SOLUTION SHEET

Medrio for Medical Device Studies

Providing You Better Data *Faster*

The Medrio Difference for Early Phase Trials

460+
Device Studies

115+
FDA Approvals

180+
Medical Device Companies

98%
Customer Satisfaction

The process for bringing medical devices to market is increasingly complex.

From regulatory challenges, to the growing number of new data endpoints—device researchers, sponsors, and CROs need nimble tools that streamline their IP development lifecycle. At Medrio, we've worked with over 180 leading device companies across all phases of clinical study and we understand your need for agile solutions. Our integrated eClinical suite offers the flexibility and functionality to support your most complex randomization and bring your products to market faster.

medrio

Reduce Your Study Timelines

Build and deploy your device studies in a matter of days with flexible tools designed for fast data entry and data accuracy. With a few clicks of a mouse, device researchers can streamline query creation, deploy mid-study changes, and instantly upload bulk study data without technical support.

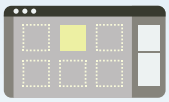
And the best part? With access to reliable, high-quality data, your clinical teams can make proactive decisions that shorten your study timelines and streamline your product development. Our integrated eSuite of EDC, DDC, ePRO, eConsent, and RTSM keeps your trials running efficiently with user-friendly workflows and the robust functionality that your device studies need.

> **"For our second study, I just duplicated forms from our first study and made a few changes. It took me just a week to build the CRFs the first time, and only a day for the second."**
>
> *Ram Sridharan, Managing Director, TCell Services*

Solutions That Keep You in Control

Your device trials require oversight of many sites, samples, and IP shipments. Without proper oversight, your trials can experience delays that end up costing sponsors between $600,000 and $8 million each day. With access to live and remote data, user-friendly workflows, and logic-based validation, your teams can deploy mid-study changes without any need for programming support or downtime.

Features Designed to Sprint Your Device Studies



Intuitive drag-and-drop interface puts you in control

Mid-study changes in as little as seven hours without downtime.

Integrated eSuite with real-time, accurate oversight to your study teams

Dynamic workflows enriched with complex skip logic, pre-set forms, and dictionary coding

Built-in functionality for statistical analysis and custom reports that don't require IT support

Access to white-glove customer service and module-specific eLearning resources

How We Deliver Better Data for Medical Device Researchers

- Access and share real-time data from any device, anywhere
- Skip validation and focus on UAT with pre-validated software
- Identify missing and duplicate data with live edit checks and logic-based workflows
- Export data in a snap with a host of on-demand queries, eCRFs, and custom reports
- Respond quickly to AE notifications, missing data alerts, and out-of-range result triggers

Conduct Cost-Efficient Studies

Costs keep steadily rising and now bringing a device to market can cost sponsors and CROs up to $500 million. Our transparent, subscription-based pricing model was designed to keep costs low in your medical device trials by eliminating programming expenses, adding unlimited sites at no extra cost, and only paying for features you need. Streamline your workflows with advanced reporting and risk-based monitoring that lower your cost of ownership and free up extra budget to reinvest elsewhere - such as site initiation or patient recruitment.

Connect Your Distributed Sites—Anytime, Anywhere

With secure offline and remote data sharing capabilities, device trial managers can deliver a feature-rich eSuite to their distributed network of study teams, sites, and sponsors. Consolidate your workflows by uploading bulk data and sharing remotely to your dispersed teams and ensure patient adherence by proactively tracking for AE/SAEs. Get access to our dynamic reports—on or offline—and stay up-to-date on remote site performance anywhere, anytime.

A Better Way for Informed Consent

We know that patient understanding is an essential part of your trials' success, and it begins with your consent process. eConsent offers a better way for your sites and study teams to reach patients, explain expectations, answer IP questions, and even enhance compliance—all without paper. Accelerate your consenting process without sacrificing global regulatory compliance and make comprehension easier for your subjects and sites. We promise you won't miss the paper.

Discover the ePRO Functionality that Device Studies Need

Nonadherence can make or break your studies; yet 40% of device study participants become non-adherent after the first 150 days. Our patient-centric ePRO was designed to increase your adherence and strengthen IP efficacy with robust functionality and a seamless EDC integration. Gain insight into your patient-reported and clinical data with fully compliant audit trails and pre-validated assessments. ePRO helps reduce patient burden while ensuring your data is more accurate and secure.

Single Solution for All Your Randomization Needs

Supply chain is a critical component of bringing a product to market. Your study timeline, budget, and overall success are closely tied to having the right IP available at the right place and time. Our flexible RTSM technology streamlines complicated supply chain considerations while minimizing IP waste and decreasing budget risk. We do this by offering a single, scalable solution for randomization and trial supply management that can adapt to any sample population size. We know your randomization challenges and how to solve them. Our RTSM solution and support team have delivered over 250,000 IPs to 2,400 sites in more than 50 countries.

> **"Having a good EDC with online/offline data capture that can record data on a tablet is crucial. And there are not many vendors that can provide that."**
>
> *Jenny Li, Senior Manager of Clinical Operations, inui Health*

Built-In Compliance

Medical device trials rely on numerous information exchanges between sites, sponsors, study managers, and suppliers. Ensure your sensitive data is secure with pre-validated software, and keep pace with the changing regulatory landscape with an eClinical suite designed to improve patient compliance.

- Built-in compliance—Good Clinical Practice (GCP), 21 CFR Part 11 Compliance, Annex 11, HIPAA, Privacy Shield, EQ5D
- Pre-Set Compliance Features—Pre-validated environment with built-in audit trails, Single Sign-On (SSO), SSL Encryption, Login and Activity Log, Two-Factor Authentication (2FA), edit checks, electronic signatures, session time-outs, and more.

ABOUT MEDRIO

At Medrio, we know that it takes a global village to achieve a healthier world. Our leading eClinical Data 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, RTSM, 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.**