EBOOK

Finding the Right EDC Solution for Your Next Clinical Trial

A Guide to EDC Buying in Today's Clinical Environment

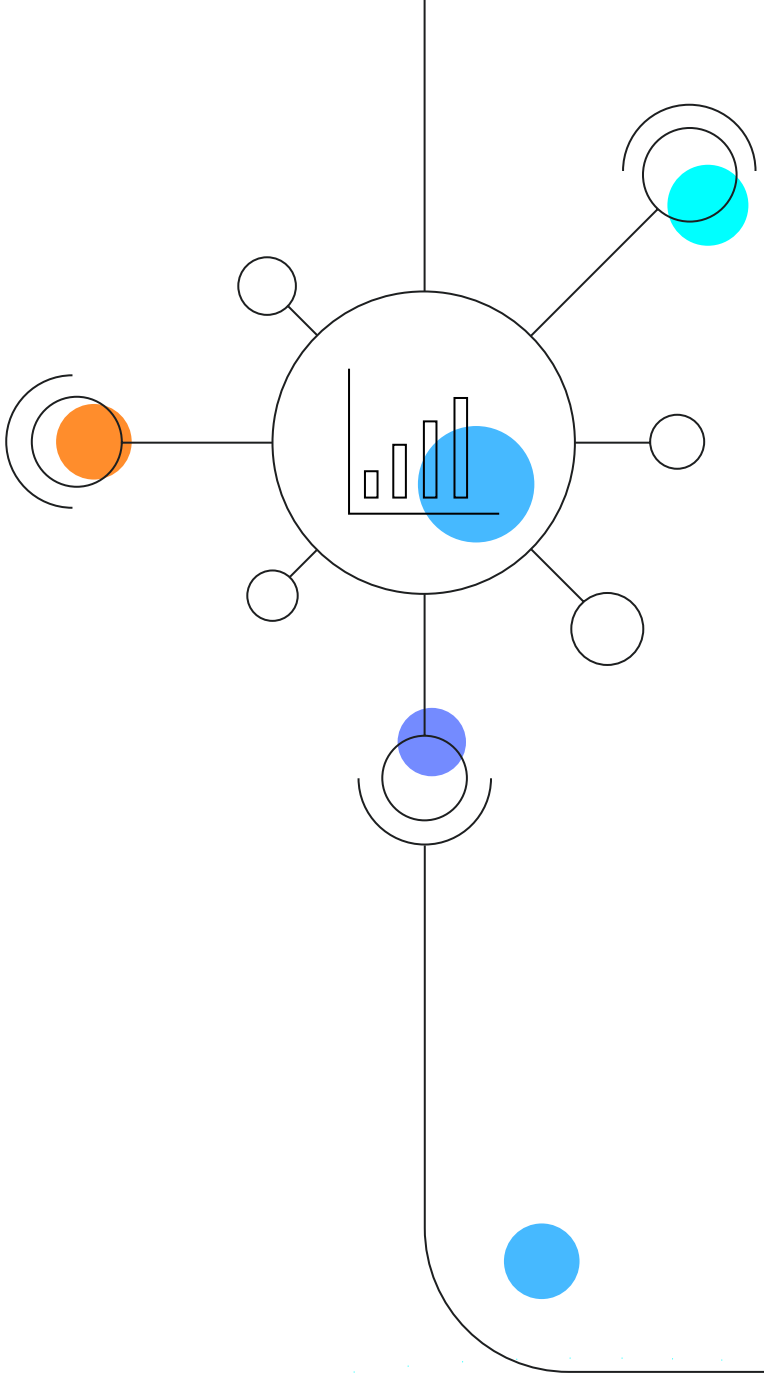
medrio

The clinical trial landscape is evolving. A 2021 analysis by the Tufts Center for the Study of Drug Development (CSDD) found that phase III clinical trials now generate 3.6 million data points on average—approximately three times more data points compared to a decade ago.[1]

At the same time, more trials are embracing accelerated programs and blending multiple phases. This means future studies will include more sites, participants, data, arms, and mid-study changes.

