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WHITE PAPER

Finding the Right Technology for Your Clinical Development Plan

Written in partnership with Advanced Clinical

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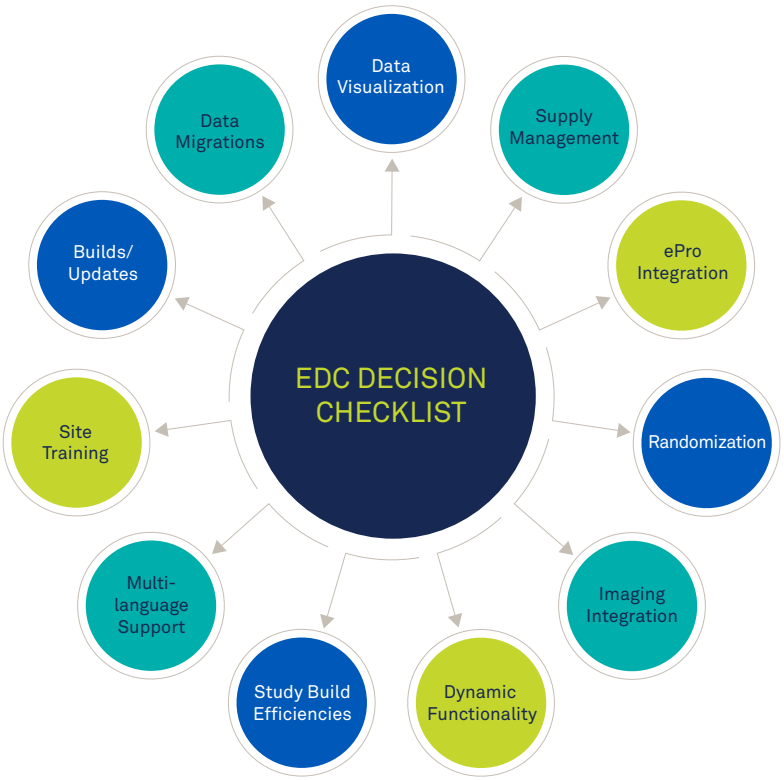
EDC Decision Checklist — Parameter Advantage



Source: Advanced Clinical

Clinical trial designs vary drastically—from single-arm PK/PD studies to fully virtual trials with embedded mHealth technology for remote patient monitoring. Different trials require different tools, and contract research organizations (CROs) and their sponsor partners need to assess which electronic data capture tools and other eclinical tools are fit-for-purpose for their trial.

Many small and midsize pharma and medical device companies look for help to determine which eclinical tools they need in order to successfully manage their clinical trials. These companies usually don't spend their resources on teams to assess new technology; rather, they prefer to invest in their clinical development programs and seek the help of a CRO partner to determine the best technology fit for their trials.

With the rising cost of trials and pressure for efficient trials, it can be daunting to choose the right technology to support a trial. Further, as new good clinical practice (GCP) guidance like ICH E6 come to maturity, companies need to identify the eclinical solutions that fit the requirements and guidance of regulators. Sponsors turn to CROs to find the fit-for-purpose technology solution for their trials in order to achieve clinical development goals with greater confidence.

CROs have the ability to lead sponsor partners through a decision tree exercise to ensure they find the appropriate EDC and companion modules to support a trial. These recommendations may change with the priorities of the trial, and ultimately determine the fit, value, and total cost of ownership with any eclinical solution.

EDC DECISION TREE

Every trial is different. By determining how EDC will be used during the course of the study by investigative sites to meet the requirements of the study, CROs can place the appropriate tools in the hands of trial sponsors.

DOES THE EDC ADAPT TO THE PHASE OF THE TRIAL AND WILL IT SCALE TO SUPPORT FUTURE TRIALS?

When optimizing the clinical development lifecycle, it is critical to evaluate every trial phase in context and ensure that the technology supports the protocol while providing the maximum return on investment. Each phase has unique challenges which demand different approaches and technology. A goal should be to find a unified platform to work across all phases of the clinical development plan.

- **Phase I** On the surface, using an enterprise EDC system for Phase I may seem like overkill, but overlooked costs, repeatable practices, and time saved in data cleaning and reconciliation will enable Phase I efficiency and speed.

  When considering technology to support early stage trials, a major consideration for functionality in an EDC system is one designed to manage mid-study changes without interrupting study operations.

- **Phase II** In Phase II trials, teams must ensure they are capturing the right data from both clinical and non-clinical sources into one source of truth to help the entire study team work in unison to quickly identify dosing, safety, and efficacy signals.

