EDC implementation: beginning at the end

Sponsor goals and objectives always need to be kept in mind when planning an Electronic Data Capture (EDC) implementation.

Scott Grisanti, eResearchTechnology, Inc

Electronic Data Capture (EDC) holds the potential to transform numerous processes associated with clinical trial data collection, management and distribution. However, successful execution of EDC initiatives is not achieved by happenstance. Thoughtful and deliberate development of a role for EDC that ensures alignment with corporate critical success factors is key to driving value.

This article will explore the transforming potential of EDC technologies with a focus on sponsor goals and objectives, as well as vendor business preparedness – key criteria for an EDC initiative. Areas that will be discussed include:

- The scope desired for the initial EDC project, its measure of success and ultimate goal for EDC in the enterprise,
- The sponsor’s strategy for incorporating EDC and related clinical data application solutions into its enterprise, and
- The likely requirements for supporting services based on the sponsor’s project scope and strategy.

Scope

The first objective is to identify the set of enterprise problems to be solved through the implementation of an EDC solution. This will help define the EDC evaluation process. Within that process should be the scope for each phase of the EDC evaluation. Simple, well-defined goals – such as the reduction of queries per page by 50%, or time to data-lock decreased by two weeks – are ideal for pilot studies. They are realistic and measurable. The ultimate goal should also be identified. While this may seem obvious, many EDC pilot projects are launched with little more than the vague goal of electronic collection of clinical data in a “to be determined” clinical trial. Often, it is unclear as to what the success of an EDC pilot will mean for the sponsor, the project team or the selected vendor.

A proper pilot study environment must be set up to measure identified criteria for success. And variables, such as insufficient hardware at an investigator site or inexperienced investigators and coordinators, should be neutralised as they will create noise around the outcomes to be measured. For instance,

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if cost-saving is not included in the measure of success, it may be permissible to provide dedicated PCs to research sites to allow a more intense focus on the achievement of key goals. Controlling variables (albeit sometimes artificially) such as the availability of appropriate site PCs, does not reflect the “real world”, but it will help the EDC evaluation team keep their eye on the scope of the project. Also, it is important that the project team be aligned with the ultimate goal of the enterprise for deployment of an EDC solution.

The selection process for an EDC platform requires a substantial marshalling of resources. The cost in time and effort to set up and conduct a pilot trial must be justified by the greater goal of solving a set of enterprise problems. It is clear that EDC can only add real value when implemented at the enterprise or program level. Therefore, while the production scope of the EDC evaluation initiative may be limited to a single pilot trial, there must be a plan in place that assesses the ability of the EDC solution under consideration to perform in the ultimate role that a sponsor has targeted for EDC within its enterprise.

Business viability is the most important organizational attribute to consider when evaluating an EDC vendor’s suitability for the “ultimate scope” of a sponsor’s overall vision. The EDC marketplace, which includes more than five-dozen participants, is dynamic to say the least. Many EDC businesses are “over-mortgaged” with the burden of too much venture capital. A venture capitalist’s or investment banker’s goals may not be consistent with solving a sponsor’s problems. EDC providers face consolidation, acquisition and bankruptcy – all events that occurred in 2003 within the ranks of what is generally considered to be the top 10 EDC vendors. Changes in management or ownership almost always result in material changes to a product’s future. It is critical that the company a sponsor contracts today will, in all material respects, be the company that arrives to deliver the solution tomorrow.

Despite a challenging environment for winning business and securing capital, the EDC market continues to spawn a number of start-ups. And – anxious to get a client – they offer “partnerships” with the vendor CEO as the project manager, affording unlimited opportunities for input into product development. This scenario may initially seem comforting to anxious project teams – but that initial sense of comfort is fraught with the problems that a start-up EDC vendor must conquer. By any measure, most start-up EDC providers are lacking the attributes required to support a significant rollout. Should a second or third sponsor enter the fray, it is unlikely that a start-up vendor today in these circumstances will be able to stay sufficiently ahead of its customers.

