

The services side of **EDC**

You have found a great EDC application – but do the vendor's services match up? Brian R Dakin guides you through what standards to expect

Most pharmaceutical companies by now have conducted either an evaluation of electronic data capture (EDC) or a pilot study using EDC, and a subset of these have moved on to wider use. However, while most evaluations focus on the details of software functionality, some neglect the importance of service in the overall product and vendor evaluation. The proper services help the implementation of EDC run more smoothly and can make the difference in a successful rollout.

Pharmaceutical companies must evaluate these services in the context of how they leverage an EDC application. One method of using EDC is to engage the vendor as an application service provider (ASP) and outsource to them all of the services related to EDC. Another approach is to use the vendor as an enabler of study development, where the pharmaceutical company uses the application themselves to design electronic case report forms (eCRFs), but the vendor still provides services for database administration, centrally located functionality and hosting. Finally, a pharmaceutical company might look to secure an enterprise licence of the EDC system, in which the company takes ownership of the entire application and the data repository while the vendor ultimately provides only a handful of ancillary support services once the system is fully implemented.

Furthermore, vendors may have different means of achieving these services ends. Some may include them as a strategic core competency for their business model. Others may take a 'best-of-breed' approach and form partnerships or alliances to outsource the function. Still others may not have identified the value-added need for a particular area of service. Customers must understand what

service elements are critical to their success, and how the EDC vendor will address them. Across the spectrum of EDC usage are several high-level categories of service to consider. They are training, help desk support, study development, hosting, customisation and integration, consulting and technology transfer.



TRAINING

First and foremost of these service offerings is training. Regardless of the context in which you leverage an EDC application, your vendor must be prepared to conduct training at a number of levels. At a minimum, training should be provided for internal resources, investigators and monitors associated with respective trials. Additionally, training for the design and development of eCRFs through a study builder, as well as data management and centrally controlled functionality should be part of the overall training curriculum. Finally, if you plan to provide any level of help desk support internally, look for assistance from your vendor in educating your help desk resources as well.

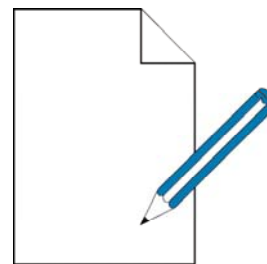
The means by which the vendor provides the training is equally as important as the training course itself. More often than not, classroom/lab exercises will be used, and ideally the vendor should have training classrooms available at their facility if necessary. Depending on the topic being covered, one-on-one training may be more appropriate than a classroom setting, especially for study development or data management topics. On-line training is also becoming more

robust and can certainly supplement training after an investigator meeting or for those who could not attend at all.



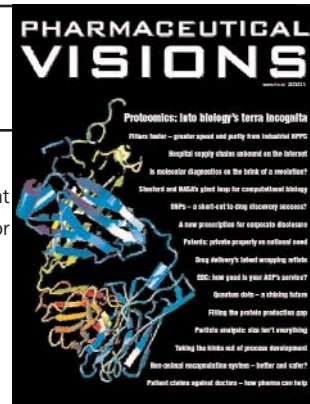
HELP DESK

Similar to the need for education before the trial is initiated, a help desk and technical support call centre can provide critical services after the trial has begun. The help desk can provide guidance to EDC end-users at a variety of levels, from issues as simple as log-in and password assistance to those as complicated as detailed technical application support. Depending on the logistics of your trial, you may need to inquire as to whether 24x7 support is available, as well as multi-lingual capabilities. You may find that an EDC provider divides these responsibilities with a strategic partner. The partner might provide the first line of support, along with the 24x7 and multi-lingual needs, while the EDC vendor can be the source of more robust technical support.