Undoubtedly, the research paradigm is shifting towards greater decentralization, further globalization, increasing data endpoints, and more complex protocols. Amidst all this change, one thing remains the same: clinical research is an expensive endeavor. With immense pressure to maximize efficiencies, research teams are searching for the right solutions to support their work. The right electronic data capture (EDC) system can set researchers up for success to build faster, robust trials. Here's what they need to know to find the right fit.

In this Guide



What is an EDC?

The original purpose of EDC systems was to digitize paper-based case report forms (CRF). At first, EDC systems were used in a similar manner as early word processors, allowing workers to digitally create and store documents. Just as word processors have evolved to match the speed of modern-day business needs, EDC systems have changed significantly to meet the needs of modern clinical trials.

Today, EDCs are no longer merely data entry systems for sites. Their function is transforming to accommodate the growing complexity and speed of clinical research. Rather than a single point of data entry, EDCs can now absorb a huge range of data sources coming from many places at different times.

In fact, EDCs are evolving into true clinical data management systems (CDMS) with the ability to support the end-to-end management of clinical trial data, including data collection, cleaning, validation, analysis, and reporting. While electronic data capture is a component of a CDMS, the CDMS itself may include additional modules and features beyond data capture.

Picking the Right EDC Provider

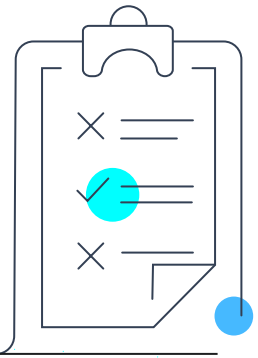
Every study is different, so the right mix of purpose-built technologies can look different for each one. There are some basics, however, that every study needs for its success. Your EDC solution should support the following:

- Secure, real-time access to clinical and patient-reported data
- Efficient data capture options with participant- and event-based workflows
- Simple mid-study updates and protocol amendments
- Consolidated monitoring with customizable ad hoc reports and visualizations
- Seamless integration of third party data sources

No matter the product stage or a sponsor's size, focus on building a toolkit that flexes and scales with you—not something that boxes you into predetermined solutions and workflows. Also, beware of too many bells and whistles. More functionality often results in more time, effort, and cost since each new option comes with a learning curve for clinicians and study staff.

As an essential system in the larger family of eClinical technology, your EDC needs to offer robust features in several areas:

- To achieve speed
- To ensure data quality & control
- For seamless workflows



What are the risks of choosing the wrong EDC?

Poor database design
Poorly designed or overly complex databases can cause data entry errors, usability challenges, and exporting difficulties.

Poor data quality and integrity
If the original study data is unreliable or incomplete (e.g., due to poorly configured or uncontrolled forms), it can compromise the validity of the results and limit the ability to draw accurate conclusions.

Regulatory approval
Failure to adhere to regulatory requirements can result in significant delays, fines, or other penalties.

Study management
Poor project and data management can result in missed deadlines, cost overruns, or inadequate staffing.

To achieve speed

Overly complicated database builds can slow a study down before it's even begun.

To achieve greater speed, choose an EDC with an intuitive design and flexible functionality that makes your study build and start-up process easy. To move forward faster, leverage EDCs that allow you to skip programming and unleash the power of automation and built-in logic.

Skip the programming

Study builders have enough on their plate. They need an EDC that meets them where they're at, which means eliminating programming from the process.

One area of a study build that often calls for custom programming is form building. One time-consuming area of a study build is form building since it often calls for custom programming. Study startup can be accelerated, however, by choosing an EDC with drag-and-drop form building which requires no code. This approach requires no coding, fewer staff, and less resources. Staff also require little to no experience building an EDC, which results in fewer disruptions during staff turnover.

On average, companies report needing

68.3 days

to build and release a study database.[2]

Look for these options to improve efficiency and make life easier for study builders:

- Add formatted text
- Add user-defined variables
- Calculate variables
- Duplicate a variable
- Create a new query definition
- Specify the action you want the system to take when the query is triggered.
- Build cross-visit edit checks
- Add an image to an eCRF simply by uploading a file
- Import a form from another study or copy an existing form (flip copy and import).

