FIVE QUESTIONS to Ask Before Choosing Your Electronic Data Capture (EDC) Provider

A Bioclinica White Paper

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Introduction

With the vast number of Electronic Data Capture (EDC) choices in the market today, how do you know which one is right for your organization? Although many of the benefits of using an EDC can be achieved with standard EDC functionality (e.g., eCRF form design capabilities, data entry, query management and data export), not all EDC systems are created equal. Many go above and beyond the core functions to provide features that deliver even greater efficiencies. Use these five questions to help choose the best EDC partner for your trial.

KEY BENEFITS OF EDC SYSTEMS:

- Faster data access
- Better data security
- Improved data accuracy and quality
- Enhanced data organization
- Increased compliance

1. What do I want from the EDC technology itself?

Consider your technology requirements in the following four areas:

1. **Configurability**

   Ask yourself - do I need all the 'bells and whistles?' Do I have a finite set of features that is required? Or, do I only need a 21 CFR Part 11 compliant data capture system? Make a list of all the features that are musts for your study and those that are just nice to have. Then, compare your list to the feature list of a candidate EDC.

   A configurable system allows features to be implemented specifically for each study's therapeutic area/protocol. An application that can be configured sits in the middle between an off-the-shelf system, which is limited only to the built-in features, and a fully custom-built application, where the sky is the limit. While picking an off-the-shelf system might risk not having the features you need, increasing customization may stretch your budget.

   With a configurable system, you pay for only the functions you need, apply only slight modifications to reuse the system in future trials, can reuse documentation and reduce

training efforts. Moreover, you can modify the application to accommodate changes during the study, avoiding revalidation and without impacting the existing collected data.

2. Flexibility

Protocol amendments are the norm, whether we like it or not. The level of configurability will help determine how flexible a system can be, particularly when determining the implications of any changes, namely cost, downtime and the need to revalidate.

Look for a database design environment that enables rapid build activities or automates change tracking. As an example of a flexible environment, if a CRF modification is needed, you should be able to check only the new or amended functionality. Ideally, mid-development database amendments will not affect data already collected or bring the entire system down.

3. Scalability

Scalability, or the lack of it, can affect whether the EDC system can grow with your organization and be able to accommodate larger and more complex studies as you move further along in clinical development. Although you might only be running a Phase I trial now, will your EDC choice allow for continuity throughout future trial phases? In other words, are you future proofing your solution?

If your current EDC choice is not able to grow with you as your needs change, you'll likely need to find a new EDC provider. Not only will this consume valuable resources to evaluate and select another provider, lack of consistency in providers can result in inefficiencies. In contrast, by choosing a scalable EDC and therefore maintaining provider consistency, you can gain efficiencies from many standpoints, including development and implementation. Your provider gains an understanding of your needs and how to configure the EDC system for you, carrying that forward from one study to the next. For example, building an eCRF library shortens development timelines in the long term for both provider and sponsor. Once the library is developed, less time is spent building and reviewing the study database in future studies.

From an end user standpoint, avoiding the need to learn different EDC systems for different studies reduces training and retraining time for new systems. Also, there is less likelihood of data capture or entry errors – ultimately resulting in better data quality.

