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The Guide to Using Electronic Data Capture (EDC) for Medical Device and Diagnostics Trials



High-quality data play a significant role in the success of medical device and diagnostics clinical trials. Studies have shown that bringing a therapeutic medical device to the U.S. market costs approximately $526.4M. With such high stakes, medical device manufacturers must place high-quality data generation, capture, and analysis at the top of their clinical research priority list. Medical diagnostics firms are under similar market pressures, combined with the unique challenge of sample management. Implementing a modern solution for data capture can provide the winning edge for medical device and diagnostic trials.

Electronic data capture (EDC) systems collect and manage clinical trial data on a digital platform, replacing traditional paper-based data capture in clinical research. With an EDC system to support your trial, you can capture data securely, expedite the clinical research process, and more easily reuse clinical data. The benefits of using an EDC system also include cost savings, reduced time to market, better compliance, and more accountability. Most EDC systems are cloud-based, which allows secure access from any location.

Is an EDC system right for your medical device or diagnostics trial? If you think it is, consider where to get started, whom to engage in planning, and how to select the best system for your trial. Switching from traditional clinical data capture methods to electronic ones requires a shift in both mindset and process. It can pay immediate dividends, such as saving time in study design and building with reusable forms and form libraries (including data validation and edit checks). But you also need to assess less tangible costs—including how easy the EDC system is to use and learn—to minimize barriers for site adoption.

Here, we distill the process of incorporating an EDC system into your trial, including the unique data requirements of device and diagnostics studies; the high value returns of streamlining processes and real-time data access; the best strategies for planning, designing, and compliance; and how to identify a vendor who will provide a superior product and support plan.

Unique features medical device trials affect data collection

Fundamental differences between drug trials and medical device trials can affect data collection processes and quality. Vendors built many of the current leading EDC systems with drug trials in mind, so it's important to note how these trials vary. Medical device trials can entail some or all of the following unique factors:

Timelines and Compliance

- Post-approval or post-market stage studies typically generate final data for submission (rather than the earlier pilot, feasibility, or pivotal stages) and medical device trials have steps, not phases

- All Class III (and some Class II) medical devices require a clinical trial in the United States, and data collection requirements differ by class.

- There might be short timelines for data collection based on the type of medical device and the medical condition that it potentially treats. For example, a cardiac implant might have a window as short as four hours. These short timelines create additional data collection challenges.

- There might be a required imaging modality so the sponsor can view the medical device and observe its function, which is the case for implantable devices. (Imaging adds another layer of data collection complexity to a medical device trial, so note that an EDC system can provide this function.)

Research Issues

- Medical devices and diagnostics are often novel compared to drug trials, which can include molecules that have been researched well before the clinical trial commences. Many devices in initial stages of research might be prototypes with a higher probability of failure, making data collection less reliable.
- Research might start with a small pilot population before moving into a larger pivotal one. Generally, the number of participants needed to demonstrate safety and effectiveness in a medical device trial is in the hundreds rather than in the thousands as required in drug trials. Smaller research populations limit the amount of data collected, leaving less room for error with collection and analysis.

Data Challenges

- Randomized and double-blind studies might be more difficult or even impossible. For example, researchers might not be able to place a placebo artificial joint into a randomized participant. This inability to randomize can compromise data quality, as non-randomized trials cannot take advantage of the limited bias that randomized clinical trials typically provide.

- There are more than 1,700 types of medical devices associated with 50,000 products that might require data collection. The heterogeneous nature of the medical device industry can make data collection and analysis more challenging for medical device manufacturers than for drug manufacturers.

Summary of Medical Device/Diagnostics and drug trial differences

- Trials tend to have fewer participants than drug trials
- Many devices and diagnostics are novel
- Might be challenging (or impossible) to randomize or blind
- Data collection might be subjective to physician technique
- Data collection might need to consider samples
- Device modifications occur during a trial
- Endpoints are highly diverse

EDC System Preferences

When you first adopt an EDC system, you need to commit time and effort for planning, training, and setup. This investment typically pays back quickly with such benefits as cleaner data, ease of real-time monitoring, reduction of post-data collection entry time, faster database lock, and overall study time decrease. In particular, you'll find . . .

- Final analysis will be more rapidly available after the database lock. Using regular In-flight study analysis and reports, the biostatistician can script the final analysis.