To achieve speed (cont.)

Use automation & built-in logic for basic tasks

The right automation, when based on built-in logic, can save your research team an enormous amount of time and, ultimately, reduce risk.

For starters, look for logic-based automatic notifications that are triggered by relevant events. Look for triggers based on built-in logic that can automatically send to multiple people, including imported distribution lists, with a single configuration.

Your EDC should allow soft and hard range checks to ensure errors are caught at the data collection point, where the data can be verified. Real-time range checks act as built-in guard rails for your trial's data. For example, the system can flag out-of-range weights, temperatures, ages, etc., reducing queries or unusable data. At the same time, logic-based reminders ensure measures are taken consistently, while skip logic creates efficiencies by eliminating irrelevant fields.

To ensure data quality & control

As we all know, the importance of quality clinical trial data cannot be overstated—maintaining data quality and control is key to ultimately getting regulatory approval. To do so, look for an EDC that allows you to test and manage mid-study changes without risk, offers real-time access to your data, and includes built-in data standardization.

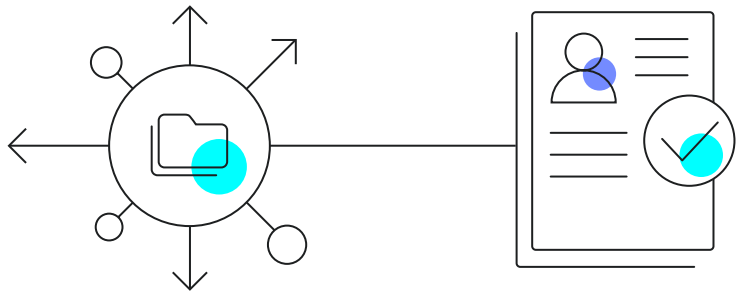
Access data in real-time

It's critical to have real-time access at every stage of your trial. Monitoring data remotely and in real time enhances the detection of safety issues and adverse events. It also reduces travel and transportation costs. Therefore, after a study goes live, study managers need to be able to resolve queries fast and assess the study's progress.

Data collected electronically, such as ePRO data, should be available within minutes to allow monitors to easily track subject health and completion rates. Real-time data access gives data managers a better sense of trial success metrics and whether key health metrics are improving. If users can easily identify low-performing sites and other issues, they can take the necessary steps to get everything running smoothly again.

Advanced reporting features to look for:

- An easy-to-export reporting system
- Point-in-time on-demand exports that don't interrupt data workflows
- Granular reports that allow filtering to see specific data or metrics



CASEBOOKS: Casebooks are the documents submitted to regulators for review. In order to save time and work, look for an EDC provider who automates the casebook creation.

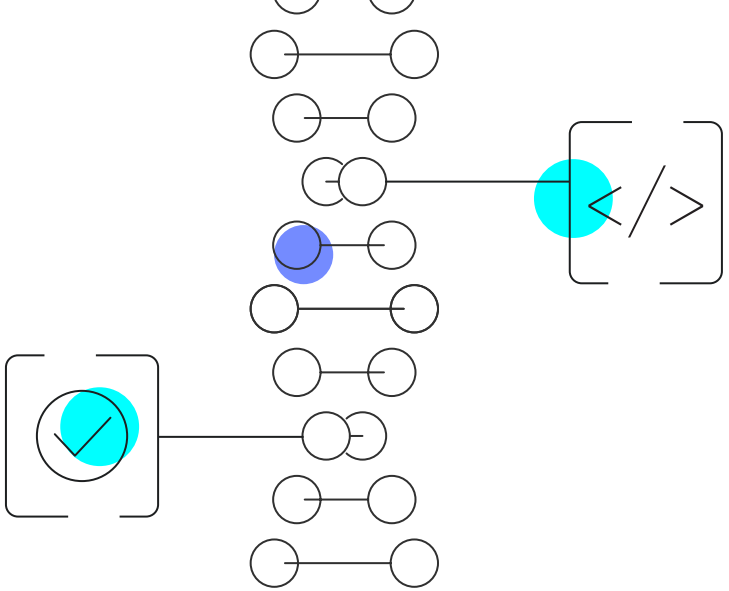
DATA EXPORTS: Some vendors provide export options that lump together both operational and clinical data. These exports make it difficult for sponsors to share specific data with regulators. Medrio allows users to easily select what data is included in their data exports. Data can also be exported into multiple common file types from the Medrio system.