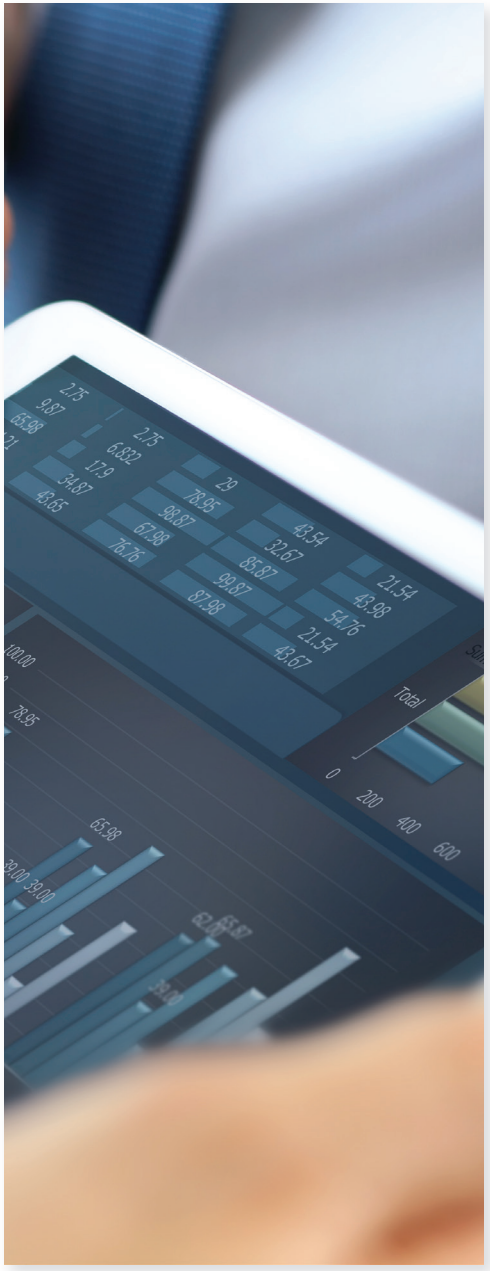
To determine whether a system is scalable, ask if it can handle different study sizes – from one with a few patients to a study with thousands of patients and multiple data sources. Also, look for one that can accommodate simple protocols to complex protocols with more demanding study designs and edit checks.

4. User Friendliness

Efficiencies from an end user standpoint extend beyond scalability to the overall user experience. If your study personnel find an EDC system difficult to use, they are likely to limit their use. Potential consequences of this include delinquent data entry, the need for more queries and additional monitoring activity. Overall site satisfaction can suffer, which can significantly affect trial success. All of this can affect the speed of study close-out and how quickly you can obtain submission-ready data.

Ultimately, you want an EDC system that makes life easier – through a user-friendly, intuitive design that is easy to learn. When evaluating a system, schedule a demo and determine if it will allow for accurate data entry, streamline the protocol setup and enable efficient query management.

During your evaluation, make sure to consider all four of these elements. The fact that they overlap makes this easier - a user-friendly system must be configurable (but not overly complicated), and scalability provides flexibility and improves the user experience. At the same time, flexibility might also limit scalability. Therefore, take a moment to determine the right balance for your needs.



2. What integrations are needed for my EDC technology?

The ability to integrate the many, often disparate systems used for management and data collection during a clinical trial can significantly reduce trial complexity, improve efficiencies and increase data integrity. Identify the systems that you will be using now and those that you think you will add in the future and the extent of integration that you will need or want.

1. What level of interoperability does the EDC system have with the other systems in your clinical trial ecosystem?

Interoperability represents the ability of computer systems or software to connect and communicate with other systems or products, even when developed by different manufacturers in different industries. When multiple systems can work together, data is automatically accessible and sharable across applications, platforms and computer languages. This expedites data collection and aggregation and allows a faster consolidated view of trial status.

When you are evaluating an EDC provider, you should ask how well their system integrates with other systems in the clinical ecosystem. Could you use the clinical ecosystem as a single source of truth, thus avoiding multiple points of data entry? Also, to ensure seamless interoperability with other systems, ask: how robust are the EDC system's APIs?