  Assembling the right data is one hurdle, ensuring the quality of the data is equally important. Many edit checks never fire, leading to more queries and laborious reconciliation cycles. Study delays are often due to these manual, error-prone activities. Dynamic functionality in a system is a key combatant in query reduction

  It's vital to have an integrated study conduct solution that provides a single source of data collection for end-to-end visibility and accountability.

- **Phase III** An effective Phase III approach needs to support both complexity and scale. Since time is of the essence, every opportunity to easily adjust the database in an efficient manner should be accommodated. This requires an EDC solution that manages the complexity of global trials with large patient populations.

- **Phase IV** Collecting real-world evidence from thousands of subjects in a diverse patient population for post-marketing surveillance requires an EDC that is easy to use, scalable, and low maintenance. A Phase IV EDC solution should be a mobile, unified platform with real-time data for safety monitoring.

DATA VISUALIZATION: IS IT NECESSARY TO VISUALIZE CLINICAL DATA?

No matter the trial, the answer here is undoubtedly yes. CROs resoundingly recommend solutions that allow sponsors to view visualization dashboards and reports in real time. These systems allow sponsors to quickly detect correlations or outliers that require attention. New interactivity capabilities allow sponsors to drill down into the data, which results in more precise and efficient actions.

SYSTEMS INTEGRATION: IS THERE SINGLE SIGN-ON AND URL ACROSS THE EDC PLATFORM?

Single sign-on for learning and credentialing makes navigation easier for sites, sponsors, and their CRO partners. In addition, consider the technical details of the EDC platform. Modern systems allow for seamless upgrades and nearly instant deployments, which allow study teams to take advantage of new features without disruptions to the overall timeline.

MODULE INTEGRATION: HOW DOES THE EDC NAVIGATE DISPARATE DATA SOURCES?

When selecting an EDC system, CROs point sponsors to technology partners who can provide integrated functionality–ePRO, imaging, lab data, RTSM, etc. Doing so gives the sponsor the flexibility to choose the best data collection tools for the trial and share data across the study platform.

RANDOMIZATION: DOES THE TRIAL DESIGN RELY ON STATIC OR DYNAMIC RANDOMIZATION? WHAT ABOUT HANDLING THE LOGISTICS OF TRIAL SUPPLY MANAGEMENT?

The EDC system should allow sites to interact with just one system to randomize subjects and dispense and manage study product via instructions delivered on the eCRFs. The best fit is a unified solution for EDC and randomization and supply management—no integration required.

IMAGING INTEGRATION: DOES THE TRIAL REQUIRE IMAGING DATA?

Many clinical trials use medical imaging as an efficacy endpoint, and in therapeutic areas like oncology, nearly all trials rely on medical imaging. For these studies, the EDC system should simplify image and data collection and be configured to immediately perform edit checks and de-identification during the image upload process along with central review and adjudication as required by the protocol. The system should automate the distribution and review process after upload, per protocol design.

DYNAMIC FUNCTIONALITY: CAN DATA BE CLEANED IN REAL TIME?

Using EDC in a clinical trial only makes sense if it allows for dynamic functionality so sponsors and CRO partners can immediately view and track the progress of data acquisition and cleanup as data is captured by the system.

Further, dynamic functionality grants researchers confidence that the appropriate information is being captured in an efficient manner, reducing wasted effort and confusion.

STUDY BUILD EFFICIENCIES AND UPDATES: HOW LONG SHOULD THE STUDY BUILD TAKE WITHIN THE EDC?

CROs recommend to sponsors that their EDC of choice should allow the sponsor to develop a standards library and provide capabilities to reuse forms, roles and permissions. This can provide efficiencies for future study builds.

MULTI-LANGUAGE SUPPORT: DOES THE EDC NEED TO SUPPORT MULTIPLE LANGUAGES?

For global studies, eCRFs will need to be displayed to sites in local languages (including Chinese, Japanese or Korean) while the data entered is still centrally viewable from a single database. Help Desk support should be available in multiple languages as well.

What Fits for Your Studies?

In the end, no matter the EDC functionality needed for a trial protocol, generating high-quality data is vital to progressing development. The quality of the data impacts everything from regulatory decision-making and valuations for licensing purposes. By using a respected EDC platform, there are numerous benefits for small and midsize pharma and medical device companies as they advance products through the clinical development lifecycle.

It's important to examine not just the cost of an EDC solution, but the cost of ownership. There's dollars, and then there's value that a unified EDC platform brings to the success of a clinical development program. Your EDC is the foundation of your study conduct practice, investing in the right EDC is the first step in boosting your agility, enabling you study teams to understand efficacy and safety signals faster than your competition, ultimately boosting your bottom line.

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info@mdsol.com | mdsol.com | +1 866 515 6044