- Real-time access to data provides superior control and quality. With it, you can integrate data as you receive it from the patient and potentially correct any issues immediately, rather than wait until the trial's end, when problem data is difficult or even impossible to trace back to the original error.

Top EDC Value Drivers

- Provides real-time access to data

- Saves time spent on query management

- Using eSource or direct data capture can reduce duplicative data entry and eliminate transcription errors

- Streamlines processes with advanced reporting and risk-based monitoring, which removes the need for on-site verification

- Cuts costs of paper related expenses (shipping, monitors, printing, storage, logistics of handling)

- Supports better data quality and reduces errors

Your EDC System Preparation Plan

- **Identify key team members**
- **Design your data dictionary**
- **Design your database and data management strategy**
- **Create a plan for risk-based monitoring and quality management**
- **Plan for participant data capture and device integrations**
- **Plan for regulatory compliance**

1 One: Identify key team members

Your EDC system planning team should include these three roles:

- **Principal investigator (PI).** Designs the study protocol for use with an EDC system
- **Data manager.** Designs and implements the database
- **Biostatistician.** Creates a strategy for analysis

With an EDC system, you capture the required data as the source document and then design the database to contain the data and allow its analysis. The data manager and biostatistician are therefore integral to the planning team from the start.

- Once the PI drafts the research protocol, the data manager reviews the case forms and recommends information capture methods.
- The data manager designs the database schema, which includes accurately mapping required input fields and applying constraints to automatically validate input data accuracy.
- The data manager also defines reporting needs, such as the duration of a procedure based on the start and end time.
- The biostatistician helps the data manager with all these tasks and also provides insight into summaries, filters, or reports that track study progress.

2 Two: Design your data dictionary

The first step in the study design for the EDC system is to identify the data you need to collect and then create electronic case report forms (eCRFs) to capture it. As you plan your data collection, focus on these questions:

- **What type and scope of data do you need to capture?**
- **Which endpoints does the study need?**
- **Which data outputs do you need?**
- **What other data collection methods and devices will be involved?**

In addition, consider the balance between collecting the right amount of data and gathering too much. The Medical Device Innovation Consortium (MDIC) surveyed sponsors to understand data burden in medical device clinical trials and found that approximately 30% of the data points collected in pivotal trials do not support core endpoints or regulatory submissions for marketing approval. These extra data points add time, money, and complexity to trials. Strive to collect only the data you need, and no more.
Finally, remember that study design is challenging for any trial, so where possible, consult with the regulatory bodies for guidance early in the pre-submission process.

3 Three: Design and test your database and data management strategy

When designing the database, consider the different capabilities that the EDC system offers, including real-time data capture and cleaning, so that you can fully leverage these features.
For example, the EDC system automatically validates data as they are submitted and issues alerts for missing data, data out of range, or data not meeting the required format. This real-time response allows the data collector to immediately correct mistakes. If an investigator misses a question during a participant's visit, the EDC system sends a real-time alert. The investigator can then obtain the answer before the participant leaves, thus preventing data errors from even reaching the monitor. With the EDC system, the monitor can review the forms closer to the submission time than can be achieved with paper CRFs. As a result, the EDC system minimizes paper and increases accuracy and data quality while reducing costs related to double data entry and data cleaning.
It also helps to test the final data extract from the design. Study teams often overlook this step, but it saves time later by requiring less data manipulation and transformation to make the data workable.

4 Four: Create a plan for risk-based monitoring and quality management

Traditional data monitoring approaches mostly occur on site. Site monitors typically visit a physical clinical trial site at regular intervals (for example, every 4-10 weeks) and check a high percentage of the data entered on the CRFs against the source, also known as 100% source data verification (SDV). But as clinical trials become larger and more complex, conducting all monitoring on-site with 100% SDV can be expensive, inefficient, and, if access to physical sites is compromised, ineffective.

Modern approaches such as remote monitoring and central monitoring can complement on-site monitoring and combine to help you create a risk-based monitoring (RBM) strategy that considers risk-based quality management (RBQM). Let's take a quick look at three different monitoring approaches:

- **On-site monitoring** includes risk-triggered visits, limited SDV, and source data review (SDR).
- **Remote monitoring** incorporates risk-triggered site contacts and SDV/SDR where possible.
- **Central monitoring** includes intelligent key risk indicators, advanced data visualizations, quality tolerance limits, and unsupervised statistical data monitoring.

