

# Realizing the Promise of Electronic Data Capture

## A Practical Guide

### INTRODUCTION

The promise of increased efficiencies stemming from electronic data capture and electronic data management (referred to here collectively as EDC) has existed for years. However, adoption of EDC as a standard clinical trial tool has been slower than expected, primarily because of the mixed track record for EDC implementations. According to the most recent benchmarking document from The EDC Forum, 70% of EDC initiatives fail to achieve expected benefits.<sup>1</sup> *The full potential of EDC has yet to be realized by the majority of clinical development organizations.*

Any clinical development function that has considered implementing—or is in the process of implementing—EDC no doubt understands that it takes more than new technology to reap its benefits. While EDC can help streamline the clinical trial process, to maximize the benefits of a paperless system, one also must institute and manage change across the organization as a whole. Put simply, fulfilling the promise of EDC requires managers to effectively implement a range of operational changes.

The authors of this paper have assisted in numerous successful global EDC implementations that achieved company objectives and expected benefits. Through that experience, the authors have identified a number of critical success factors, “must-haves” and “must-avoids,” and general guidelines that managers should follow if they are to realize EDC’s full potential. To share those key success factors, as well as common mistakes to avoid, this paper is organized into four parts:

1. Critical Success Factors in Global EDC Implementation
2. Five Steps to Successful EDC Vendor Selection
3. Process and Role Changes Required to Successfully Implement EDC
4. Effective Testing, Training, and Rollout of EDC Solutions

While this paper is not intended to be a comprehensive guide to EDC selection and implementation, it is intended to provide a framework that will help managers plan their efforts, organize their thinking, and guide their actions.

### PART 1: CRITICAL SUCCESS FACTORS IN GLOBAL EDC IMPLEMENTATION

#### CRITICAL SUCCESS FACTOR ONE: STRONG LEADERSHIP AND AN UNDERSTANDING OF EDC’S CHALLENGES

Making EDC the new standard in an organization requires unambiguous executive support and strong project leadership. All areas within and aspects of clinical development are affected by the change.

Through experience, the authors have learned that successful EDC projects must involve the following key roles:

- Executive sponsor—usually the vice president of Clinical Development
- Project sponsor—usually the senior director of Clinical Operations
- Steering committee members, including the most senior
  - Biostatistician
  - Data Manager

- Monitor (Clinical Research Associate (CRA))
- Study Manager
- Clinical Information Technology (IT) Specialist
- Medical Director
- Senior Project Manager, who serves as the day-to-day project leader

#### Common Mistake: Treating EDC as a Data Management or a Clinical Operations issue

Clearly, Clinical Monitoring, Data Management, and Study Management are affected by EDC. However, the Biostatistics and Medical Director functions, both of which often serve important support roles in clinical trials, are also integral to the success of EDC. As such, clinical development leadership must gather and incorporate these groups’ input to the EDC processes.

#### Common Mistake: Allowing the internal IT function to drive the implementation process

EDC implementation is not simply a computer system implementation. In fact, EDC technology is only the tool that enables the critical changes that lead to benefits. However, since IT has traditionally managed new systems implementations and since IT



is typically structured to manage internal projects, many EDC efforts are given over to IT to lead.

While IT is an absolutely critical component of a project, if the project is perceived as being driven by IT, end users' acceptance of the system may be hampered. Unless Study Managers, Data Managers and Monitors, and other key functions are involved in the implementation, few benefits or expectations will be realized.

### **Common Mistake: Ignoring knowledge gained from past EDC experiences and external vendors**

Prior to launching a major EDC initiative, realistic assessments of the challenges ahead must be conducted. Most clinical development organizations interested in making EDC the standard have some experience with it—either through utilizing in-house systems, working with CROs that employ a system, or outsourcing the EDC portion of a study to an EDC vendor. The key for clinical development organizations is to capture the learnings from these experiences to enhance future, full-scale implementations.

### **Common Mistake: Choosing the wrong technical approach**

A number of potential system opportunities exist. Tools are available to build EDC systems internally. However, many organizations rely on external technology vendors for EDC implementation. While the vendor arena remains fragmented, several leaders have emerged:

- Phase Forward
- Oracle
- eResearch Technology
- Phoenix Data Systems
- Medidata Solutions
- DATATRAK
- eTrials
- Ninaza

Given the range of options, the project leadership team must have a clear EDC strategy to ensure the correct technical approach is selected.

## **CRITICAL SUCCESS FACTOR TWO: SET AGGRESSIVE TARGETS**

One of the primary responsibilities of project sponsors and the steering committee is to establish explicit targets for the EDC project, relative to both timelines and benefits. Aggressive benefits targets encourage the implementation team to move from simply installing the system to questioning how clinical development processes and procedures can be improved overall. While a fine line exists between aggressive and unreasonable goals, companies with cautious targets often fail to realize the full potential of their change efforts.

### **Common Mistake: Allowing too much time for implementation**

EDC implementations, like all major projects, must have momentum. In most cases, the most successful initiatives are those with aggressive targets. Although EDC programs are highly complex and involve a large number of moving parts, fast-tracking implementation provides better results. Establishing a strong sense of urgency, as well as a bold timeline, makes dedicating resources and completing tasks more efficient.

### **Common Mistake: Setting “reasonable” benefit expectations and targets**

Many companies develop their project benefits targets in a group environment, such as a steering committee meeting. Doing so often results in “lowest common denominator” targets that are selected because they are the least objectionable to a range of stakeholders. While these targets support easy consensus, they fail to drive change.

Instead, aggressive benefits should be developed by the executive sponsor and shared with steering committee members for their comments and support. The executive sponsor should actively defend the benefits targets to ensure the pressure to produce results remains high. Examples of typical benefits include: five-fold reduction in number of manual queries, two week last subject/last visit (LSLV) to database lock (DBL) and reduction of data management outsourcing by 20%.

## **CRITICAL SUCCESS FACTOR THREE: MAKE PROCESS REDESIGN THE CENTER OF THE CHANGE**

To benefit from EDC systems, everyone involved in clinical operations must modify the way they work. From the CRA's approach to site visits to the data manager's approach to database lock, every aspect of clinical operations must change to leverage the technology. These process changes must be defined in advance of the system rollout. Defining the new processes should be the basis of the entire EDC effort.

### **Common Mistake: Adapting technology to existing processes**

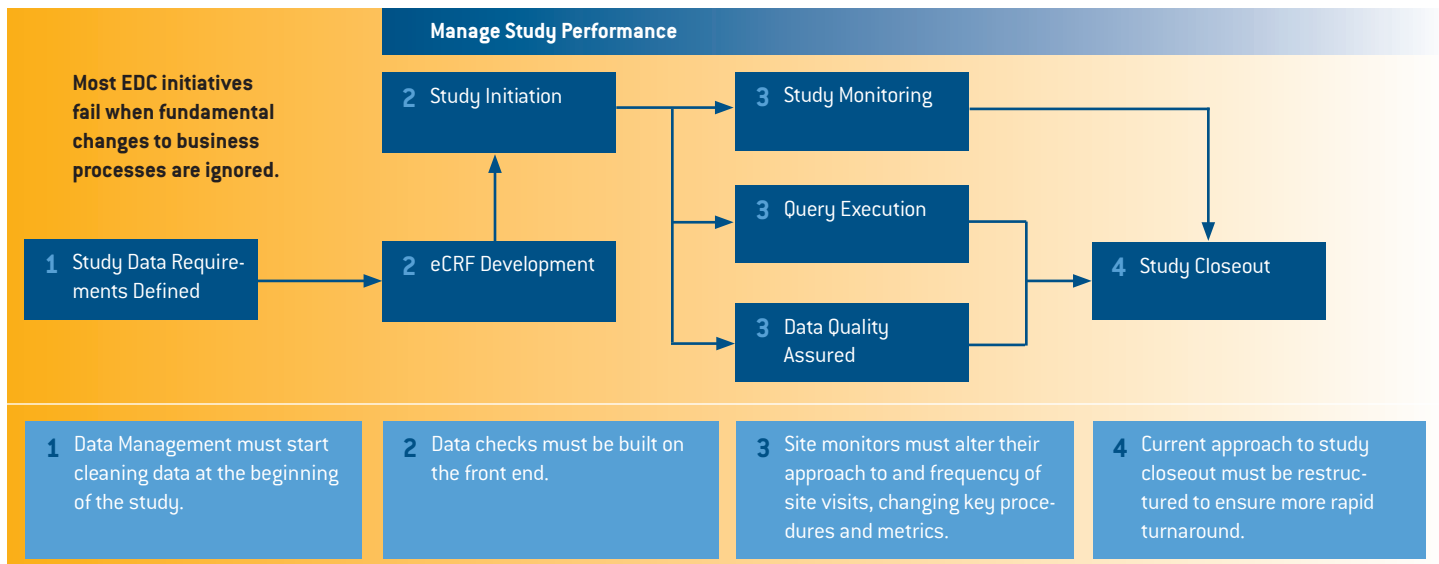
Work processes are often refined over a number of years. In most cases, they have been revised over time to support the existing paper-centric environment. Attempting to modify EDC software—regardless of whether it is packaged or custom built—to support existing work processes will lock in all the inefficiencies in the current environment. In contrast, adapting work processes to the new software enables companies to fully leverage the technology.