To ensure data quality & control (cont.)

Standardize data through medical coding

As clinical research globalization trends grow, data standardization is becoming more important than ever. Medical coding standardizes varying terms and data against a dictionary to ensure data consistency.

Look for an EDC that allows adverse events (AEs), medical histories (MHx) and contraindicated medications (ConMeds) verbatim terms to be mapped to appropriate 'preferred' terms from the Coding Dictionary. This is essential for accurate data analysis and is ever more useful with the increasing globalization of clinical trials.



Choose an EDC that makes it simple to add and configure necessary dictionaries

Dictionaries utilized/supported by Medrio

MedDRA

According to meddra.org, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), MedDRA was developed in the 1990s as "a rich and highly specific standardized medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans." Its growing global use by clinical research organizations, regulatory authorities, and pharmaceutical companies supports the global protection of patient health.

WhoDRUG

As international reference for medicinal product information, WHODrug is maintained by the Uppsala Monitoring Centre and available in English and Chinese. It covers both conventional medicines and herbal remedies. The data is continuously updated, with new releases twice a year, on March 1st and September 1st.

Veterinary Dictionary for Drug Regulatory Activities (VeDDRA)

This list of standard clinical terms is used in reporting suspected adverse events in animals (or humans) after exposure to veterinary medicinal products.

To ensure data quality & control (cont.)

Ensure mid-study changes without risk

Since 2015, the prevalence and the mean number of amendments per protocol have increased across all clinical phases, according to the same report.[4] What's more, protocol amendments represent the largest cause of unplanned delays and unbudgeted costs in a clinical trial.

In a 2021 report, Tufts (CSDD) reported that...

Additionally, each of these mid-study updates typically takes approximately 30 days to complete before the study can resume—or go live again. Furthermore, the report cites mid-study updates and system flexibility and customization as top challenges with EDC capabilities.

What is the takeaway from all these stats? It's critical to look for an EDC with an always-available test environment to support the validation of study-level changes. For example, Medrio's three-tiered (Dev/Test/Live) environment can accelerate the implementation of mid-study changes by eliminating downtime by allowing users to see how changes will impact actual study data and workflows.

Mid-study changes are inevitable, with a Tufts (CSDD) 2023 report stating that

over 75%

of studies face at least one.[3]

...studies average

4 planned and

4 unplanned

mid-study updates, although this varies greatly by study.[5]

To maximize operational efficiency

As clinical trials decentralize, the ability to collect electronic data from various sources is important for operational efficiency. Tufts Center for the Study of Drug Development reports that applying decentralized clinical trial (DCT) methods in Phase II and III studies can reduce a phase's duration by three months.[6] In the same report, they mention...

...an average increase in value of

$8.6 million

per investigational drug—nearly a 5x return on investment (ROI).

Therefore, when choosing an EDC, it's important to look for a partner with a suite of integrated solutions that support clinical trial workflows—traditional, hybrid or decentralized—to support operational efficiency.

Leverage the benefits of eSource

eSource improves how efficiently a study team can capture, record, verify, integrate, and share data from multiple sources. It also:

- Supports cleaner data entry (e.g., real-time edit checks)
- Eliminates reconciliation time to resolve duplicative data entry
- Reduces bottlenecks for assessments
- Lowers the need for source data verification (SDV)
- Offers immediate access to validated data
- Supports real-time monitoring and progress updates
- Reduces data queries
- Incorporates existing data streams from EHRs, labs, devices, and sensors
- Reduces trial complexity and site burden
- Increases the amount and quality of research data collected
- Accelerates timeline to database lock

By funneling eSource through your EDC, in-clinic workflows can easily be replaced with automated virtual ones. The right selection of eSource products within your EDC can create convenience and efficiency for both participants and site staff.

To maximize operational efficiency (cont.)