Several significant market participants reported in 2003 that losses had been narrowed, or that profitability – after tens of millions in venture capital – had been attained. Yet, the private nature of most of these companies makes it impossible to verify such claims. Sponsors must evaluate a vendor’s financial position and its impact on the vendor’s ability to effectively achieve the sponsor’s ultimate goal – namely, delivering enterprise class solutions. In defining the scope of an EDC initiative, it is helpful to balance a candidate vendor’s ability to:

- Meet and exceed the measure of success defined for the initial production trial, and
- Ensure the viability and the capabilities required in the form of product, people and processes to effectively realise the ultimate role for EDC in the sponsor organisation.

Strategy

It is critical to verify the alignment between a sponsor’s goals and objectives of an EDC initiative with a potential vendor’s ability to execute the operational requirements to meet those goals and objectives.

Technology- and knowledge-transfer is an often-identified goal of a sponsor evaluating EDC solutions. Generally, technology-transfer refers to an EDC vendor’s proven ability to shift the day-to-day management of and system support for an EDC environment from its professional services staff to corresponding sponsor staff. This shift sometimes – but not always – is accompanied by physical movement of the EDC software from a vendor-managed hosting facility to the sponsor’s internal computing infrastructure. To some sponsors, physical control is more important than physical location. For other sponsors, the two are bound together. Regardless of which, it must be made clear what the ultimate goal is and whether a vendor can accomplish that goal.

Knowledge-transfer suggests an approach that provides a structured environment to support the ability of sponsor staff to assume responsibility for the configuration of studies within the EDC software environment. Knowledge-transfer programs must be tailored to the skill-sets and priorities of sponsor staff. Options such as classroom training, web-based learning, self-help systems and on-the-job training should be offered. Hybrid teams of sponsor and vendor staff should be developed to support a staged transition. And the EDC provider must have the infrastructure to provide the support necessary to guarantee successful knowledge-transfer.

While most EDC providers tout technology- and knowledge-transfer, the capability and/or desire to deliver on this promise varies widely from one EDC vendor to another. In some cases, this is due to the fact that the underlying software and business...
model were simply not developed with technology- and knowledge-transfer in mind. The software may not have been designed as a packaged application that can be installed in a standard replicable manner. The tools needed for configuring a study may require in-depth understanding of underlying software code and line level scripting in one or several programming languages. The services model may not include educational curricula for configuring and managing studies. Finally, the vendor’s business model may assume or even require indefinite, ongoing services revenues from each sponsor for the continuation of operations.

It can be difficult to ascertain a vendor’s technology- and knowledge-transfer capabilities during standard sales presentations and supporting demonstrations. In addition to measuring business viability, in-depth discussions with professional services staff will provide an insight. Sponsors should ask to see not only standard operating procedures for a vendor’s implementation methodology (especially with regard to the areas of technology- and knowledge-transfer), but also work practices and case studies. They should also interview implementation staff to compare consistency between practices and procedures, and review representative samples of training materials and product-transfer documentation.

Finally, and perhaps most importantly, sponsors should take a page from the book of President Ronald Reagan: “Trust, but verify.” Speak with one or two vendor customers who have successfully completed, or are well underway with, technology- and/or knowledge-transfer programs. And do not necessarily limit those discussions to identified references. Use personal industry contacts to better understand the vendor’s performance ability. Ask users to describe their experience. Ascertain if the collaboration with the vendor was structured, organised, repeatable and flexible enough to meet unique requirements. This approach will help establish a clear picture of whether the potential EDC vendor’s technology- and knowledge-transfer capabilities are sufficient to support a sponsor’s goals.

An element of many EDC strategies is to provide an environment that helps to bind investigators more tightly to the sponsor. This can be accomplished through the provision of more real-time feedback, enabled by electronic collection, and real-time reporting of clinical data. Communication and collaboration capabilities must be designed to enrich investigators’ experiences. An EDC portal with a digital dashboard can be the solution that delivers a “best practices” environment specific to the user’s needs and includes items such as:

- Key trial metrics such as enrolment, monitoring activities and data collection/quality/locking status, and

- Trial documents, such as protocols, case report forms, informed consent forms and investigator agreements.

A comprehensive EDC study portal is an environment that fosters an electronic research network that extends beyond data-collection to a variety of collaboration and communication activities that meet the needs of investigators, provide value input to sponsors and support enhanced patient care.