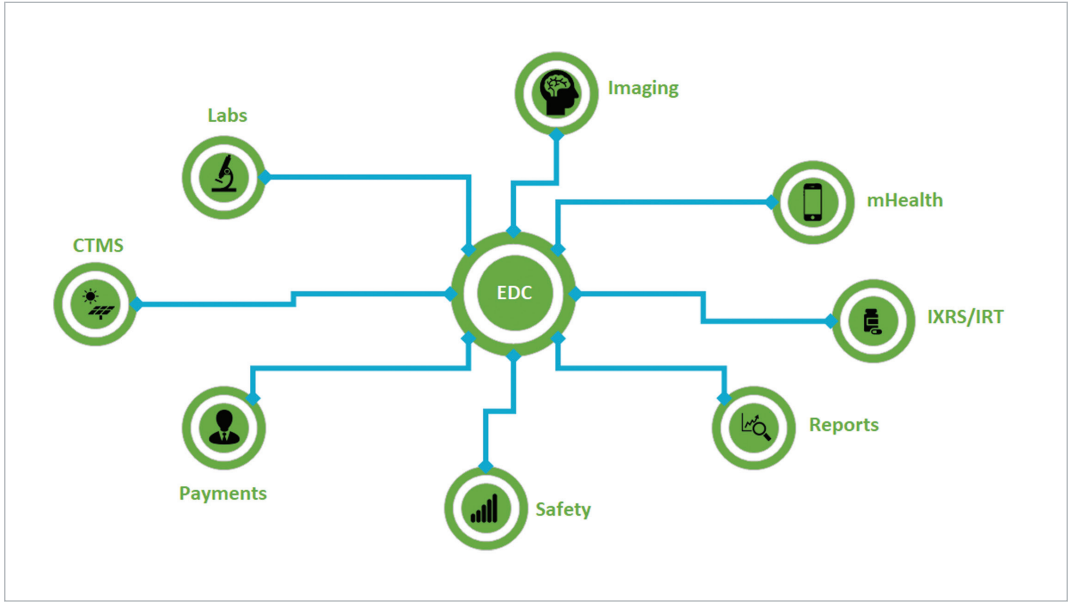


FIGURE 1: Multiple electronic systems are often used in clinical trials, requiring data integration

2. Does the EDC provider have other in-house systems and/or partnerships with third-party systems that are already effectively integrated with the EDC system?

If existing integrated systems are also able to meet the needs of your studies, study startup timelines can be significantly reduced by signing up to use these already established integrations. Before deciding, however, take the time to evaluate whether these other systems will meet your needs.

3. Who will handle the necessary reconciliations arising from integrations with the EDC system?

Regardless of how seamless we want our integrations to be, there will inevitably be some data reconciliation that will need to occur. In these cases, you want to know going into the partnership who will perform these reconciliations, make sure the data is consistent between the multiple systems and provide the holistic data output at the end of the study.

For each of the integrations – determine if there will be a push or pull scenario. For example, if there are changes in the integrated IRT, will there be an automatic push of that data, or will reconciliations need to be performed? If the provider is performing this task, how often will it be completed? Then, you will know how current your data will be at any time.

4. Who will troubleshoot any issues in integrations with other systems in the clinical trial ecosystem?

One statistic overheard at an annual SCDM conference has stuck with me: one in three integrations in the clinical trial ecosystem fails and does not provide the desired results. Therefore, chances are high that the system will break. Usually, the EDC provider is responsible for determining if there any issues and how to resolve those issues.

Rather than assuming the EDC provider will perform any troubleshooting, make sure that this is the case up front. Then, what plans will be in place to address the break in a timely, efficient manner so the integrations can resume functioning? Also, can you work with the EDC provider to avoid issues in the first place by ensuring a robust data transfer protocol and the presence of a data contract that is renewed every time the system changes?

3. What combination of technology and services do I need?

Then, you need to start considering the practical aspect of moving a chosen EDC into your system. We'll remove the cost from the equation temporarily – the cost will be a key

deciding factor, but it is important to first work out your needs and then find a solution that fits both your needs and your budget. There are two broad line items to consider for your EDC solution:

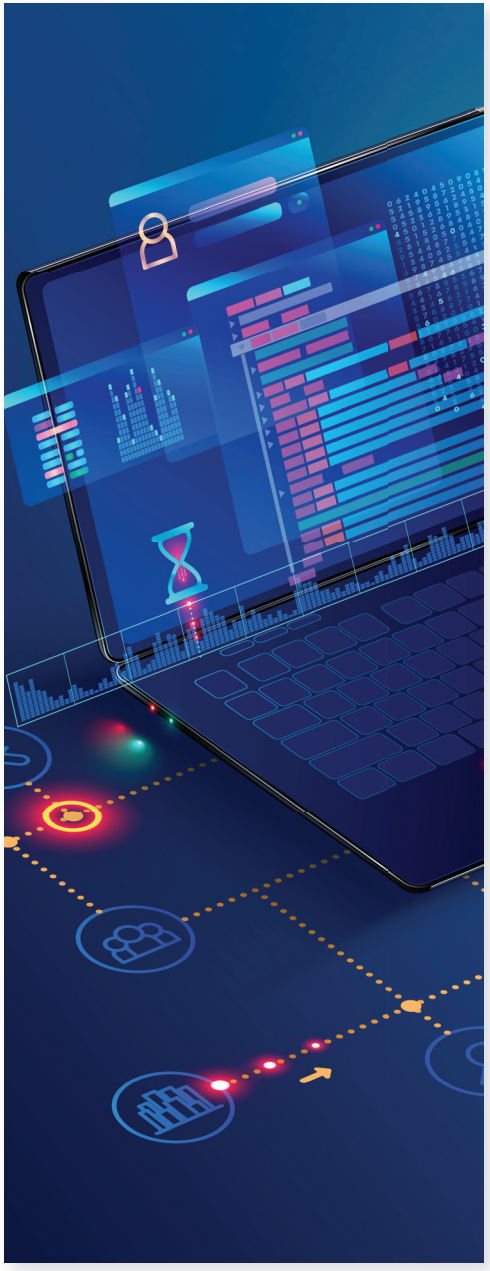
1. **The Technology Itself**
   Questions 1 and 2, described earlier in the paper, provide the framework for technology evaluation. Then, it is time to look at choosing the right combination of technology and surrounding services for your EDC.

2. **Professional Services**
   A team will be needed to implement the technology - from developing the list of requirements through the build to go-live and beyond to study close-out and extracting submission data. To determine if you already have the resources to support this or you will need assistance with these services, there are three primary areas to consider:

   a. **Specifications and requirements**
      These are often handled by the sponsor's data management team. If your data management team is not experienced with the EDC provider or system, you might need assistance from a business analyst standpoint to turn your requirements into a valid specification from which to build the system. Determine if the EDC provider has requirements for acceptable input documentation for the EDC build itself. Then, do you have the resources to consolidate that documentation, not only during the initial build but also for change management during the study's maintenance phase and through to study close-out?

   b. **System configuration**
      Consider whether your team has the bandwidth and knowledge base to build and configure the study database. Determine if this is even an option from the provider's standpoint. While the decision is partly based on a technology limitation, you'll want to know if you are structured to take advantage of the option if it is available from the provider.

      Advantages of building and configuring the system yourself include cost savings and potential timeline savings by removing the need for continuous review and approval of requirements and documentation.



However, the potential time savings may be compromised by the initial time investment. Since it will likely be your team's first time working with the system, it will probably take them longer to configure the system.