By redesigning work processes to optimize benefits of the technology, less time will be invested in system programming, and future support needed for the system will be reduced. While a few key system components may require special programming, the barriers to supporting these changes should be minimal.

### **Common Mistake: Limiting process change to system support only**

While adapting to the new technology is critical, an EDC implementation offers the unique opportunity for a wholesale review of current operating processes. In addition to those changes driven purely by the EDC system, other non-system-driven issues also should be examined. As such, EDC sponsors and the steering committee need to clearly support the entire range of process changes that can add value to clinical operations.

Figure 1.1: Key Process Changes Required for EDC



#### CRITICAL SUCCESS FACTOR FOUR: USE A PROVEN PROCESS CHANGE METHODOLOGY

Effective process change requires the right balance of risks and rewards. While it may be efficient to tackle all process changes in a single meeting, doing so rarely reduces the risk of failure. Typically a tested and proven process change methodology offers the best opportunity for ensuring that both efficiencies and risks are well managed. Campbell Alliance's RAPID EDC Methodology, for example, typically calls for the process to be broken into 5 to 10 sub-processes for purpose of redesign.

#### Common Mistake: Redesigning with the wrong people

The complexity of day-to-day activities must be considered when redesigning processes. Successful redesign projects involve experienced line-level personnel that support a specific function. While it is tempting for senior managers of a given function to drive the process, they are often so far removed from current operating conditions that they overlook key details in the redesign.

Rather than involving themselves in process change, senior managers should serve as sounding boards to teams of line-level personnel that are empowered to affect change. A sound methodology should support this relationship.

#### Common Mistake: Treating phase 1 studies and phase 2-4 studies the same

While the work processes in phase 1 studies share many of the same steps and procedures as phase 2, 3, or 4 studies, the needs of phase I studies are sufficiently unique to require special attention. However, when processes are redesigned across all phases, they are typically driven by the needs of phase 2-4 studies. If phase 1 processes are not considered separately, the opportunity to gain phase 1 staff acceptance and ultimately achieve project benefits for phase 1 studies is reduced.

While some organizations have gone so far as to implement separate EDC systems for phase 1 and phases 2-4, typically, a single system with specially tailored phase 1 work processes can suffice.

#### CRITICAL SUCCESS FACTOR FIVE: MANAGE ORGANIZATIONAL CHANGE

EDC implementation invariably alters the alignments and responsibilities of various roles in clinical development. For example, EDC can significantly alter or eliminate some roles in CRF development, and EDC often drives change in the roles of and relationship between Data Monitoring and Data Management. As a result, organizational change must be managed as actively as process change. And ideally, organizational changes should be rolled out simultaneously with the new EDC system and new work processes.

#### Common Mistake: Separating process change from organizational change

Given that process change is best supported by line-level personnel and organizational change is usually driven by senior management, it is tempting to treat them as two separate, parallel processes. However, this approach requires the two visions be reconciled before implementation is finalized. This reconciliation typically occurs near the end of the project after both visions have been fleshed out. The result is a mad scramble to make changes where the two visions diverge.

Usually, organizations are most successful when they allow the redesigned processes to be the primary driver of organizational change. By doing so, organizational change can be conducted to support and align with the process change.

#### CRITICAL SUCCESS FACTOR SIX: TEST BOTH SYSTEMS AND PROCESSES TOGETHER

Any new computer system must be tested before it is rolled out. This is a standard IT approach to system implementation. Yet, as mentioned previously, the benefits of EDC are achieved through work process changes. Despite this fact, few organizations jointly test the new processes and the EDC system. The authors' experience has shown that an end-to-end process test utilizing the production version of the EDC system can help avoid problems and ensure that work processes are followed.

## **Common Mistake: Relying solely on IT to conduct testing**

Traditional systems testing is often a technical effort driven by IT. Given the importance of joint processes and systems testing, Campbell has found that IT needs to partner closely with clinical operations stakeholders to conduct testing. Campbell also has found that testing can serve as a “train-the-trainer” opportunity, providing clinical operations stakeholders with a broad understanding of both the system and processes before conducting training.

## **CRITICAL SUCCESS FACTOR SEVEN: DEDICATE THE RESOURCES NEEDED FOR TRAINING**

All the hard work involved in an EDC implementation is lost unless personnel are adequately trained on both the new system and work processes. Training should be designed around and provided to unique roles, especially if the responsibilities have changed. Such training is best provided by those line-level personnel who designed and/or tested the new processes and thus can discuss the logic behind new processes and the system.

In addition to dedicated trainers, EDC sponsors and the steering committee need to assume that all resources in clinical development will need between one and two days of training—approximately one day for systems training and half to three-quarters of a day for process training.

## **Common Mistake: Providing inadequate time for process training**

Surprisingly, there is often a strong resistance to providing adequate time for process training. Although in most cases the changes made to work processes can be extensive, in many instances leadership assumes—at their risk—that one to two hours for process training will be sufficient.

Failing to provide adequate time for formal process training burdens personnel with having to teach themselves using whatever form of documentation is available. Self-instruction on new processes rarely produces adequate results. Organizations should expect process training that supports EDC implementation to take between half and three-quarters of a day, depending on the level of change each role will experience.

## **A BRIEF CASE STUDY**

Now that the critical success factors and common mistakes associated with EDC implementation have been described, it is helpful to review an example of a successful one. The following case study provides a solid overview of how to successfully manage change within an organization when making EDC the standard.

### **Background**

A “top 5” pharmaceutical company faced a number of major strategic issues. Its growing pipeline was placing great pressure on the Clinical Development function. Economic realities dictated against hiring more staff to handle the increased workload, so function leaders needed to change the way the organization operated—to do more with less. One critical decision was to improve the efficiency of clinical trials and improve the speed of the capture and management of subject data by implementing a paperless system.

The authors’ firm, Campbell Alliance, was engaged to help the client redesign all global trial-related processes—from eCRF development to study close-out—for phases 1-4.

### **Past EDC Experiments**

The company had previously experimented with a range of EDC systems, including one developed in-house. This proprietary, laptop-based system had been developed and deployed at a legacy organization. The solution proved popular with both investigators and study monitors. However, the system was cumbersome to manage and difficult to reconfigure as a solution for all global studies, as it required the organization to provide each participating site with a laptop configured specifically for each individual study. In addition, the company had utilized packaged EDC software solutions for several studies, but had never moved beyond the “experimentation” stage to realize the true benefits of the system.

### **System Selection**

The company conducted a robust analysis of its experiences to develop a list of key requirements needed from the EDC system. Next, personnel performed two separate system selection processes—

one for phase 1 and another for phase 1-4 studies. Both processes included reviews of the internally developed and the packaged EDC systems. Personnel conducting the separate reviews identified the same optimal solution—and selected the same packaged EDC system.

### **Process Redesign: The Center of Change**

One key take-away from the company’s past experience with EDC was that it represents much more than the implementation of new technology. Management understood that changing the way the organization conducted clinical trials was central to realizing the benefit goals it had set. Simply implementing EDC on top of paper processes would result in failure.

The company identified two areas of focus that were critical to the success of their EDC effort:

- **PROCESS REDESIGN:** The authors worked with senior management to establish an effective project structure that included resources from all critical functions, representation from different global regions, and subject-matter experts in key process areas. The project involved separate process redesign teams for phase 1 and phases 2-4. Teams were structured to focus on specific aspects of the clinical trial process, such as eCRF creation and data monitoring.
- **PROGRAM LEADERSHIP AND COMMUNICATION:** The authors worked directly with the client’s senior management to provide guidance for this large undertaking, confirm process changes were clearly understood and accepted by leadership, and ensure processes drove system design rather than the other way around. Working sessions were conducted with the project steering committee at critical junctures to communicate process and organizational change recommendations, receive input from the steering committee, and promote consensus on appropriate changes among steering committee and project team members.

### **Overview of the Approach**

The authors used a well-developed methodology for redesigning business processes and changing organizational infrastructures. In addition, the client brought its own proven methodology to the effort.

A critical step in beginning the process redesign effort was to effectively combine these two methodologies to develop a single approach to process redesign and organizational restructuring that would meet the client's targets and expectations in the aggressive time frame established.

A high-level overview of the approach taken to redesign business processes, manage organizational change, test processes and system together, and train key employees is provided below.

### Process Redesign

The cornerstone of the process redesign efforts were two sets of three-day process redesign workshops for each critical function area. In the first workshop, process redesign teams were tasked with defining high-level enhanced business processes and identifying process changes required to implement the enhanced processes. Team members were assigned as "champions" of the process change effort and charged with removing barriers to successful implementation throughout the organization.

During the three weeks between meetings, team members resolved open issues identified during the first workshop, communicated the required process changes to their colleagues, and generated feedback on the teams' recommendations. Additional information gained from these activities served as critical input to the second workshop.