RBM incorporates all of these approaches and deploys each method to make the most sense for the study. It includes a blend of on-site and remote monitoring determined on multiple factors, including study risk level, study complexity, client requirements, regional requirements, and site capability.

RBQM is an overall approach to monitoring and quality management that includes RBM as a subset. RBQM allows sponsors to build quality directly into the study design, instead of being reactive and focusing only on monitoring quality as issues arise. RBQM follows Quality by Design (QbD) principals and applies RBM control mechanisms to ensure overall quality in a study. This systems-wide approach encourages cross-functional engagement in a holistic and risk-based approach to clinical trial management and oversight.

To develop your monitoring strategy, select the combination of methodologies that are best suited to your study based on its design and required data collection, the risks you are willing to accept, and the study regions and their regulatory guidance. When selecting an EDC system, ensure that it supports these practices.

5 Five: Plan for participant data capture and device integrations

A key advantage of the EDC system is that you can integrate it with modern participant-facing data capture technologies. These technologies can increase trial efficiency, decrease participant burden, and improve participant experience. Modern clinical trials can leverage a variety of these technologies, including eConsent and ePRO.

Enrolling participants with eConsent can significantly reduce enrollment time and cost. For a medical device trial, avoid the limitations of a single data collection method and combine standard eCRF and ePRO functionality, preferably with additional techniques like surveys and integration with external data sources via their application programming interface (API).

Device integrations are critical for seamlessly enabling medical device trials and facilitating the direct transmission of device data to the EDC system. You can leverage EDC system integration to continuously capture device data during device development studies or to monitor participants remotely during a clinical trial. Typical study devices include scales, home pulse oximeters, and thermometers. You can push data from these devices directly to the EDC system through a dedicated connection.

Look for an EDC system that is data standard agnostic so that you can capture data directly from multiple data sources (eSource), including clinical trial management systems (CTMS), medical devices (including the Internet of Things (IoT)), and wearables. A well-designed application programming interface (API) will have clear documentation and a knowledgeable support team.

6 Six: Plan for regulatory compliance

Understand the regulations that apply to your trial. In particular, select an EDC system vendor who understands how data capture is subject to these regulations. Regulations vary by country and by region. The European Union issued new medical device industry regulations in 2017. Learn more about rules specific to the medical device industry.
For the FDA and EMA, both drug and device trials follow the same requirements for protecting human subjects, maintaining records, and disclosing financial relationships. Those requirements include:

- **HIPAA,** or the Health Insurance Portability and Accountability Act, was developed in 1996 and became part of the Social Security Act. The HIPAA rules' primary purpose is to protect health care coverage for individuals who lose or change their jobs.
- **GDPR,** or the General Data Protection Regulation, is a legal framework that sets guidelines for collecting personal information from individuals who live in the European Union (EU).
- **ISO/IEC 27001** is an information security standard, part of the ISO/IEC 27000 family of standards. Knowing that an EDC system meets this standard ensures your vendor is accustomed to regular information security audits and can serve as a knowledgeable partner in support of your inspections.
- **21 CFR 812** establishes the United States Food and Drug Administration regulations on 21 CFR Part 812, Investigational Device Exemptions. Notably, the Investigational Device Exemption (IDE) requires hands-on device training for investigator and site staff and protocol training. (Note: drug trials follow 21 CFR 312.)
- **21 CFR 11** establishes the United States Food and Drug Administration regulations on electronic records and electronic signatures.
- **21 CFR 50** establishes the United States Food and Drug Administration regulations on human subject protection.
- **21 CFR 54** establishes the United States Food and Drug Administration regulations on financial disclosure.
- **21 CFR 56** establishes the United States Food and Drug Administration regulations on Institutional Review Board (IRB) requirements.

Pro Tip: It can be challenging to keep up with regulatory changes, so consider using a tool such as the Compliance Navigator from BSI.

Selecting an EDC system for medical device and diagnostics studies

When you choose EDC software for medical device and diagnostics clinical trials, you enter a realm of unique requirements related to connectivity, security, privacy, API integration, specific interfaces to hardware, and regulatory considerations. Vendors built many of the leading EDC systems with drug trials in mind, which affects the design of licensing modules, and implementation, operation, and applications of these systems.