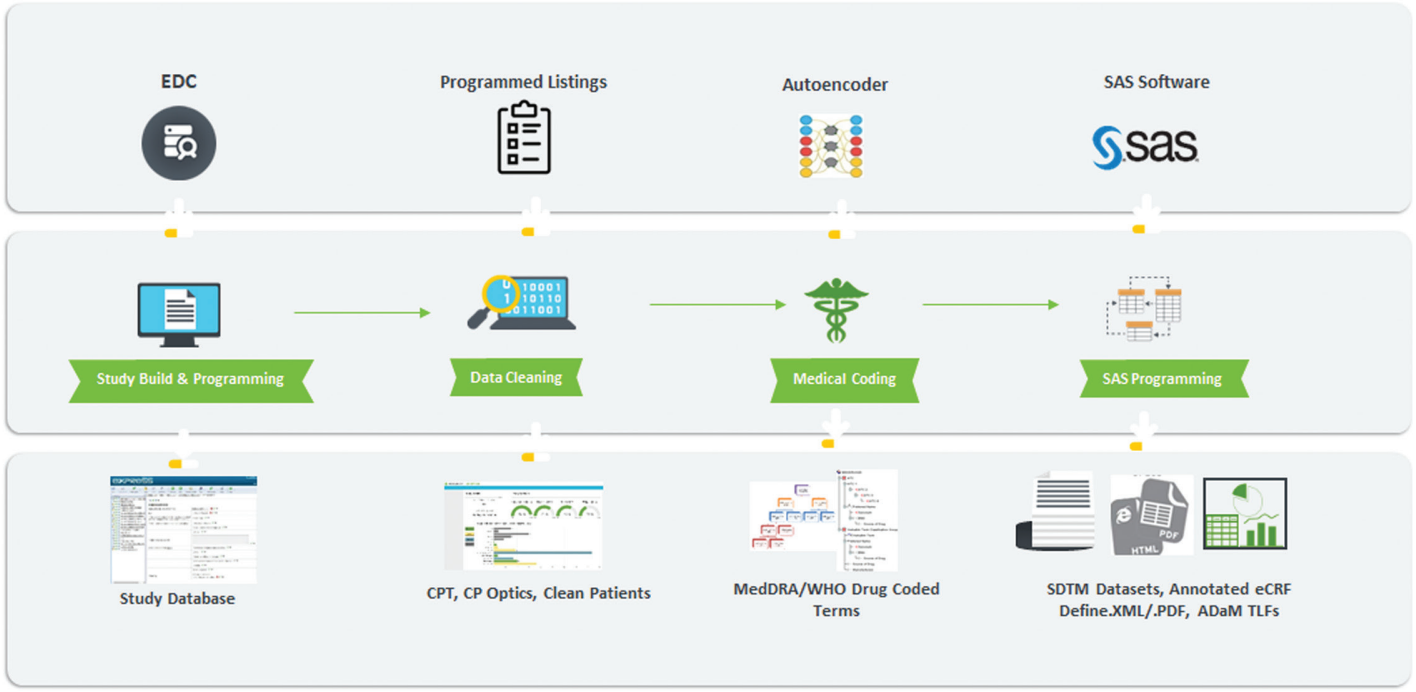
Also consider that the provider will have greater insight into best practices for system configuration based on your specific requirements. The way in which you choose to implement a set of controls or assessment fields could lead to system performance issues down the line. For example, you might select a single log-form page from the end-user and visibility perspective, but the result could be an eCRF that requires a lot of scrolling and time to complete. Loss of connectivity halfway through data entry could mean starting over. For some of these decisions, an experienced partner can help guide the best choice.

c. **Project management**
Who will handle the timelines, deadlines and deliverables? Does the provider have a professional services resource group for this activity, or do you need to put on your Provider Management hat? If the provider has this service, also consider if you need it just for the start-up activities - after the system moves into the production environment there are fewer deadlines, and you might be able to handle it at that time.

Achieving 8-10-week build times are possible with the right technology but become more probable with the right professional services team.

4. Who will provide the data management services?

An EDC system does not exist in isolation. For a thorough evaluation, make sure to look beyond the system itself to the data-related systems and teams surrounding and supporting it. There are three main areas of consideration here.



1. **End-to-End Services**

   Consider who will manage the data after the study build: study maintenance, implementation of dictionaries and tools required for medical coding, medical coding, annotated eCRF creation, XML definitions, data cleaning, clean patient tracking, SDTM and TLF generation and study closeout. Do you have the trained resources internally to provide these services through the course of the study, especially across multiple studies? Will you be able to manage the ebb and flow of resources that are required as the study demands change, while also adhering to the timelines so database lock remains on time?

   Will the provider help to establish a robust data management plan? Who will be responsible for providing adequate training to the study staff including detailed, hands-on instruction for completing study documents?

2. **Supported Auxiliary Systems**

   End-to-end data management services often require auxiliary systems. For example, in addition to programmed edit checks, study-specific checks via listings are required, and it is useful to know if the EDC vendor has programmed listings available to perform those checks. Other important components include licenses to medical dictionaries and SAS software, an effective medical coding tool and access to programmers.

