SOLUTION SHEET

Medrio EDC

Gain Control and Accelerate Your Studies

3,600+
Studies
across all phases

90%
Reduction
in transcription errors

3 weeks
Average
First Patient In

The Value of a Quality Electronic Data Capture Solution

Clinical trials are complex and time-consuming, but using your EDC shouldn't be. Many systems are riddled with inefficiencies that result in lengthy, expensive study builds, cumbursome mid-study changes, and delayed access to crucial study data. You need a reliable, central hub that maximizes your efficiencies and allows you to reach your goals sooner—all while tightening up your costs and giving you full control over your clinical trial research.

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Medrio EDC was purpose-built for sponsors, sites, CROs, and clinical researchers to eliminate these inefficiencies. Our intuitive Electronic Data Capture (EDC) solution was designed to keep you in full control of your study data by offering cutting-edge flexibility without unnecessary complexity. Aggregate and manage all of your source data from one central location and allow approved individuals to access that data from any device at any time of day. We remove the need for programming or outsourced study builds so you can focus on what matters most: building a healthier world.

Unprecedented Speed and Flexibility

- Autonomous—While other systems may require you to rely on their eClinical team for every build or mid-study change, our point-and-click interface, rich feature set, and ample self-service eLearning courses give you the tools to build confidently (and drastically reduce your study build time in the process).
- Flexible—With configurable data monitoring and an extensive form library, you can build queries and approval steps that match your unique workflows.
- Agile—Medrio users average 2.8 week study builds, compared to the industry average of 12 weeks. And some companies even achieve first patient in (FPI) in just seven days when using our system!

> **"Medrio is an incredibly intuitive system to learn, much simpler to learn than other traditional EDC systems I have used. Very efficient workflow for quickly building a clinical database, with lots of more advanced features that can be leveraged as needed.**
>
> *— Nicholas Gelman, Clinical Data Manager, Sangamo Therapeutics*

Mid-Study Changes: Anytime, Anywhere

- Full Control—No need to take your study offline or reach out to tech support for your next mid-study change. Medrio EDC empowers users to make mid-study changes in as little as 5 to 10 minutes.
- Lower Cost—Without the need for programming or IT staff, researchers are empowered to make mid-study changes quickly and accelerate their study builds without extra time waiting or excessive cost.

Lower Cost of Ownership with Full Functionality

- Total Transparency—Our EDC doesn't come with complex pricing or invisible extras. We offer transparent, straightforward pricing options that include additional modules, hands-on training, and mid-study changes at no additional cost to you.
- Cost-Effective—Medrio EDC offers better robust functionality and ease of use, yet costs 63% less than two of the leading EDC competitors.
- Built for Success—With increased data accuracy and autonomy to build your studies the way you want them, Medrio lowers your total cost of ownership and keeps your studies comfortably within budget.

> **“I have done about twenty clinical studies with Medrio. It is easy to configure a study, design the forms, and deploy. If mid-study changes are required, they are easy to accomplish in Medrio.**
>
> *— Michelle Harden, Clinical Data Analyst, Quidel*

Built-In Regulatory Compliance

- Fully Compliant—Our EDC meets or exceeds all global data collection regulations - such as ICH/GCP,21 CFR, GDPR, and HIPAA - so you can focus on your trial and trust that your data is compliant.
- A Finger on the Pulse—We stay on top of current events and recent regulatory changes, and then seamlessly adopt these frameworks into our software so you never have to worry that your EDC is up-to-date.

Data Quality and Integrity

- Real-Time Access—Gain instant visibility to study data - anywhere, anytime - while enabling better decisions, shortening study timelines, and reducing the need for on-site monitoring by up to 50%.
- Seamless Integration—Leverage Medrio’s eClinical suite of DDC, eConsent, and ePRO to seamlessly feed data into our EDC and enable real-time data sharing while improving data quality and patient comprehension.
- Reduce Validation Burden—With dynamic branching and automatic edit checks, you can implement changes into our EDC database without the need for programming or manual data validation.

Meet Pam – A Clinical Trial Operations Manager

Pam manages multiple studies for a large CRO. One of her many tasks is slicing and dicing data to keep her Sponsor informed of a study’s progress. She can’t imagine how she’d manage this—and still maintain her sanity—without a subscription to Medrio’s Electronic Data Collection (EDC). Our EDC gives her complete control of all study data, making it easy for her to run any report she desires. It also gives her access to fantastic customer support, which saved her at 2 a.m. on a Saturday when one of her European study sites had trouble syncing data.

In one of her more extensive studies, she also added Medrio’s ePro and eConsent solutions. Both of these products worked seamlessly with the EDC and put all data in her hands in real-time. Under pressure to get that particular study up and running quickly, our EDC also helped Pam achieve FPI in just under three weeks. Pam was one happy and relieved manager.

Compliance You Can Count On

We hold our technology to the strictest of standards so you can focus on more pressing issues and confidently know your data is compliant. When there are regulatory changes or new FDA guidance, we take steps to integrate these frameworks into our software—with no downtime to you—so you never have to worry that your EDC is up-to-date.

Built-In Regulatory Compliance

- Exceed Regulations—Our EDC meets or exceeds all global data collection regulations - such as ICH/GCP,21 CFR, GDPR, and HIPAA.
- A Finger on the Pulse—We stay on top of current events and recent regulatory changes, and then seamlessly adopt these frameworks into our solutions for compliance you can count on.

FDA ICH GCP E6 (R2) · HIPAA COMPLIANT · Information Security Management System ISO 27001 Certified · Gamp · FDA 21 CFR Part 11 · EU GDPR COMPLIANT

Growing a Trusted Partnership

Our intuitive EDC was designed to put you in the driver's seat. And our professional services team is ready to hand you the manual. With over 375 secured approvals, our dedicated team of product experts and data scientists understand your unique study needs and are here to help you build a strong foundation for your clinical trial models. From setting up your first study, to comprehensive onboarding, and even 3rd party builds—our experts are here to ensure you have the tools for successful EDC once handed the keys.

The Value of Full-Service Support

- Tailored Onboarding—Gain access to module-specific onboarding packages tailored to your unique workflows and designed to bring the entire configuration process in-house.
- Professional Project Management—Dedicated PMs are committed to delivering high quality services and software that keeps your studies on time and on budget.
- Data Management Services—Full service support of plan development, data reconciliation, and database delivery and study closeout.
- Technical Services—Lean on our experts for API integrations and exports, provisioning and troubleshooting, as well as hardware provisioning and fulfillment.

ABOUT MEDRIO

We're Medrio and we know that it takes a global village to achieve a healthier world. Our leading eClinical Data Management solutions have helped sponsors, CROs, and sites from all trial phases and therapeutic areas secure over 375 regulatory approvals. Whether conducting traditional, hybrid, or fully-virtual trials—our adaptive platform of EDC, DDC, eConsent, 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.

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