During the second workshop, process redesign teams refined and added details to the initial to-be processes. The teams then identified tools and

documentation needed to support execution of the redesigned processes. Work plans were developed, and owners were assigned to developing the supporting tools and documentation. The authors worked closely with client team members to support communication and build individual work plans. Next, they consolidated individual team member work plans into work plans that would govern the development effort.

### Organizational Change

Once processes were redesigned, the redesign teams identified roles responsible for executing each step in the new processes. The authors then facilitated a three-day workshop with the project steering committee to discuss the new processes and associated roles, receive steering committee input, and determine the potential impact the process and role changes would have on the Clinical Development organizational structure.

### Process and System Testing

Process and system testing is critical for future success. Given the significant alterations to the work to be conducted and the global scale of those changes, testing the redesigned processes and EDC system prior to conducting "live" clinical trials was crucial. As such, once process and role changes were agreed upon and supporting tools and documentation were developed, more than 75 detailed scripts were developed based on every potential scenario an employee would encounter while executing a clinical trial. These scripts included all redesigned process steps, as well as exercises to test whether the system, as designed, would

support the execution of the new processes.

The team also conducted a simulated study in which a cross-functional team of employees executed all processes using the system. This exercise identified opportunities for improving the processes and supporting tools, documentation, and the system prior to going live.

### Organization-Wide Training

The significant changes stemming from EDC implementation also required in-depth training for study team members. In addition to the system training, the team developed detailed training modules specific to critical roles—eCRF developer, study monitor, data manager, and study manager—for clinical development staff. These training modules provided a detailed walk-through of all process steps in which each role was involved. Trainers, who had been members of the process redesign teams, delivered role-specific training to their colleagues who would conduct clinical trials using the new EDC system.

## IN CONCLUSION

For an EDC implementation project to achieve organizational goals, the critical success factors detailed above must be integrated into the program. While no magic bullet exists, clinical development organizations will have a much greater opportunity to achieve benefit targets and surpass expectations if they follow the guidelines and avoid the common mistakes mentioned above.

Figure 1.2: Overview of EDC Implementation Approach

Project Process Overview		
Time		
Develop EDC Goals and Metrics	Redesign Processes to Maximize Value	Implement Changes and Train Staff
<ul style="list-style-type: none"> <li>Work with senior management to develop goals</li> <li>Identify and document expected benefits</li> <li>Develop a plan for measuring performance against goals and anticipated benefits</li> </ul>	<ul style="list-style-type: none"> <li>Develop work processes to support the execution of clinical trials using EDC</li> <li>Understand and document changes to critical activities such as study monitoring, data management, and study management</li> <li>Test the execution of work processes using the EDC system prior to going live</li> </ul>	<ul style="list-style-type: none"> <li>Translate role changes into potential organizational changes</li> <li>Support the communication of organizational changes</li> <li>Develop and deliver training to support the execution of new work processes using EDC</li> <li>Measure performance against stated benefits</li> </ul>

## PART 2: FIVE STEPS TO SUCCESSFUL EDC VENDOR SELECTION

### OVERVIEW

Decreasing go-to-market time for individual products, as well as the overall product pipeline, is a primary concern of pharmaceutical companies. An effective EDC strategy is essential to achieving this goal. Moving from paper-based to electronic clinical trials creates several quantifiable benefits, including

- Faster study close-out: reduces time from last study/last visit (LSLV) to database lock by up to 70%<sup>1</sup>
- Reduced workload and corresponding cost: reduces data entry, query management, and site monitoring workload, thus eliminating an estimated \$250,000 to \$350,000 in costs per study

To fully achieve these benefits, a company should leverage EDC technology to complete the following key activities:

- Capture of clinical trial data electronically at the investigator site
- Real-time query generation and resolution
- Integration of data with back-end systems, such as a clinical trial management system (CTMS) and statistical analysis software
- Remote monitoring of study and site performance by Study Managers and Site Monitors

The success of these activities is largely determined by the selection of the most appropriate EDC vendor. This white paper will provide readers with tools and insights to

- Better understand the EDC technology vendor landscape
- Apply a disciplined, pragmatic process to EDC vendor selection efforts
- Evaluate EDC vendor capabilities using a “real-world” approach

### DECIDING WHETHER TO RENT OR BUY

Prior to selecting an EDC vendor, pharmaceutical companies must decide whether to “rent” the capability through an application service provider (ASP) model or “buy” the capability through a technology transfer arrangement with their vendor of choice.

**Table 2.1**

Model	Description
ASP	<ul style="list-style-type: none"> <li>■ Vendor owns and hosts the software on its servers.</li> <li>■ Customer pays a monthly subscription fee for use of the software.</li> <li>■ Vendor provides professional services to handle study setup and electronic case report form (eCRF) design.</li> </ul>
Technology Transfer	<ul style="list-style-type: none"> <li>■ Customer purchases the software, which may be hosted on its or the vendor’s servers.</li> <li>■ Customer tailors the software as appropriate to meet its specific operational needs.</li> <li>■ Customer resources conduct all study set up, eCRF design, and study conduct activities.</li> </ul>

The ASP and technology transfer models are described in Table 2.1 above.

The authors believe that ASP vs. technology transfer is not an “either/or” decision. Rather, the choice corresponds to different points in an organization’s progression towards full commitment to conducting EDC trials.

The ASP model is appropriate for companies “experimenting” with EDC. The model enables customers to realize some benefits of EDC trials on a study-by-study basis, without having to make a commitment to a single vendor. While this allows companies to gain experience with EDC technology, many of the benefits of EDC are never realized through the ASP model. Table 2.2 below explores advantages and disadvantages of the ASP model.

In contrast, the technology transfer model is more appropriate for companies making a commitment to conducting the majority of their clinical trial electronically. In order to realize the full benefits of EDC, a company must:

- Redesign clinical trial processes and organizational structures
- Customize the software to support redesigned processes
- Implement and test software and processes in tandem
- Train resources on new EDC-focused job functions
- Conduct pilot EDC studies, learn from those experiences, and revise processes, organizational structure, and software accordingly
- Manage the change until EDC is the standard method for capturing, analyzing, and managing clinical trial data

**Table 2.2**

Approach	Advantages	Disadvantages
ASP	<ul style="list-style-type: none"> <li>■ Allows companies to try multiple packages</li> <li>■ Limits organizational commitment—process and organizational design are not expected</li> <li>■ Costs less than technology transfer on a single-study basis</li> <li>■ Allows studies to be “up and running” in a matter of weeks</li> </ul>	<ul style="list-style-type: none"> <li>■ Offers few quantifiable benefits</li> <li>■ Fails to capture key learnings at the operational level, as key processes are executed by the vendor</li> <li>■ Costs more than technology transfer on a relative basis</li> <li>■ Limits staff learning curve by testing different vendor packages</li> <li>■ Increases confusion amongst staff and investigators through lack of commitment to a single solution</li> </ul>

**Table 2.3**

Approach	Advantages	Disadvantages
<b>Technology Transfer</b>	<ul style="list-style-type: none"> <li>Drives significant financial and efficiency benefits</li> <li>Supports organizational evolution toward fully automated clinical trials</li> <li>Enables staff to become functional experts in EDC technology</li> <li>Forces standardization and consistency of clinical trial processes throughout the organization</li> </ul>	<ul style="list-style-type: none"> <li>Demands higher initial financial and time investment</li> <li>Requires significant commitment from multiple functional areas</li> <li>Requires redesign of clinical trial processes, changes in multiple roles, and significant re-training of staff</li> </ul>

Table 2.3 above explores advantages and disadvantages of the technology transfer model.

In order to make the “rent vs. buy” decision, companies must determine where they stand in the progression from paper-driven to electronic trials. Is the company still learning and developing a comfort level with EDC technology? Or is it ready to standardize on one platform?

Wherever the organization is in its progression between initial evaluation and total commitment to EDC, it is necessary to make the rent vs. buy decision prior to beginning vendor selection.

