

# Are You Ready for EDC Technology Transfer?



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By Brian Dakin, Director of the Project Management Office at CB Technologies, Inc.

The use of electronic data capture (EDC) for clinical trials as an internal application by the pharmaceutical industry is continuing to gain momentum. To date, most EDC clinical trials are utilising EDC software on an application service provider (ASP) basis, meaning that the sponsor licenses the software on a trial-by-trial basis, relying on the vendor for the support functions of training, trial development, hosting and help desk, among others. Now that clinical organisations have become familiar with various EDC applications through outsourced projects, many are planning to bring this technology in-house. However, as with any software implementation project, significant planning and readiness is essential for success. At any given time there are tens of thousands of software projects taking place around the world. Up to two-thirds of projects will exceed schedule and/or budget, and of the most expensive projects, nearly half will be cancelled because they are viewed as being 'out of control'.

Successful software projects demand careful planning and deliberate execution. Conversely, software projects are more likely to fail for two reasons – lack of knowledge and/or lack of resolve to conduct software projects successfully. By fully educating yourself about what needs to take place during this transition and by carefully planning the execution, you can greatly improve your odds of success.

## WHAT

What do you hope to accomplish with EDC in-house? This question alone might give pause for thought. As a clinical trial sponsor, you most likely have EDC in the field at investigator sites and with monitors, but are you ready to design and build e-CRFs yourself? Are you able to provide hosting services for the central repository where all of the clinical data will ultimately be collected? Can you provide help desk services to address functional and/or technical questions from investigators and monitors at remote locations? Considering these questions can help you decide if you should take a phased approach to EDC implementations or bring it in-house all at once.

## WHY

Once you have determined what it is you want to accomplish, you need to be able to justify why. As with any software implementation, either a cost/benefit analysis or value proposition is presented to those controlling the budget. From a cost perspective, there are one-time and recurring expenses to consider. Benefits are typically not as straightforward to calculate and are driven by many factors. How many trials do you plan to conduct with EDC? What is the breakdown between phases of those trials? Other statistics such as average duration of a trial, number of sites and number of patients all need to be considered. The answers to these questions will be different for every organisation, and those interested in bringing EDC in-house must be prepared to answer them.

## WHO

You have convinced your organisation that this is a valuable initiative and have the green light to move forward and continue planning. But who needs to be involved in order for this EDC effort to be successful. As with any software implementation project, those resources will fall

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into two categories – IT staff and ‘business’ personnel (in this case clinical resources), who can address the requirements of the software functionality. If an EDC application has not yet been chosen, will these resources be involved in the selection process? Based on the application chosen, is there an expectation as to the technical skills required to operate and maintain the software in-house? Can training be provided to the internal project team members if they do not have those technical skills? Will the project team members be fully dedicated to the project, or will they divide their time between this and other responsibilities? For a small organisation with limited resources, this may in fact become the largest constraint for the project.

#### WHERE

If you have chosen to host your EDC applications, the ‘where’ questions will be very important, and may have additional costs involved. First, the fact that clinical trials involve highly sensitive and business critical information means that a secure data centre for hosting the data repository and server equipment is a necessity. Secondly, based on the answers to some of the ‘why’ questions above (number of trials, average duration, number of sites and patients and so on), you and your application provider will need to assess how much hardware is necessary to operate the application. The EDC vendor will provide an installation and operational qualification plan (IQ/OQ) that outlines the minimum requirements for hardware, but depending on the workload placed on the machines, you will probably want more robust equipment. Additionally, assuming the software is scalable, hardware can be added to balance the workload and optimise the overall performance. Thirdly, depending on the architecture of the application, high speed, highly reliable connectivity might be critical for success.

#### WHEN

The duration of a technology transfer project will be highly dependent on many of the questions above, particularly in regards to what you are trying to accomplish and who is available to assist in doing so. If you have a large scope of work and only a few resources available, expect your EDC implementation to take quite a while. If time is a constraining factor, you may want to reconsider the current scope of work, and take on a phased approach to the project. Additionally, the application’s vendor might be able to provide some resources to assist your facility. When estimating the timeline for the project you should be sure to

examine the entire process, from installation and training on the application, through documentation, testing and validation, and into final acceptance and production rollout of the software. Unlike most other software implementations, you will probably not have the luxury of conducting an EDC trial in parallel with a paper process or an older RDE application. Therefore, it is even more important to get it right the first time, so it is critical to set your expectations to take the time necessary to address all of the phases of the project appropriately.

*“Electronic data capture vendors will have processes and methodologies that will guide the customer through the implementation process from kick-off to production. Additionally, you should look to the vendor for process ‘best practices’ in developing your internal SOPs and documentation. Their internal practices may be valuable to your organisation as well. ‘How’ is just as important (if not **more** so) than the other categories of questions because even the best applications suffer when utilised within an inefficient process.”*

#### HOW

Finally, the all important question of ‘how’ – how will we go about completing this technology transfer process? Just as important is how will we go about conducting the process of developing e-CRFs? Are we trying to adapt new technology to our existing process, or will we allow that technology to enable process improvement? Electronic data capture vendors will have processes and methodologies that will guide the customer through the implementation process from kick-off to production. Additionally, you should look to the vendor for process ‘best practices’ in developing your internal SOPs and documentation. Their internal practices may be valuable to your organisation as well. ‘How’ is just as important (if not **more** so) than the other categories of questions because even the best applications suffer when utilised within an inefficient process.

Making the commitment to bringing an EDC application in-house is a huge step, and not one to be taken lightly. That commitment must be well thought out, well planned and well executed to ensure success. ♦

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