

Important Aspects to Consider When Choosing an EDC System

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Electronic Data Capture (EDC) is the common data collection approach for clinical trial work. There are multiple EDC platforms and they range in cost and capability. The information you might want to consider in an EDC platform varies with the level of involvement in the project(s) you are planning. If you are dependent upon the CRO for delivering the final data and do not require access to the EDC platform, then you may just wish to focus on added costs that involve the EDC system. However, if you plan to use the system for repeated trials or utilize the system yourself, a more in-depth review is warranted. This article highlights and answers specific questions that should be considered when selecting an Electronic Data Capturing (EDC) System.

Selection of an EDC system should consider a variety of factors:

- System cost
- System features
 - Trial management feature
 - Query tracking and resolution
 - Ability to collect or manages source documents
 - User role management and security
 - Integrated coding facility
 - Data import/export capability
- Complexity of the database build and update process
- Vendor responsiveness and support

Additional details are provided below.

Vendor Communication

Can the vendor work with you to get the proper database?

Is the vendor working with you to ensure the EDC solution meets your needs beyond just getting data into a system?

Vendor support and communication is essential when using an EDC system to get the correct database design and facilitate training. The vendor should be able to understand your situation and act as part of your team. A client representative should not have to have an IT degree to talk with their EDC provider. Further, the vendor should assist where needed in making sure the procedures you use in conjunction with their system are adequate to meet the regulatory standards you operate under.

Cost

Does the pricing model match up to your needs and budget?

Vendors have different pricing models available for the client to choose from and some systems with greater features may have correspondingly higher costs. As a client, it is important to separate out requirements versus nice to have features. Further, you should also determine if milestone payments are used and what criteria must be met by the EDC vendor for the milestones to be attained.

Managing Users

How does a system manage user access and data security?

Where does the database physically reside?

All EDC systems will have some form of user security to control access, log activities, and ensure the integrity of stored data. If you have certain requirements such as the region where data are stored, then make sure that an EDC vendor can provide the answers within reason. A central concept to computer and data security is controlling who can access or update data, how it is stored, and how it can be retrieved. The vendor should be able to explain this.

Technical Features

Can users build their own databases or create customized reports?

Does the system contain trial management and tracking features?

How is data cleaning performed?

Are there special features that are must haves for a system from the company perspective?

Basic system functionality and efficiency of the system tools go a long way toward making an EDC system usable. As noted above, this may be a cost versus feature balance, but evaluating and comparing features and usability can be used to eliminate systems missing critical features or at least provide a preference between two similar systems of similar cost.

Stat One EDC

Stat One EDC was built specifically for clinical trials to offer a cost-effective solution while maintaining a wide array of tools for data cleaning, tracking study progress, and facilitating communication with a project. The build process efficiently guides the user to create good clinical databases that are suitable for statistical analysis. The cost and re-usability features of the Stat One EDC make it an attractive solution for a variety of settings.

If you are interested in discussing the Stat One LLC, please contact me at bdemuth@statonellc.com.