**THE EDC VENDOR SELECTION PROCESS**

Key steps to successfully identifying potential solution providers, evaluating their capabilities and business models, and ultimately selecting the right partner to meet the company's needs include the following:

**Step One: Categorize Solution Providers**

One of the most confusing aspects of choosing an EDC solution provider is navigating the fragmented vendor landscape. Companies can simplify their selection process by segmenting EDC providers into the following categories:

**Table 2.5**

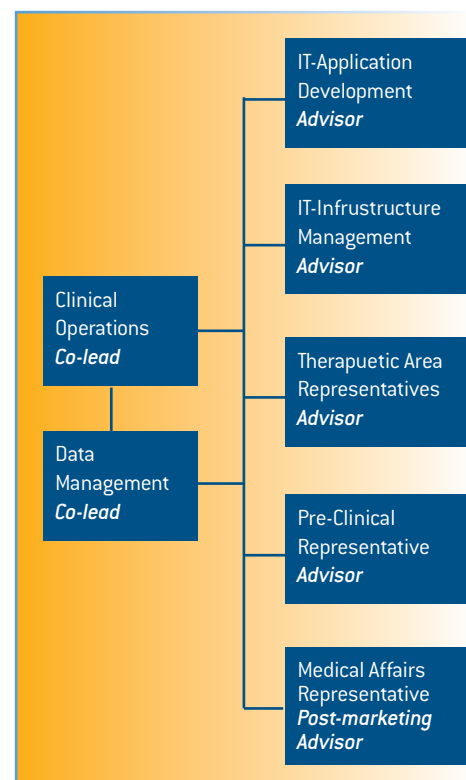
<p><b>“eClinical Suite” Providers:</b></p> <ul style="list-style-type: none"> <li>Vendors in this category provide a range of eClinical solutions including EDC and CTMS, as well as peripheral solutions like patient diaries and interactive voice response systems (IVRS).</li> <li>Vendors in this category include etrials, Phase Forward, and Oracle.</li> </ul>
<p><b>EDC Specialists:</b></p> <ul style="list-style-type: none"> <li>These vendors exclusively provide EDC solutions.</li> <li>It is critical that the specialist's solution can be easily integrated with other clinical systems.</li> <li>Vendors in this category include Medidata, eResearch Technologies, and Datatrak International.</li> </ul>
<p><b>Late-Stage Specialists:</b></p> <ul style="list-style-type: none"> <li>These specialists offer solutions that meet the specific needs of late-stage, or post-marketing studies such as Phase IV, investigator initiated studies (IIS), and patient registries.</li> <li>Vendors in this category include Ninaza and Outcomes Research.</li> </ul>

**Step Two: Involve the Right Players**

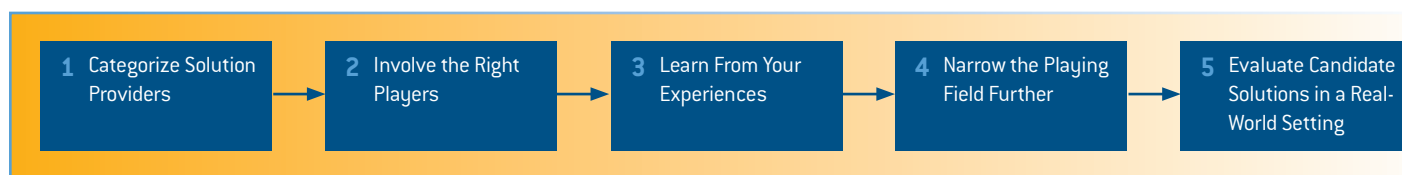
Companies too often view selection of an EDC vendor as an exercise driven by the IT and Data Management groups. While IT and Data Management are clearly stakeholders in the process, they are by no means the only critical parties.

Given the wide implications of using EDC technology, it is recommended that a cross-functional team of executives be formed to consider the optimal solution. This team must include representation from all clinical trial phases being considered. An ideal selection committee construction may look like this:

**Figure 2.6: Sample EDC Implementation Team**



**Figure 2.4: Overview of EDC Vendor Selection Process**



## Step Three: Learn From Your Experiences

Most pharmaceutical companies have conducted at least one clinical trial using some form of EDC and can build upon this institutional knowledge. Past experiences with specific EDC providers is critical information to gather, as there is no research more valuable than past experience. Key questions that will help a company gain insight based on its experiences include:

- What vendors has the organization worked with in the past?
- How many studies did each vendor support for the organization?
- In what phase was each of those studies?
- Which vendors have worked in what therapeutic areas?
- What elements of each vendor's product suite did the organization utilize?
- Was the study managed by the organization or through a CRO?
- What were the positive experiences with each vendor?
- What were the negative experiences with each vendor?

In the case that an organization has no specific institutional knowledge, informal networking among peer companies at industry events and organization meetings can serve as a rich source of information. Industry analysts and consultants can also provide valuable insight. However, it is critical in soliciting peer advice to consider the source and any incentives they may have to recommend a particular solution provider.

## Step Four: Narrow the Playing Field Further

After categorizing vendors and gaining insight from institutional experiences and peers, a company should develop a "short list" of two to four EDC solution providers. This short list should be comprised of providers with the potential to meet an organization's specific needs.

The needs that drive the development of requirements for an EDC system vendor include intended use of the EDC system and specific features of the organization's clinical trial processes.

Using the following vendor evaluation checklist, an organization considering their EDC options can catalogue the critical elements of each vendor's solutions, ranging from technical modules to professional services support.

**Table 2.7: Vendor Evaluation Checklist**

Evaluation Category	Elements of the Evaluation
<b>Phases supported</b>	<ul style="list-style-type: none"> <li>■ Phase 1</li> <li>■ Phase 2-3</li> <li>■ Phase 4</li> </ul>
<b>Product suite and integration with other tools</b>	<ul style="list-style-type: none"> <li>■ CDMS</li> <li>■ IVRS</li> <li>■ Patient diaries</li> <li>■ Reporting tool</li> <li>■ SAS/statistical tools</li> <li>■ Safety reporting</li> <li>■ Milestone tracking and payment tools</li> </ul>
<b>Reporting</b>	<ul style="list-style-type: none"> <li>■ Types of reports available                             <ul style="list-style-type: none"> <li>▪ Study management reports</li> <li>▪ Site management reports</li> </ul> </li> <li>■ Presentation of reports</li> <li>■ Source of reports (provided by an integrated reporting module or a pure play vendor such as Cognos or Crystal Reports)</li> </ul>
<b>Entry and management of user information</b>	<ul style="list-style-type: none"> <li>■ Sponsor and site information</li> <li>■ Pre-go-live and post-go-live</li> </ul>
<b>Conduct of source data verification (SDV)</b>	<ul style="list-style-type: none"> <li>■ Mechanism for conducting SDV off-line?</li> </ul>
<b>Freezing and locking mechanisms</b>	<ul style="list-style-type: none"> <li>■ Level of freezing and locking                             <ul style="list-style-type: none"> <li>▪ Case book</li> <li>▪ Form</li> </ul> </li> <li>■ User rights for freezing and locking</li> </ul>
<b>Study management</b>	<ul style="list-style-type: none"> <li>■ Study home page or portal</li> </ul>
<b>Safety reporting</b>	<ul style="list-style-type: none"> <li>■ Integrated part of the solution or additional solution required?</li> </ul>
<b>Supporting services</b>	<ul style="list-style-type: none"> <li>■ Site technical provisioning</li> <li>■ Help desk</li> <li>■ Training of sponsor and investigator personnel</li> <li>■ Professional services</li> </ul>
<b>Company experience and viability</b>	<ul style="list-style-type: none"> <li>■ Number of customers</li> <li>■ Number trials supported in relevant, specialized therapeutic areas, if appropriate</li> <li>■ Solution roadmap</li> <li>■ Cash flow and long-term viability</li> <li>■ Company growth plans</li> </ul>

### Step Five: Evaluate Candidate Solutions in a Real-World Setting

Once the playing field has been narrowed to two-to-four candidates, a company can begin to evaluate the solutions against their most specific requirements.

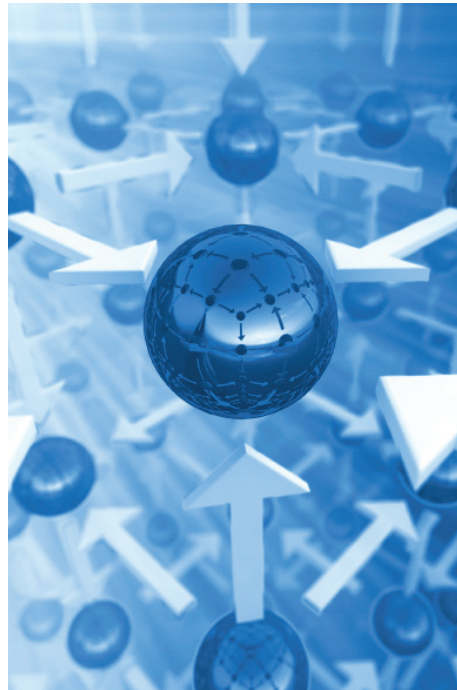
In order to truly understand whether an EDC solution will meet the needs of an organization, it must test the system in its own clinical trial process. Usually, a scenario-based testing exercise is appropriate, in which candidate EDC solution providers execute critical clinical trials processes based on scripts and data provided by the organization.

While developing scripts and sharing relevant data with EDC vendors creates extra work for an organization, the exercise provides the most realistic opportunity—short of actual trial conduct—to observe the candidate solutions in action. Following are a set of recommended scenarios to test:

- eCRF development, including the creation of edit checks and testing
- Site technical evaluation and provisioning
- Site technical training
- Importation of study user names and profiles—both sponsor and site—into the system
- Creation and viewing of site-specific performance reports
- Electronic source data verification
- Freezing of data and locking of forms
- Study close-out activities

As scenario-based exercises are conducted, each vendor should be evaluated not only on its solution capabilities but as a potential partner in future EDC endeavors. The following criteria can be used:

- How well did the solution meet specific requirements?
- What level of customization will be required?
- How much technical training will be required to comfortably conduct clinical trials using the system?
- How responsive was the vendor to requests, and how comfortable were interactions with the vendor's management and staff?
- How open was the vendor to providing critical experience and financial information?