If your data must comply with the Medical Device Regulation (MDR), you need a system validated for clinical data collection. Follow these guidelines:

- Choose a vendor with the necessary quality procedures in place.
- Validate the method according to the requirements specified under the ISO14155 GCP standard for medical devices and other industry standards, such as those referring to data security.
- Verify that the vendor has documented verification and validation, and quality assured the system according to standards: for example, IEC62304, ISO13485, or similar V-model standards for software.

Some technology solutions are more flexible than others and offer add-on features and modules that streamline other study conduct processes. For example, some systems let you add customized automated notifications, an often valuable feature for reducing study risk and improving response time.

If you plan correctly for the EDC system, you can also leverage it to streamline workflows. For most effective results, make sure to include a project manager, monitor, and investigator in the EDC planning process. A strong familiarity with the system will make it easier for the monitor to track all the nuances related to the protocol. Ensuring participant safety is also a critical factor in EDC success.

Questions to ask when evaluating EDC systems for medical device and diagnostics trials

To procure the EDC system that best meets your needs, you need comprehensive details from your vendor. You might start with these questions, which cover such issues as pricing, scalability, integration, training, support, and more.

1. How does the pricing model work? Is the system within your budget? Are you choosing based on price alone, and if so, how might that compromise the results?

2. What type of reporting is available? Is there data reporting and visualization? Is there access to live data, status reports, and data export (all must-haves for any manufacturer that needs to comply with the MDR)?

3. Is the system scalable and flexible should the study grow? Does the vendor team explicitly plan for scaling and can they effectively support the effort?

4. Does this company have a clear and robust vision? And can you see yourself working with them for the next four years? Do you share a similar working style and approach?

5. What is the vendor's track record with medical device and diagnostics approvals?

6. Is the customer support team familiar with the needs of medical device and diagnostics teams? How much do they charge for their support? What is the average reply time?

7. What type of training does the vendor offer, and how much do they charge for it?

8. Does the system adhere to modern software design principles, platform support, and availability? How old is the technology?

9. Can the system integrate with channels like email, SMS, and other APIs for communication and data collection without needing expensive and time-consuming custom implementation? Is there an API, and if so, how easy is it to use?

10. Do you already use ePRO or believe your study could benefit from it? Does the EDC system provide an integrated ePRO solution?
11. Does the system provide medical device and diagnostics connectivity and full control of data capture planning?
12. Is there a comprehensive and free demo? (Your decision process can benefit from hands-on practice to get a real feel for the system.)
13. Do you have direct experience with the vendor or word of mouth recommendations from trusted colleagues? Can you find positive reviews on a trusted forum?
14. Do you need a self-service platform?
15. Are there well-designed software validation and SDLC processes? How do their release cycles work? Does the process align with your own business practice?
16. Are eSource and Direct Data Capture supported?

For more details, consult our list of features you should look for in an EDC system.

Conclusion

The right EDC system can modernize your medical device and diagnostics clinical trials and maximize your productivity. With proper planning and design, you can take full advantage of EDC features, including streamlined processes and real time data access. The upfront investment will quickly pay off with immediate qualitative benefits, such as improved accuracy and accountability, and long-term benefits, including business transformation. Plan for incorporating an EDC system at the start of your study, or add it to an existing study to ease burdens and accelerate progress.

Every medical device and diagnostics trial has unique requirements. Choose an EDC system that is purpose-built for medical device and diagnostics clinical trials from an experienced, highly rated vendor.

About Castor

A global health tech company, Castor enables manufacturers and research organizations to maximize the impact of data through clinical trial automation and data reuse, while supporting a patient-centric, decentralized approach to research.

Castor's platform has supported more than 4,100 commercial and academic studies that cover a broad range of disease areas including oncology, diabetes, cardiovascular disease, central nervous system, rare diseases, and infectious diseases.

Castor's capabilities include:

Electronic Data Capture (EDC) to maximize productivity in clinical studies and integrate data from different sources

Electronic Patient Reported Outcome (ePRO) forms to administer surveys and collect clinical data into a centralized platform

Integrations to capture data directly from multiple sources, including patients, clinicians, devices, wearables, and EHR systems

eConsent to facilitate and automate patient enrollment processes

Services for study set up and study conduct to help reduce study build time, capture higher quality data, and get to market faster