STUDY DEVELOPMENT

If you are leveraging an EDC vendor as an ASP, there is a good chance that you



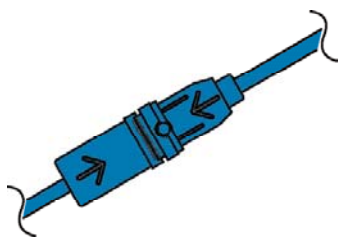
Article reprinted
from *Pharmaceutical
Visions* 4/2001

have contracted with them to design and develop the eCRFs that will be used in your clinical trial. If you conduct an audit of the vendor, be sure to ask if they have a robust study development methodology, including testing and validation processes. Furthermore, examine the process for conducting mid-study updates during the course of the trial. This 'mini' process can be just as important as the process for developing the initial trial, and sometimes take just as long to execute.



HOSTING

In addition to study development, you will most likely require hosting services if you are using your EDC vendor as an ASP. Depending on the particulars of your clinical trial, you will want to look for areas of additional comfort in the hosting services being provided by your vendor. Topics of discussion should include data backup, connectivity (speed, bandwidth and redundancy), data centre security (logistics and software), the ability to provide data replication and the vendor's disaster recovery plan.



CUSTOMISATION & INTEGRATION

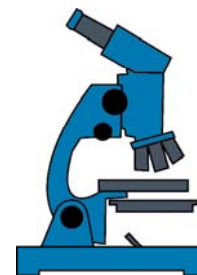
In preparation for an EDC enterprise implementation, your current processes for conducting clinical trials may require you to examine some customisation and/or integration with other clinical systems for your EDC application. As mentioned in the Autumn 2001 edition of *Pharmaceutical*

Visions, while there are certainly benefits to implementing a stand-alone EDC system, additional value will be achieved once your EDC system is fully integrated in your clinical IT environment. Furthermore, some specific data extracts or reports may be critical to your organisation, and ideally you would like to see these included in the implementation. Work closely with your vendor to outline the specific requirements for extracts and reports, and ensure they ultimately meet your needs.



CONSULTING

To ensure the highest level of success, you may wish to leverage any post implementation consulting services offered by your vendor. These consultants can provide a smoother transition onto your EDC product as well as supplement any training your organisation has already received. Unlike other system implementation projects, such as an enterprise resource planning (ERP) system (SAP, Oracle Financials, JDEdwards, etc) which can run in parallel for a month or a quarter with your existing processes, the ability to conduct a clinical trial in parallel with an existing system would be an extraordinary effort. With time being of the essence in the world of clinical trials, it is critical that your EDC implementation be correct the first time around. Therefore, leveraging consultants to assist with your first trials can be of tremendous value. Whether they are engaged for the technical skills required, the short-term need for additional resources while current trials are completed in older systems or processes, or simply to coach and mentor study development and central site activities beyond the initial training, on-site consultants provided by the vendor can dramatically assist in your EDC success.



TECHNOLOGY TRANSFER

Finally, if you have been engaging your EDC vendor with ASP-based clinical trials thus far and are considering taking on either the study development responsibility or a full enterprise licence, you should be thinking about services around technology transfer. Technology transfer is the catch-all phrase for the set of activities required to transform the end-users and support team at a pharmaceutical company into a savvy and successful EDC shop of their own. Most vendors will follow a methodology that at a high level orchestrates the installation and validation of an EDC application in your IT environment, along with many of the other services previously discussed. This composition of services is advantageous to the customer in understanding the total effort involved, rather than engaging the vendor step-by-step. Additionally, there may be some financial advantages to packaging all of the services together through a technology transfer engagement; they might be bundled with the software licensing rather than having above-and-beyond expenses priced separately.

As you can see, the number of services are vast, and their coverage typically flexible to the needs of the customer. EDC vendors recognise the need to complement their EDC products with solid services, and working closely together with their customers to understand service requirements and expectations is an integral component to success with these applications. Although mentioned at the beginning of this article, it is worth repeating again – the proper services help the implementation of EDC run more smoothly and can make the difference in a successful roll-out. ●

CONTACT

Brian R Dakin, director, strategy consulting, CB Technologies, Inc.
Tel: +1 610 280-7400
E-mail: b_dakin@cbtech.com