*In order to truly understand whether an EDC solution will meet the needs of an organization, it must test the system in its own clinical trial process.*

### IN CONCLUSION

The fragmented vendor landscape, lack of a “one-size-fits-all” solution, and complex requirements of the clinical trial process can make the task of identifying, evaluating, and selecting an EDC partner appear daunting.

Engaging EDC providers in an ASP model is one way to reduce complexity, but this option fails to generate the promised benefits of EDC. To fully receive these benefits, an organization should select a provider offering a technology transfer approach to EDC.

Organizations ready to commit to EDC as their standard method for collecting, analyzing, and managing clinical trial data should follow five key steps in selecting an EDC partner:

1. Categorize Solution Providers
2. Involve the Right Players
3. Learn From Your Experiences
4. Narrow the Playing Field Further
5. Evaluate Candidate Solutions in a Real-World Setting

The organization that is willing to invest the time, energy, and focus into methodically executing the five critical steps of EDC vendor selection increases its chances of developing a successful partnership and, ultimately, realizing the promised benefits of EDC.

## PART 3: PROCESS AND ROLE CHANGES REQUIRED TO SUCCESSFULLY IMPLEMENT EDC

### OVERVIEW

To say that conducting a clinical trial is a complex undertaking would be a serious understatement. Conducting clinical research means managing everything from creating case report forms, through monitoring sites, to locking databases. It can involve numerous sites and thousands of subjects in multiple countries around the world—and that is when things go smoothly. In reality, clinical research also involves resolving countless queries, recruiting often hard-to-find subjects, and cleaning mountains of data, all while enduring intense regulatory scrutiny.

In other words, conducting a clinical trial is hard work. Yet over the years, pharmaceutical firms, biotechnology companies, and research organizations have found a way to make it happen. So is it any surprise that these same clinical development organizations are not eager to give up on a system they believe already works in order to implement electronic data capture (EDC)—technology that requires change to this already complex system?

It is this very resistance to change that contributes to the fact that almost 70% of EDC implementations fail to meet expectations<sup>1</sup>. Organizations try to implement the technology without adapting the clinical development processes that support it. They are then disappointed when they do not

recognize all the promised payoffs of EDC.

The benefits of EDC, such as simplified site monitoring, elimination of double data entry, and faster database lock, are only realized by organizations that are willing to tackle the organization and process changes necessary to support the technology. In this section (Part 3), we will discuss what changes are necessary for implementation and how best to go about making them.

### SUMMARY OF EDC-DRIVEN PROCESS CHANGES

EDC is more than just new technology; it's a new way of thinking about clinical trials. Implementing EDC while maintaining the processes that supported a paper-based system is like trying to play a CD on a turntable. The technology is only effective when it is supported by the right base of business processes.

One fundamental premise regarding the success of EDC is that the benefit potential will not be reached unless clinical trial processes are redesigned and key roles are updated so that they integrate efficiently with the EDC solution.

These process changes must occur at several key points along the clinical trial process, as illustrated in the diagram below.

The critical process changes start with defining the study data requirements (Fig. 3.1, A). In a traditional, paper-based clinical environment, defining these requirements is an iterative process that is done in concert with case report form (CRF) development. As the CRF evolves, so do the data requirements.

This back and forth process is extremely time-consuming, as it leads to delays due to revisions, false deadlines, and general confusion.

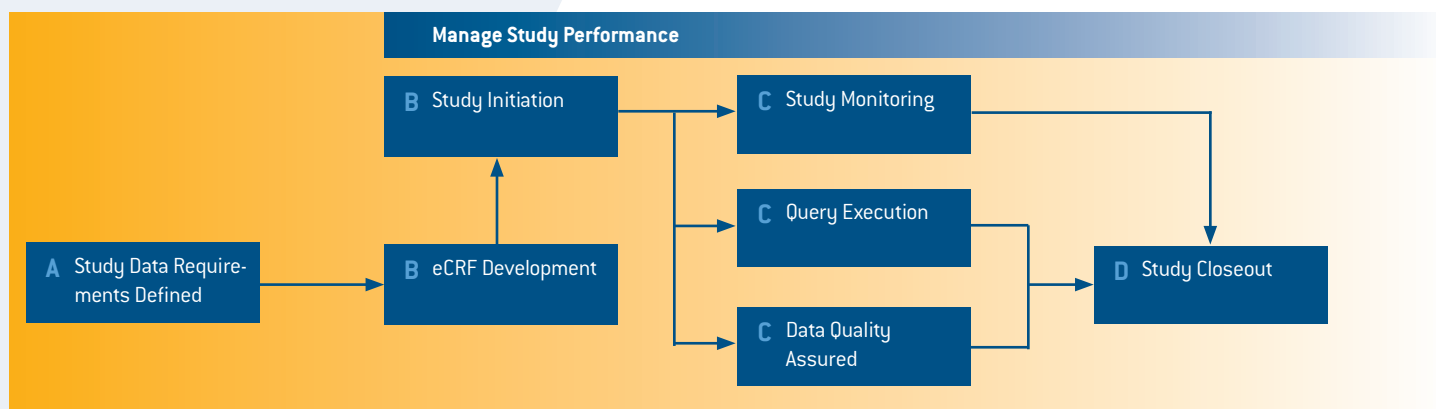
When implemented, EDC solutions make it very difficult to edit the data requirements that underlie the electronic case report form (eCRF). Effective clinical development organizations will view this condition as an opportunity to create a well-defined set of study data requirements on the front end. When critical issues like desired data endpoints and structure of site visits are addressed as “final” on the first go around, then time-consuming revisions and misleading deadlines can easily be avoided.

When data requirements are thoroughly developed on the front-end, the creation of eCRFs becomes much easier (Fig. 3.1, B), and EDC can begin delivering tangible efficiency gains. An eCRF must be built in a serial fashion, and having a strong set of data requirements facilitates a smooth building process. It is only when clinical organizations maintain the paper-based tradition of jumping back and forth between edits to the study requirements and edits to the eCRF that implementing EDC becomes a burden instead of a benefit.

Process change is also critical in study monitoring (Fig. 3.1, C). EDC makes it possible for Site Monitors to gather information on a continuous basis without having to make as many site visits. This shift in capabilities requires the underlying responsibilities and procedures to be altered if benefits are to be realized.

The attributes of a successful Site Monitor shift significantly once EDC is implemented. The most obvious need is for an increased degree of technical

**Figure 3.1: Points of Critical Process Change for EDC**



know-how. EDC allows those with the necessary technical skills to successfully monitor the sites without the frequent site visits required under a paper-based system. In turn, site monitors must have the communication skills to build and foster relationships remotely, as their degree of live interaction with investigators significantly decreases.

In addition to the shifting nature of investigator relationships, remote monitoring also means that data is constantly being collected. In order to keep up with this more rapid stream of information and the simultaneous flow of data from multiple locations, a successful Site Monitor must possess strong project management skills.

More effective project management is the driving force that enables the more rapid study closeout (Fig. 3.1, D) promised by EDC. Paper-based clinical organizations often experience the greatest delays at study closeout. Traditionally, this was when the data first began to be cleaned. Creating and replying to all the queries at one time created a significant bottleneck in the closeout process. Implementation of EDC solves this problem because an effective Site Manager can resolve data issues as they occur. When query resolution is successfully managed throughout the monitoring process, then study closeout becomes more streamlined and free of traditional paper-based study roadblocks.

## ROLE CHANGES IN CLINICAL DEVELOPMENT

As clinical processes change, so must the underlying roles. The EDC transition primarily affects clinical roles in three areas: data management, site monitoring, and study management. These role changes do not just affect the core clinical staff; they affect everyone with a hand in the clinical process.

Using EDC, data management begins earlier in the study cycle. Because eCRFs must be built in a serial fashion, there is a stronger incentive to correctly define the data requirements the first time. To accomplish this goal, input is gathered from a wider range of participants, including the site staff that will be collecting the data in the field.

EDC also affects data management during the site monitoring process. Site Monitors, Investigators, and site staff should all expect a shift in workload from a post-study peak to a steady flow through the life of the study. While the number of live site visits

may decrease with EDC, the amount of interaction between site monitors and site staff greatly increase to support the continuous flow of data and related queries.

In fact, the site staff's role is greater throughout the entire clinical process. Once the eCRF is completed and the study begins, the remote access capabilities enabled by EDC mean that the role of the primary site contact must be realigned to support the constant stream of data. The ability to directly query a site throughout the study means that the primary site contact's role is much more active and involved.

This ability to constantly query sites and collect data also creates a shift in study management responsibilities. To leverage this improved data access, study managers must change their approach to reporting study progress to incorporate the new information that is constantly available. Increased access to data also allows study managers to make decisions in a more real-time manner. To do this effectively, they must develop new approaches to identifying and resolving study-wide and site-specific issues on an ongoing basis.