If portal functionality is an important part of the EDC solution, sponsors must consider the balance of command and control functions (for example, different resources available for different user roles), and communication and collaboration capabilities (for example, Web-based training, database resources, discussion groups and reports).

For some sponsors, an EDC project is part of a larger initiative designed to determine the optimal approach for addressing a number of clinical research back-office functions. As many sponsors are considering the creation of an organisation and technology platform to facilitate comprehensive in-house clinical data management, EDC is becoming a component of a grander eData management plan. In evaluating EDC solutions, these sponsors must consider whether a vendor offers a robust clinical data management back-end that can be leveraged for EDC and paper studies using the same library of clinical data standards. Application solutions in other adjacent areas – such as adverse event management and reporting, and/or trial management and monitoring – may enter into consideration.

Whether it is a core EDC system, portal or other clinical research back-office application at issue, regulatory compliance is of the utmost importance. Engaging a sponsor’s regulatory staff early and often in the initiative is a key requirement, as the analysis of regulatory compliance is critical and must occur simultaneously with the evaluation of the technology and services. Vendor-provided validation kits, standard operating procedure kits and associated services will compress the time and resources required to accomplish goals and objectives, and are another test of a vendor’s technology- and knowledge-transfer mettle.

Supporting services
While sufficient support services to effect proper technology- and knowledge-transfer is unlikely to be an issue for initial proof of concept pilot EDC studies, the availability of such services in a variety of areas is critical to a sponsor’s ultimate scope and strategy for enterprise EDC.

The effective roll-out of enterprise EDC involves the management of an increasingly complex and geographically far-flung network of sites. Appropriate support of such investigator networks is well beyond the capabilities of all but the largest
of organisations. Key vendor criteria for this area include the availability of site qualification services to ascertain the readiness of a site’s technical infrastructure and staff to engage in an EDC study. A solid site qualification program should include not only the means to identify high-risk sites, but also a mechanism to provide the special support and attention they require.

Site training offerings should extend beyond standard investigator meeting sessions to include Web-based training curricula that can re-enforce classroom style training and be used to address inevitable turnover in site staff. Ideally, courses should be “customisable” and extensible to include study- and sponsor-specific information.

Last but not least, help desk support should be available 24/7 to answer site-based questions pertaining to the EDC system and its use in a particular study. Real-time language translation services should be available to support an increasingly diverse investigator pool in outlying geographies well beyond North America and Western Europe.

More innovative EDC vendor partnerships include relationships with IT providers that, in turn, can provide access to networks of investigators and/or patient recruitment services. Traditional areas for such partnerships include the provision of PCs and Internet connectivity to sites in remote or otherwise technologically underpowered areas. EDC vendor relationships with large IT organisations can also provide support to sponsors in establishing a regulatory-compliant computing infrastructure capable of accommodating a technology-transfer program.

Conclusion
While EDC software may be the foundation for successful EDC initiatives, a number of closely related areas play equally important roles in the success of enterprise EDC implementation. The EDC vendor that understands how these areas map to a sponsor’s ultimate EDC scope, strategy and need for supporting services is the vendor that will help address the critical business issues identified by the clinical development enterprise.

Scott Grisanti is responsible for managing eResearchTechnology’s (eRT’s) global sales, marketing and alliance activities. In this capacity, he has worked extensively with sponsors in the pharmaceutical, biotechnology and medical device segments, along with CROs and government organisations, to provide products and services that optimise the collection, management, analysis and distribution of cardiac safety and clinical data. Mr Grisanti joined eRT from ClearCross, Inc, a leading provider of Global Commerce Management solutions, where he served as Area Vice President of Sales and was responsible for launch of the company’s initial e-commerce products and services. Prior to ClearCross, he was Director of Sales for supply chain execution application provider, Metasys, Inc, with responsibility for sales and marketing efforts targeting the contract logistics services marketplace. Before joining Metasys, Mr Grisanti served as Director of Workflow and COLD Business Development for Computron Software, where he also served as a Director in the channel sales organisation. Earlier, he was Director of UNIX Product Marketing for Information Builders, Inc, providers of the FOCUS 4GL and EDA/SQL middleware.