Maximize API integrations

Whether you want to enter data directly into a tablet when in a nursing unit, a clinic, or a participant's home, choose an EDC that supports data entry both online and offline. Also, consider whether an EDC's API integrations, data upload capabilities, and partnerships support third-party data integration.

The value of API integrations can sometimes be underestimated. CROs and sponsors can leverage APIs to seamlessly integrate source data securely. Straightforward integrations stand to improve data integrity and visibility—the very lynchpin of a treatment or product's pathway to market.

While it may seem easy to add on tech in a piecemeal fashion, doing so adds risk, burden, and inefficiencies in execution—especially if integration and interoperability are not considered upfront. Look for an EDC partner that provides additional and integrated modules. These integrations support:

- Faster and easier data transfer
- Improved data quality review
- Optimized site and participant data collection
- Smoother supply chain workflows

Buying Beyond the Basics

Your EDC should have advanced functionality, such as intuitive UI, behavior-based workflows, and bring your own device (BYOD) options while supporting shorter study starts and mid-study changes. And the platform needs to be backed by a partner who offers broad expertise and a consultative approach. In short: look for the right tech and the right partner.

Look for the right tech

When selecting an EDC for your study, the tech needs to meet you where you are. Your EDC solution should be user-friendly, scalable, and connected through one centralized interface. Look for an agile, cloud-based solution that allows for full control with technical backup anytime.

Look for an EDC with a simple setup and an intuitive, drag-and-drop interface. The right tech will let you build studies rapidly without requiring any coding expertise. In addition to simple study builds with no programming, you'll want full control with the ability to make mid-study changes quickly and independently without taking a study offline or relying on technical support.

Look for the right partner

Besides scrutinizing the product, it's important to scrutinize the provider. Ideally, they should act as a true partner rather than simply a vendor. With increasingly strict regulatory reviews and an ever-shrinking pool of skilled personnel, the right technology—with the right partner behind it—is critical for optimizing your resources and guaranteeing financial solvency.

A true partner should offer:

- Robust technical and service support (from employees, not a call center)
- In-house expertise with subject matter experts
- On-demand training modules for self-service

Good vendors will act as counterparts who can help you choose solutions that fit your trial's current and future needs. Their guidance should help separate needed functions from extra bells and whistles. The right technology provider's insights will create efficiencies that benefit the sponsor, study team, sites, and participants.

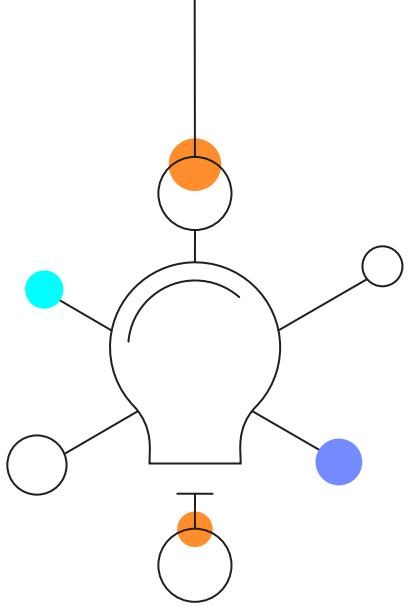
Modern Trials Require a Modern EDC

Clinical research is rapidly evolving. Don't risk your trial's viability with a partner that's too clunky to innovate or too new to be proven. With almost two decades leading the industry, Medrio understands your challenges and can meet you where you are on your growth journey.

At Medrio, our goal is to understand your study's requirements and to provide a comprehensive package of technology and services to meet your needs. So, if you want a partner with expertise, longevity, and dedication, there's only one choice: Medrio. Don't settle for anything less.

About medrio

Founded in 2005, Medrio is a leading healthcare technology company providing eClinical solutions, including EDC, eSource, and ePRO, for clinical research. The company's cloud-based software platform and mobile suite of products 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 across drug, device, diagnostic, and animal health trials. Medrio has extensive experience in all study phases and leads the market in early-phase trials. The company serves over 500 customers globally, with headquarters in San Francisco and offices in numerous domestic and international locations.



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