**Table 3.2**

<b>eCRF Development</b>	Processes involved from developing study-specifications through publishing the eCRF
<b>Study Initiation</b>	All tasks required to prepare study teams and sites for study conduct
<b>Site Monitoring</b>	Activities required to effectively monitor sites using EDC, from first subject/first visit, through source data verification, to last subject/last visit
<b>Query Management</b>	Processes focused on addressing and closing all types of queries generated during the execution of a study
<b>Ongoing Data Management and Database Closure</b>	Management of data during the course of a study and all activities required to prepare the study database for closure
<b>Study Closeout</b>	Steps required to archive site and study data, remove site access to the EDC system, and decommission technical infrastructure
<b>Study Performance and Reporting</b>	Information and reports made available by EDC and required to more effectively manage an EDC study

## KEYS TO SUCCESSFUL CLINICAL TRIAL PROCESS CHANGE

### **Key One: Set measurable goals and break the process up into manageable pieces**

It is easy for an organization to commit to using EDC as its standard for executing clinical trials. It is much more difficult to understand how to make that commitment a reality. Realistically, organizations planning to convert their clinical operations to EDC must create smaller, more-actionable, incremental goals for implementation. This is done by breaking the process up into manageable pieces.

In clinical development, even the smallest task has multiple stakeholders who must be involved in the integration of EDC. After all, the clinical trial process is a highly complex undertaking, comprising multiple sub-processes that are dependent upon the successful execution of the others. So it is best to break the process into logical sub-processes for the purpose of redesign, then "re-assemble" the end-to-end clinical trial process at the conclusion of the exercise. Following is a logical breakdown of clinical trial sub-processes:

Breaking the clinical development process down into these smaller pieces is the most effective way to manage the change of such a complex process.

**Key Two: Treat process redesign as a global, Clinical Development-wide effort**

While creating manageable pieces is effective, treating the redesign process as a solely technical function is not. One of the greatest temptations of organizations implementing EDC is to take the path of least resistance and treat EDC as a Data Management effort. While Clinical Data Management has a large stake in the outcome of an EDC implementation, it is clearly not the only group affected.

It is only through including all affected groups within a clinical organization that EDC is successfully implemented. The redesign effort needs to include input from each of the following groups, and these groups must also endorse the final outcome of their combined efforts.

- Clinical Data Management
- Monitoring
- Biostatistics
- Clinical study teams
- Safety
- Development Information Technology
- Regulatory and Compliance

Beyond including these functional groups, companies with a global presence must also account for regional differences in how trials are conducted. This includes recognizing regional nuances in the process and organizational structure within their own organization.

**Key Three: Redesign as a group**

In order to effectively include all of the process stakeholders while simultaneously addressing the complexities of each clinical sub-process, organizations should tackle redesign as a group.

Unlike other redesign efforts, clinical development is not a process that is effectively addressed through a study and report model. While conducting fact-finding interviews about the current process and reporting back with a suggested new process may be effective for simple redesign efforts, those who attempt to apply the typical study and report model to clinical development are generally unsuccessful.

Given the criticality and complexity of the clinical trial process and the multiple departments affected by its redesign, the authors believe that the only way to effectively redesign the process is as a group. A group structure allows for the needed interaction among the stakeholders for each clinical development sub-process.

Each sub-process should be redesigned by a cross-functional team focused specifically on the detailed activities involved in a particular process. The team should include representatives from the functional areas most likely to be affected by or have influence on the changes generated by the team. For example, the study monitoring process redesign team should include more than just Monitoring staff. Clinical Data Management and Clinical Team staff should also be involved, because the activities and processes of all three functions are interdependent. In the same manner, global organizations must look beyond functional interdependencies to include the perspectives of the monitoring staff in different regions so that the redesigned study monitoring process also accounts for varying global practices. Such inclusive redesign teams are able to focus on creating ideas and developing solutions creatively and quickly.

In the authors' experience, it has been useful to hold two process redesign workshops during the redesign phase, spaced two to three weeks apart. Following is an overview of each workshop, as well as the activities conducted during the period between workshops.

**Table 3.2**

<b>Process Redesign Workshop One</b>	Teams initially focus on understanding the scope of their sub-process and their benefit goals. Upon reaching agreement, teams develop a high-level, first-draft process flow and capture the key change ideas incorporated in the redesigned process. This includes identifying any issues and barriers standing in the way of making the change ideas a reality.
<b>Inter-Workshop Period</b>	Team members meet with appropriate colleagues throughout the organization to discuss key change ideas and understand how best to resolve issues and remove barriers. Teams meet regularly to discuss progress, resolve issues, and discuss topics that will ultimately inform the finalization of new processes in redesign workshop two.
<b>Process Redesign Workshop Two</b>	Teams reconvene to apply findings from their activities since the first workshop, finalize the redesigned processes, and identify the roles that will execute each activity in the redesigned processes.

At the end of the workshop process, the members of the process redesign teams will be the true EDC experts within their organization. Their understanding of the processes is necessary to support successful execution of studies, and they will serve as mentors to their colleagues during the organization's transition to EDC. Workshop participants are well-positioned for this role, as they are the ones who developed the solutions.

**Key Four: Create a culture of ownership**

Of course, the process redesign groups can only develop effective solutions if they are empowered to do so. An organization must commit not only to implementing EDC, but also to implementing the necessary process changes. Senior-level support must be given to each process redesign group so that they can make the changes necessary to truly affect their particular sub-process.

This ability to affect change is particularly important because transition to EDC creates many opportunities to improve processes that have nothing to do with EDC. In a system as complicated as clinical development, it is rare that sweeping changes can be made. The opportunity to make changes throughout the clinical development process is not one that organizations should take for granted.

After all, the complexity of clinical trials and the necessary degree of regulatory scrutiny has created a culture within many clinical development organizations where overbearing checks, reviews,

signatures, and documentation are the norm. While process redesign teams are examining the clinical development process from the perspective of EDC, they must also know that they are free to challenge these cultural norms and break the “rules” put in place over time. This allows for the removal of process steps that do not ultimately add value to the end result.

The resulting culture of ownership is what drives successful EDC implementation and the organization's ability to reap the benefits of this technology.

#### **Key Five: Create generalists out of specialists**

Beyond process ownership, the group workshop format also realigns individuals' perspective so that they see the clinical development process as an interrelated whole. This is important because over time, clinical development organizations have evolved into groups of highly specialized roles that focus only on specific elements of the clinical trial process.

Organizations benefit from this specialization in that individuals become very efficient and effective in their designated roles. At the same time, specialization can cause individuals to lose visibility into how their work affects the work of others.

As the organization begins the end-to-end process redesign effort, individuals within the organization must be acutely aware of how changes to one part of the process can greatly affect—positively or negatively—the success of other seemingly unconnected steps in the process.

Creating this awareness is as simple as putting representatives from different specialized areas in a room to discuss the process together. In this environment, individual participants are forced to think as members of the broader organization. As a result, the revised processes the group designs to support EDC implementation will support the broader organizational needs.

#### **Key Six: Link closely with technical implementation**

In addition to experts from each functional area, workshop groups should also include technical experts. While clinical trial process redesign and implementation of the EDC system travel along separate parallel paths, they are inextricably linked in the sense that each work stream must inform the activities of the other.

This connection is supported through technical representation on the process redesign teams. These resources can be from the organization's internal IT group or from the EDC software provider. The key is that they are experts in the functionality of the software and can provide input regarding the software's ability to effectively support the redesigned processes the team is creating.

It is also helpful to create issue-focused working groups to tackle technical issues related to process redesign. These groups can be focused on many different issues. The most common of these issues include the following:

- Long-term integration of systems to create a fully integrated eClinical infrastructure
- Incorporation of external data, such as IVRS, labs, and patient diaries
- Handling of severe adverse events (SAEs)
- Core configuration of the EDC system

#### **Key Seven: Test processes, system, and supporting tools together**

All efforts in implementing EDC technology and redesigning clinical trial processes are in preparation to support the organization in conducting clinical trials in the most efficient manner possible. The first study teams to execute redesigned processes using EDC will be operating in an environment of change and uncertainty, and must be effectively supported. It is during the execution of these initial studies that the stakes are highest—positive experiences will generate support for the initiative, while negative

experiences could stall the organization's efforts and lead to inadequate adoption and lowered return on investment.

It is recommended that, prior to supporting initial study teams, organizations test redesigned processes and supporting tools, along with the EDC system, in as real-world an environment as possible. This exercise, known as a Conference Room Pilot, simulates the conduct of a clinical trial from end to end using scenarios that document all activities in the trial. Role players execute redesigned processes, enter data into the EDC system, and use supporting tools for guidance, while observers document any and all changes required.

The Conference Room Pilot serves as a highly valuable final step in the process redesign exercise, enabling organizations to find potential issues with processes and supporting tools prior to their use in the “real world.” Addressing these issues prior to rollout eliminates their impact on initial study teams, ultimately making for a smoother rollout and increasing adoption of EDC and redesigned processes.

