't the right match for the study at hand. In order to get the job done quickly and efficiently, Study Builders required more flexibility in the study build process. They would need a solution that could offer:

- More freedom to make changes to eCRFs after creating them in a development environment
- A distinction between the testing, validation, and go-live environments
- The autonomy and flexibility to deliver training by Sponsor instead of being confined to an EDC-mandated training regimen

The team realized that, without these capabilities and resources, they couldn't reasonably expect to meet the timelines of the study. Having already invested approximately a month of activity to the study build process, they now faced a critical decision: to continue with the prospect of launching a sub-optimal system, or take the risk of switching in mid-development, leaving a short time frame for system completion. The sponsor decided to take the risk - they would dismiss the original EDC and start again with a new provider. In order to recoup the time they'd already invested, it was more important than ever that they find a solution offering top-tier efficiency and user-friendliness.

# Solutions

Medrio offered the speed, efficiency, and flexibility that the study demanded.

The decision to dismiss the original EDC was a bold one, and the sponsor didn't take it lightly. Study Builders had already completed the majority of the study build, and as the sponsor began evaluating alternative EDC vendors, they were fully cognizant of the significant timeline concerns that starting over could create. Some of the staff at the sponsor company had both used and evaluated Medrio at previous companies earlier in their careers, and had been impressed by the feature-functionality and cost-efficiency of the software. They had found that Medrio, while intuitive and effective across all study phases, was a particularly good fit for early-phase studies, and could be deployed very effectively in tight timeframes. For this reason, the sponsor had a high degree of confidence in selecting Medrio to rescue the study build.

## What Medrio brought to the table

It didn't take long for the team to feel the impact of the switch. There were a variety of ways Medrio was able to outperform the original EDC:

- Medrio provided strong, flexible skip logic functionality.
- The data management team found it easy to make changes to eCRFs after building them.
- The Medrio system was easy to deploy and intuitive to use.
- The flexibility to opt out of formal EDC training, and instead integrate training with the Study Initiation Visit, facilitated further compression of the timeline.

These features enabled the speed, efficiency, and flexibility that the study demanded. Equipped with a user-friendly and highly functional EDC system, the research team were able to mitigate any impact to the study timeline that the EDC switch had threatened to create.

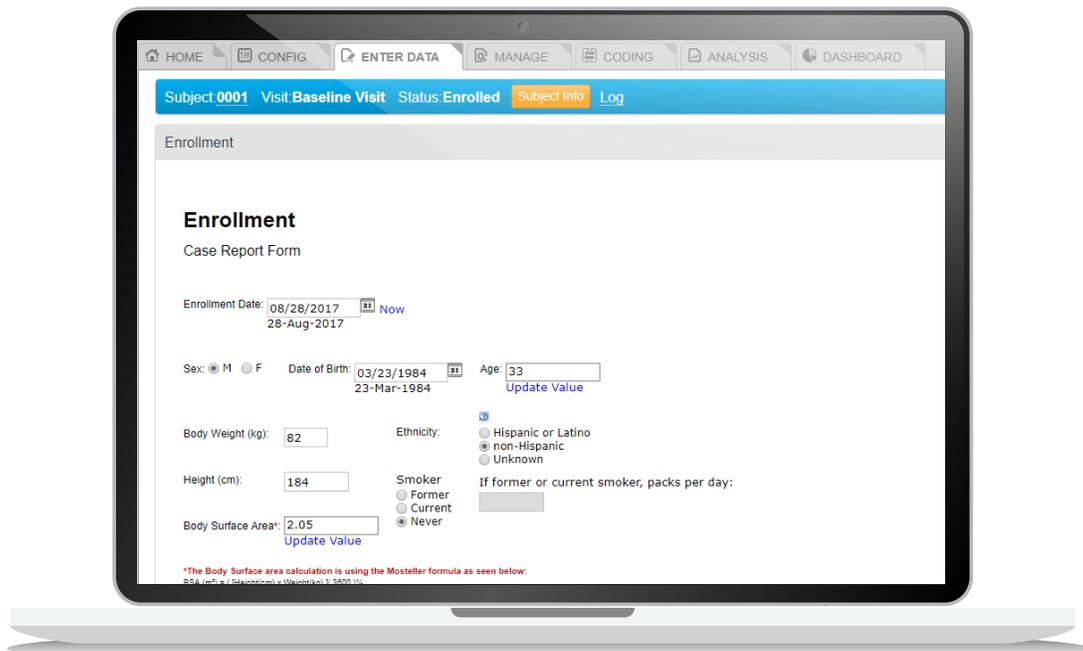
# Results

“We definitely felt a big difference with Medrio. The process was much more efficient.”

- Temple Herlong, Managing Member, Study Builders

These advantages, combined with the general user-friendliness of Medrio's interface and the absence of any required programming during study build, led to a rare but game-changing achievement: Study Builders was able to complete the initial study build in a mere three days. Considering the breadth of the workflow involved - the data managers were tasked with creating 28 unique forms, four visits, and over 200 edit checks - this was no small feat. “Typically, a comparable study takes about three weeks to build,” said Temple Herlong, Managing Member at Study Builders. “We definitely felt a big difference with Medrio. The process was much more efficient.”

Indeed, providing efficiency and flexibility in study build at an affordable rate are central components of Medrio's mission as an EDC company. But Medrio, of course, is just one player in this story. The adept risk management by the study sponsor, the EDC savvy of Study Builders, and the simplicity, efficiency, and flexibility of Medrio all played crucial roles in keeping the study on track.



An enrollment form demonstrating skip logic, one of the Medrio features the researchers found especially useful. As the user has indicated that the subject has never been a smoker, the “packs per day” field is grayed out, saving time in data entry.

# Conclusion

“If an eClinical solution isn't providing the necessary speed and efficiency, sometimes it's necessary to take a risk and switch to a proven innovator capable of meeting those needs.”

- Mike Novotny, founder and CEO, Medrio

Dealing with variables and obstacles is part of the nature of clinical research. How sponsors react in these situations can be a major factor in deciding their success or failure. “In clinical research, it's natural for sponsors to find themselves facing some tough decisions,” commented Mike Novotny, founder and CEO of Medrio. “If an eClinical solution isn't providing the necessary speed and efficiency, which are so important in this industry, sometimes it's necessary to take a risk and switch to a proven innovator capable of meeting those needs. The research team that took on this study handled this situation expertly.”

## About Medrio

Medrio offers an integrated eClinical SaaS platform designed to eliminate paper from 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 speed, simplicity, and control in database build and data management. Users have access to a world-class support staff backed by a top-tier customer satisfaction rating. Medrio is also the EDC industry's momentum leader, outgrowing the industry by a factor of 4 and the Phase 1 study market by a factor of 11. Medrio has served over 2,000 clinical trials of all phases and therapeutic areas, with an emphasis on early-phase studies. The company's software has been used in clinical trials conducted across the globe and submitted to all major regulatory bodies.

For more information, or to schedule an online demonstration or request a free trial, please visit [www.medrio.com](http://www.medrio.com).

## About Study Builders

Study Builders is a California-based clinical research-focused consulting company composed of professionals with years of experience in building and managing clinical trials. We are a small company by design, with low overhead so that we can remain agile and able to quickly and effectively build solutions that work for our clients. Our team is made up of EDC system designers and developers, SQL and Access database developers, SAS programmers, data managers, web and mobile applications developers, UI designers, and website designers. Each is an experienced consultant in his or her field and clients are only charged for the consultant work that they need.