

A Look at EDC Implementation

Keep in mind that **any journey begins with a single step.**



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So you think that EDC is an over publicized topic? What more could possibly be written about the benefits, challenges, and integration of EDC for clinical studies? Here is one more installment of the EDC development saga.

Any CRO will tell a potential client that it has developed, integrated with, or is otherwise aligned with an EDC package or provider. This is a CRO mantra right up there with: "Yes, we are CFR 21 Part 11 compliant" and "Of course we have experienced sites and monitors available for your therapeutic area."

When tasked with researching, designing, building, and integrating an EDC solution into a core clinical data management system and work flow, there are a few things to consider.

Briefly, the challenges that are usually encountered provide a good chance to reevaluate, review, and refine the data work flow process to make it more efficient, flexible, and secure.

Challenge No. 1: Keeping Everything the Same, Yet Different

Many CROs have forms based on work flow as well as detailed SOPs for receiving the forms electronically, performing double data entry, and creating and resolving data clarification conflicts. Most CROs can turn out queries within 48 hours of receiving data. When trying to convert this process flow into an EDC system, it becomes evident that the clinical data needed by the sites for collection and review has to be accessible by the sites. But often a CRO's data managers are reluctant to give up the control to sites that would allow them to directly answer queries; they still wanted to review data changes before they were applied to the database. A compromise is to incorporate both departments: sites would be able to directly respond to queries, and the final review and input of corrections would still come from data management. Thus an important quality check has been added to the work flow.

Challenge No. 2: Staying Faithful to the Core Process Work Flow

When looking into EDC application and services, it is easy to become swayed by all of the bell and whistles that are available. Companies need

to keep their focus on how they do business. Each application will capture data and store the information, but the key element is to make sure that the tool completes the given task in a manner that meshes with the company's current business philosophy and practice, and not work on a parallel track.

Challenge No. 3: Remembering the Human Element

The human element relates to the users and the EDC suppliers. For the users, it is important to make sure that there is a relatable process from which they can gain a sense of familiarity. The users of the tool need to be able to put the pieces together on how everything works. Make sure the system is intuitive as to how the process flow is designed. The EDC supplier should have a knowledgeable help desk technician who can assist with the quick "how do I" questions.

Challenge No. 4: Avoiding Too Much Rigidity

Project managers who are responsible for developing a new system always go into the creation process with at least an idea of an expected outcome. Too often, one department — in this case IT — might proceed full-tilt toward bringing its vision to reality. It is of primary importance at this point to remember the axiom that no effective department works in a silo.

The people who will be selling, using, and helping others with the system will have much to contribute as to what its best functions might be, and how the tool will play out in the marketplace. Bringing all related stakeholders into the loop at the onset will get everyone to buy into the new system, and they will be enthusiastic when it arrives.

Challenge No. 5: Avoiding the Expectation of Overnight Acceptance

Change is good. Unless, of course, you are the one who is trying to implement that change. If this happens to be you, then expect countless discussions on the limitations and shortfalls of the system. Most, if not all, of this frustration stems from the learning curve and will eventually smooth out. Keep in mind that any journey begins with a single step. ■

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