## **CONCLUSION**

Obviously, the process of redesigning a clinical organization's operations to effectively work with EDC is not an easy one. But considering the alternatives—inefficient paper-based trials or poorly-executed EDC trial—the decision to undertake the redesign effort is a simple one.

## PART 4: EFFECTIVE TESTING, TRAINING, AND ROLLOUT OF EDC SOLUTIONS

### OVERVIEW

Many organizations that invest in EDC systems and related process changes still fail to achieve their expected benefits. Why? In many cases, EDC implementations fail at the very end—the testing, training and rollout of the EDC solution.

Testing, training, and rollout come at the end of a long and challenging implementation process. Often the staff members who are the primary drivers of the EDC project have been working on the effort for over a year, sometimes two years. By the time the EDC project has reached the final stages, key team members may begin to be pulled away to other, high-priority initiatives or simply lose interest in the EDC initiative. So, when their energy, knowledge, and drive are needed most, many of them are no longer available to see it through to a successful conclusion.

Also, because these tasks occur at the end of the implementation cycle, budget overruns earlier in the project are often extracted from the budget originally earmarked for testing, training, and rollout. These unfortunate circumstances are analogous to moving a ball to within feet of the goal line and then failing to score.

Typically, organizations that gain the greatest benefits from EDC are those that keep the project momentum strong and preserve the budget necessary to support these final implementation steps. There are, of course, many other factors to consider as well. This document provides a five-step approach to streamline the process of EDC testing, training, and rollout including

1. Testing and revision
2. Approach to training
3. Training the clinical organization
4. Rollout to the clinical organization
5. Making continuous improvements

### TESTING, TRAINING, AND ROLLOUT PROCESS FOR EDC SOLUTIONS

#### Step One: Testing and Revision

For the purposes of this chapter, we focus on the testing of new processes and the final acceptance of the EDC system by the users, usually called “user acceptance testing.” This testing deals with proving that the system and processes are fit for their intended use and are conducted in addition to any technical testing, which ensures that the hardware and software are functioning according to specification.

#### Conference Room Pilot Testing

As discussed earlier in this book, the key to successful implementation of an EDC system is the development of revised work processes that take full advantage of the software by changing fundamental assumptions about what, how, and when work is performed.

If an effective process design methodology is employed, the newly designed processes have a greater likelihood of success. However, the development of these processes is never perfect. Testing is needed to detect flaws before staff and sites are trained on the new work processes. This need is further heightened when the development of the new processes is broken into segments and given to multiple teams. In these cases, the various segments need to be tested as a whole to find points of potential redundancy or overlap.

The best approach to testing the processes and their interaction with the software, is through a “conference room pilot.” The goal of a conference room pilot is to conduct a rapid but complete run-through of all the processes defined by the EDC project using the actual software and realistic test data. The most effective conference room pilot tests are conducted with representatives of the actual roles that are expected to complete the process.

#### Preparation

The first set of decisions that must be made relates to the amount of effort and risk that are acceptable. Testing is all about risk mitigation. The primary reason for testing is to reduce the risk that a problem with that process is discovered after training, when corrections are time consuming and costly to implement.

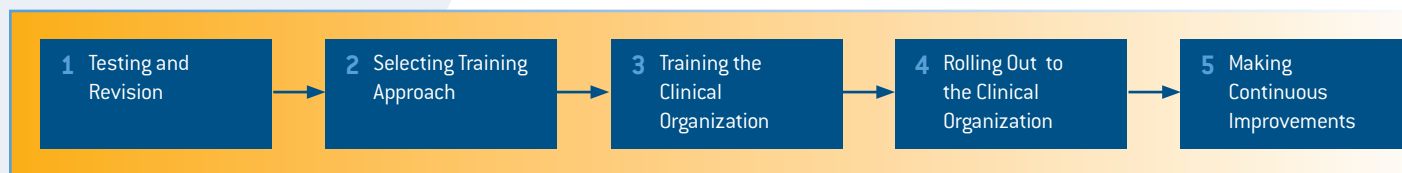
It is not feasible from a timeline and resource standpoint to test every possible scenario that could occur after the system goes live. Therefore, the leaders responsible for testing need to understand how much risk they are willing to assume.

The authors’ experience has shown that valuable testing can be condensed into as little as one week, focusing on the key processes and work steps, or expanded to up to four weeks, covering most major and minor processes, as well as exception processes.

To determine risk tolerance in this instance, a practical exercise is the best approach. Often the amount of risk willing to be assumed is expressed in terms of the amount of time and resources the organization is willing to invest in testing. Where the organization falls on that continuum (i.e., taking from one week to four weeks for testing) is a statement about its risk tolerance

To prepare for the conference room pilot test, a set of test scripts need to be developed. Test scripts

Figure 4.1: Steps in the Testing, Training, and Rollout Process



define the testing scenario to be executed by the attendees. These scripts include background on the specific situation, lay out the work steps necessary to complete the scenario, and include any data needed to be entered into the system.

Test scripts are developed to match the overall scope of testing, and they reflect the risk tolerance discussed earlier. Testing will only be as effective as the test script, since the attendees will only cover what is included in the script.

After establishing risk tolerance and developing test scripts, managing the logistics is the third most critical variable to the success of conference room pilot tests. Attendees must be identified and time on their calendars must be made available—no small task for such an intensive period of time.

The most successful conference room pilot tests include cross-functional attendees, even for sections that are primarily driven by a single function. By being present during sessions where other functions hold primary responsibility, these cross-functional attendees can identify issues that might affect their functional area later. Such representatives may include

- Study Managers
- Data Managers
- Clinical Study Monitors
- Individuals from supporting processes, such as Safety, Biostatistics, or Regulatory

In addition to covering the key roles, the representatives should also cross key geographic areas, especially if North America, Europe, and/or Asia are planning on using the same processes. A sufficient number of attendees must be present to be able to resolve issues that arise during the meeting.

An adequate meeting place must also be found for the pilot—often a large conference room that can be retained for an extended period of time. The selected site must be equipped with the technology needed to utilize the system. Often conference room pilot tests are more effective if multiple work stations are made available. Since the pilot test is attended by many staff members, a video projector can be valuable to allow those not in front of terminals to see the progress of testing.

The attendees will also need copies of both the

process documentation they will be following and the systems support documentation.

#### *Execution of the Pilot Test*

Conference room pilot tests require strong facilitation, or they can quickly degenerate into a series of overlapping conversations with little focus. The facilitator is responsible for tracking progress against the test scripts and assigning a lead person from among the cross-functional team members to execute each section of the test scripts.

As issues are discovered, the facilitator determines if the issue can be resolved quickly by the attendees. If so, the group confers and suggests a solution. If the issue cannot be resolved quickly, the facilitator assigns a sub-team of the attendees, and if practical, the sub-team of attendees moves to a separate room to discuss a solution. The sub-team may need to contact others that are not in attendance to gather additional information or get different perspectives.

The suggested solutions are documented and immediately tested. If the solution is satisfactory, the process documents are updated to reflect the new solution. If the solution is inadequate, the issue resolution process continues. The facilitator is responsible for managing the timeline and avoiding delays.

#### *Final Revision*

Based on the results of the conference room pilot test, the process documents may require a final revision. The final revision needs to focus specifically on:

- Incorporating final changes
- Ensuring that terminology, numbering systems, and connection points between processes are used consistently

The final version of the process documents need to be signed off on by the testing team before training can occur.

#### *User Acceptance Testing*

Each organization has its own internal definition of what comprises user acceptance testing (UAT). The authors define UAT as the tests necessary for the organization to have confidence that the processes or systems being tested are fit for their intended purpose. Each EDC project team must meet with their internal standards-setting function to determine what should be included in the UAT for their EDC implementation.

In some organizations, the scenarios covered in the conference room pilot test are considered adequate to support UAT. Other organizations require specific



structures and approaches to UAT that are not supported by the conference room pilot test.

The goal should be to complete as much of the UAT as possible simultaneously with the conference room pilot test to avoid rework and lost time.

## Step Two: Selecting the Training Approach

The first step in developing a training program for EDC is to determine the optimal approach to training. The approach can either be process-driven or role-driven. Each type of training has its advantages and disadvantages, as discussed below.

Process-driven training brings together those staff members (roles) responsible for delivering results at the end of the EDC process to collectively learn how to execute the process. This type of training has the advantage of clearly defining how trainees will work together to achieve the intended results. This also helps establish lines of communication among various roles. The disadvantages of this training approach are the logistical difficulty of training staff who are involved in a range of different processes and the inability to focus on the needs of any one role during training.

Role-driven training breaks out each role and reviews sections of EDC processes that the role is expected to support. Role-driven training enables trainers to provide instruction on the updated roles and responsibilities of a single position. The training session(s) can be staffed by their peers to help facilitate knowledge sharing. A focused, role-driven training session also eliminates the need to sit through training aimed at other roles. However, while the role-driven approach keeps trainees focused on their individual responsibilities, it can be somewhat disjointed in that it only covers certain parts of the process, some of which may not be used until months later. This approach also makes it difficult for trainees to understand how each work task contributes to the end result of the process.