For data monitoring purposes, good reporting systems are necessary to check the data and keep track of clean patients over the course of the study. Therefore, you'll want to determine if the EDC system has a good reporting system from which you can pull on-demand reports for this purpose.

3. **Reporting of Data Quality Issues**
   Early identification of data quality issues results in quicker resolution and less impact to timelines. Unfortunately, when teams are tasked with both clinical operations and data management, data issues can go unnoticed or unreported. For example, site-based data entry errors or protocol deviations might not be reported. However, having separate, dedicated data management teams, with a sole focus on the data and who work directly with the sponsors, often means that such issues will be reported faster, resulting in quicker issue identification and mitigation.

5. How will my EDC provider help get my drug to market faster?

Faster time to market is a key reason for employing an EDC solution in the first place. Therefore, you want to make sure the EDC provider you choose can help you meet this goal. We've identified several important attributes.

1. **Standard Operating Procedures (SOPs)**
   Does my provider have tried-and-tested, robust, clearly-communicated processes and procedures in place? Good SOPs should include detailed instructions for standard practices and daily processes that assure that the tasks are conducted to meet the study as well as regulatory requirements. They help guide the team through the procedures, avoid procedural deviations and establish uniformity throughout the study.

   Regarding timelines, when everyone in the study team knows what to do and when to do it, you eliminate the possibility of downtime when a team member is waiting for a task to be finished by someone else when it should have been their responsibility in the first place. Clear expectations regarding required inputs and the subsequent outputs from each individual process will also limit confusion as you move from activity to activity, specifically during the study close-out process.

2. Standards

Standards facilitate seamless data flow from start to finish, improve data traceability, enhance data availability and facilitate interoperability. This is especially true when working with multiple, disparate systems and across multiple sites. With standardized data elements and data definitions, data can be transmitted between systems in the same language, reducing database build time, eliminating the need for data reconciliation, allowing data to be accessed quicker and expediting database lock.

In addition to the mandated use of Clinical Data Interchange Standards Consortium (CDISC) standards and Clinical Data Acquisition Standards Harmonization (CDASH) guidelines, standard data management plans (DMPs), standard coding guidelines, standard data review guidelines (DRGs), standard eCRF completion guidelines and standard edit checks may or may not be used by the EDC provider. Because these standards reduce the effort required to build and maintain the database and related data, it is worth asking a potential EDC provider what standards they currently have in place.

3. Analytics

Data visualization is the new form of communicating study status. These visualizations are based on analytics that help you understand where you stand at any time. Will you meet your timelines? Are you progressing through the maintenance phase and toward closure?

One such key analytic that can be visualized is clean patient status. Data visualization of clean patient status helps identify the issues that need to be resolved for all patients to be clean and to expedite database lock. For example, in a recent 7-year study with 8000 patients, Bioclinica broke the sample into smaller subsets to declare patients clean. We looked at what was pending for each patient and then identified the low-hanging fruit – patients with only one or two issues to resolve - followed by the more complex patients. We were able to lock the database much earlier because the patients with only one or two issues were cleaned faster and the additional focus on complex patients meant they were also cleaned faster.

4. Data Availability

To save time at study close-out, determine if you will be able to extract the patient data you need on an *ad hoc* basis throughout the study, or will you need to wait for someone else to access it for you?

Also, accurately tracking study progress relies on the data being available. For quicker transitions through the closeout phase, it can be beneficial to recognize when tasks are ahead of schedule, to possibly start other activities earlier. Shaving off a day or two here and there can make all the difference for submitting on time or even early, which is key to faster times to market.

Summary

Using these five questions as the basis for evaluating potential EDC providers will help find the partner that will most likely meet your specific needs. Before reviewing the options, take a minute to compile a list of your needs and wants, including those for future projects. To ensure a comprehensive approach, look beyond the EDC technology itself to consider the supporting systems and project teams. The right EDC partner will collaboratively work with your study teams to achieve success.

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