Determining the appropriate training approach, process- or role-driven, is the first decision that must be made prior to developing the training materials. The second decision is the delivery method.

### Delivery

Training can be delivered through various methods, including through live instruction, computer-based or printed learning materials, or a hybrid approach.



*The first and most important step to successful testing, training, and rollout of EDC solutions is the organizational commitment to apply the same energy and resources to the final phases of the implementation that were applied to the initial phases.*

Live instructor training in the standard classroom setting usually consists of one or more instructors for each class of trainees. It may be provided face-to-face or through a shared electronic classroom using software such as WebEx or LiveMeeting. This approach allows instructors to answer questions on an ad hoc basis and ensures trainees are focused on the class content. Instructors can also monitor the comprehension level of trainees and change the pace of training appropriately. The challenges with this approach are the cost, in terms of both person-

nel time and logistical costs, and the scalability if a large number of people require training in a short period of time.

Materials training involves instruction either over the Internet, via a software package, or through printed learning materials, typically consisting of a training manual and work book. This approach is efficient and requires neither trainer costs nor the logistical costs of face-to-face meetings; it also allows trainees to complete the course at their own pace. However, it does not allow for any real-time interactions for those who have questions and makes it difficult to assess the trainee's level of engagement or understanding.

A hybrid approach employs some combination of the above types of training. A typical scenario for such an approach is face-to-face training at an investigators meeting and electronic training for those investigators who cannot attend the meeting. The logistics involved in this type of training, however, can be considerable.

### Training Materials

As a case example, let's use our recommendation of role-driven training. Clearly, if training is going to be electronic, then the approach for developing materials described below must also include the efforts associated with putting those materials into a training tool.

Once the training approach has been selected, the materials can be developed. Training materials should consist of the following:

#### Training manual (organized by role)

- Rationale for EDC implementation
- Overview of EDC processes
- Specific process training
- Discussion about supporting documentation
- Discussion of additional help

#### Trainer's manual (organized by role)

- Training manual organized by role
- Trainer's support materials

### Development of the Training Manual

#### Rationale for EDC

Everyone trained should understand the expected benefits of EDC and have a clear view of their part

in achieving those benefits. The explanation of the expected benefits should be very brief and focused on the specific future contribution of the individuals being trained. Whenever possible, it should include how the benefit is being measured and how the trainees are expected to track results.

### Overview of EDC processes

Each role being trained is generally only responsible for a sub-set of the processes needed to support EDC; however, it is important to understand how that sub-set fits into the overall process. The goal of explaining the entire EDC process is to ensure that every sub-set of processes is clearly linked to the final results. This section often includes an explanation of the other roles involved in EDC processes, as well as instruction on how to read process diagrams.

### Specific process training

At the heart of the training materials should be the process documentation that was developed during the process redesign phase of the implementation. The first step is determining which processes involve the role being trained. This sub-set of the process documentation should be modified to highlight those work steps owned by the role being trained.

### Discussion about supporting documentation

The process documentation should also refer to any support documentation that answers questions about why or how a certain step is completed. The discussion should include a description of the support documentation, an overview of the contents, and how to access the materials. Selected details from the supporting documents can be included in the training session when needed to clarify a point, but specifics such as these should be kept to a minimum due to the usual time constraints of a training session.

### Discussion of additional help

It is highly likely that trainees will need two types of support following training:

1. Technical support for using the EDC and related systems, including password management and hardware support
2. Process support for following the processes defined in the training, including guidance on how

to suggest improvements to the existing processes. Support systems must be put in place to meet both of these needs. The systems may be built in multiple tiers, with simple issues handled by local “power users” and more complex issues handled by centrally located experts. How to access those support systems must be explained at the end of training. Support reminder materials, such as stickers or magnets with names, phone numbers, or websites, can also be helpful.

### *Development of the Trainer’s Manual*

In addition to the Training Manual discussed above, the Trainer’s Manual should include support materials that provide an explanation of how to execute the training, including training logistics and guidelines for a certification exam.

Training logistics should be clearly described to ensure that training is being conducted and documented correctly. For example, a process for gathering names of attendees and providing the attendees with credit for receiving training should be included.

A set of notes should be developed to support the consistent training of each role. These notes are usually developed on a page-by-page basis to accompany the Training Manual and highlight the key points that the trainer should make when providing the training. The details provided in the notes are related to the approach the organization is taking to training. If training is being provided centrally by experts, the notes can be minimal. Alternatively, if training is being provided in a cascade format with trainers that have limited subject expertise, the notes must be more robust and complete.

A certification exam, if relevant, should be included in the training materials. Some organizations require a written exam at the end of training to acknowledge attendance or certify competence. The testing materials should be developed based on the type of certification goal and the content of the Training Manual.

The process for conducting the test and grading the tests should be clearly defined. If test results are not immediately available, an explanation should be provided about when and how the results will be available. Certification forms should be provided to the trainers for distribution to the trainees, as appropriate.

## Step Three: Training the Clinical Organization

As the approach to training should have already been decided, training execution consists primarily of managing the logistics of training. Campbell has found that training is most effective when provided within two weeks (four weeks at the outside) of when that training will begin to be applied. The challenge, therefore, is to manage the logistics so that training occurs as close as possible to the time when the trainees will begin using the information.

If, for whatever reason, there is a lapse of greater than four weeks between the time of training and when the training is first applied, the organization should consider providing refresher training just prior to when the training will be applied.

## Step Four: Rolling Out to the Clinical Organization

EDC systems are, by their nature, rolled out on a study-by-study basis, since it is inefficient to convert a study to EDC after it has been launched. For EDC system rollout, the first step is to identify which studies are going to be using EDC and the timelines associated with those studies. Using this information, a training schedule associated with those studies can be developed to ensure that the staff is prepared to leverage EDC. Training must begin well in advance of site activation if the eCRF (electronic case report form) is to be developed in time for the study to go “live.”

Besides training of internal staff, another key to successful rollout is the management of the logistics and training of each clinical site. Each site must have the proper equipment to use the EDC system. While this equipment varies by software, a set of standards must be developed to judge the capabilities of the site’s pre-existing software, hardware, and communications environment.

Each site will need to be judged against the standards and any inadequacies identified. The sponsor or site must then remedy the inadequacies detected or the site will be excluded from the study. Each site participating in the study will be required to have its staff certified on the EDC software and will need to be trained on how the use it.

Site training can be performed one of three ways:

1. At the site by a sponsor instructor, often the study monitor
2. At the site through electronic training
3. At a central location, often at an investigator meeting

At the end of training, each staff person at the site who is certified is given the ability to access the EDC system.

Each site will need a set of instructions on how to request additional support regarding hardware, software, communications, or other issues concerning the use of the EDC system. Many organizations use the clinical research associates as the first line of support. Other organizations leverage the same help desk set up to provide internal support to the pharmaceutical or biotech company.

## Step Five: Making Continuous Improvements

Following the rollout, the EDC system and processes will be used in live study environments. It is inevitable that areas for improvement will be identified by those staff people involved in using EDC. Areas for improvement need to be captured in a central location. Many organizations use their internal help desks for this purpose. Other organizations set up centralized databases where suggestions can be entered.

A group of EDC “power users” must be made responsible for tracking these suggestions for improvement and determining when, if ever, some of the improvements should be implemented. This group will be responsible for developing a formal revision schedule for updating the EDC system and processes. Typically, this schedule is on a yearly basis, although in the first year, a revision may be completed after six months.

As suggestions for improvement are made, they need to be classified by the power users. Some recommendations resolve critical errors or inadequacies in the current approach to EDC. The suggested change(s) to the current approach must then be

communicated to the organization rapidly, ahead of any formal revision schedule. Other recommendations include areas for improvement that are beneficial but not urgent, and should be held for the scheduled revision cycle. Some either do not benefit the entire organization or contradict the policies or approach fundamental to the EDC system. These should be closed without action.

Regardless of the classification of recommendations related to potential improvements, an acknowledgment should be sent to the staff person who provided the suggestion to thank them for their input.

## CONCLUSION

The first and most important step to successful testing, training, and rollout of EDC solutions is the organizational commitment to apply the same energy and resources to the final phases of the implementation that were applied to the initial phases. A successful conclusion to the EDC implementation effort requires organization, planning, and resources. Those organizations that invest in those three areas achieve the greatest value for their total EDC implementation effort.

1An Approach to Benchmarking EDC Performance: Results of a Feasibility Test. The EDC Forum. June 2004. Available at: <http://www/EDCforum.com>. Accessed on September 13, 2004.

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## ABOUT CAMPBELL ALLIANCE

Campbell Alliance is the leading management consulting firm specializing in the pharmaceutical and biotechnology industry. The firm's clients include most of the world's “top 20” pharmaceutical companies, as well as numerous emerging and midsize firms. Campbell Alliance is organized into practice areas, each specializing in a critical industry function, including Brand Management, Business Development, Clinical Development, Managed Markets, and Sales.

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