Electronic data capture (EDC) can reduce errors in data going from an investigative site to a biopharmaceutical company by 70 to 80 percent. EDC technology can also cut database lock times to a matter of hours, thus making results available at the earliest possible point in the process rather than the typical four to eight weeks or longer. Improving quality and shortening timelines are at the heart of drug development programs and clinical trials within those programs. So, why doesn't everyone use EDC for all trials?

To address that question, we need to explore the factors that go into selecting and implementing such technologies, including the current corporate use of EDC tools and data standards. A company that has not yet selected a primary EDC tool and has not yet developed end-to-end internal data standards has an enormous opportunity today—not only to take advantage of the progress but to influence the future.

Gartner estimates that if all companies adopt EDC and data standards, they have the potential to save the industry as much as $6 billion per year. Clearly, depending on how and when they implement those initiatives, each individual company could also reap benefits.

EDC—JUST ONE PART

Before exploring EDC, it is important to clarify that it is but one tool/process in the realm of an eClinical trial—a study "in which primarily electronic processes are used to plan, collect (acquire), access, exchange and archive data required for conduct, management, analysis, and reporting of the trial" (CDISC). EDC focuses on the collection/acquisition aspect of an eClinical trial. That, in turn, addresses the use of technology and the movement of electronic data throughout the entire process. This is an important distinction because EDC cannot be expected to deliver the desired impact if it is used as an independent point solution.

It is unrealistic to expect a technology solution provider to offer an end-to-end eClinical solution today, especially in the current environment of numerous competing solutions and no true market leader. It is also unrealistic to expect our scientifically inclined stakeholders to all agree that one solution will fit all needs. That necessitates the use of data standards to facilitate the exchange of data among different solutions on the eClinical continuum.

Fortunately, data standards are currently available that can be implemented to support the acquisition, exchange, submission, and archiving of clinical trial data. Many vendors, and certainly contract research organizations, support the use of the CDISC standards, particularly when the trial sponsors request their use. The further upstream in the process the standards are implemented, the more benefit will accrue. To be more specific, because an eSubmission standard is endorsed by FDA, the logical step to streamline an eClinical trial from end-to-end in terms of data flow is to collect the data in a format that makes it easy to populate a submission dataset.

SELECTING EDC TOOLS

First, it is important to understand the definition of eClinical and the value that standards can provide throughout a process employing multiple technologies. Then, the considerations that immediately come to mind during a technology selection process can be viewed with an eye toward the broader environment. Suggested considerations include, but are not limited to, the hosting environment, user acceptance, user support, regulatory requirements, cost, and support for the standards.

Hosting environment. A company must decide if it wants to host the database or if it would prefer to have a CRO or EDC vendor responsible. Sometimes, for an initial EDC trial, it is helpful to have an experienced party involved in the early stages and later determine whether it should be trans-
ferred in-house. If a sponsor company has in-house experience, some vendors will provide solutions that can readily be implemented in house without excessive service costs.

**User acceptance.** Usability and flexibility of the system are key factors to ensure that both the site personnel and in-house staff are positive and accepting of the tools. The vendor should be able to provide usability testing and user acceptance results.

**User support.** Users in house and at the investigative site need a good support system. Support may be provided by the vendor, the sponsor, a CRO, or a combination of two or three of them.

**Regulations.** The regulation that most directly applies to EDC (21 CFR 11) and FDAs guidance document, Computerized Systems Used in Clinical Trials (CSUCT), have been revised over the past few years. The CSUCT guidance addresses both the requirements of 21 CFR 11 and other regulations covering clinical trial records. The regulatory environment is generally quite supportive of using electronic data capture tools, especially for patient reported outcomes.3

**Cost.** Most companies send out a number of requests for proposal (RFP) and do a cost comparison. It is important to establish a set of project requirements that allow a valid comparison across the proposals.

**Support for standards.** The vendor and the system should support data interchange standards—particularly CDISC’s Operational Data Model (ODM), Laboratory Data Model (LAB), and Study Data Tabulation Model (SDTM), when applicable for purposes of the tool. With that support, the data collected can be readily integrated with data from other studies (even if collected using another standards-based tool) in the same standard format for eventual integrated reports and submissions. Data in a standard format will also be more valuable and marketable in the case of mergers, acquisitions, codevelopment arrangements, or transfers of products. In addition, many vendors and CROs that support the CDISC standards, particularly ODM, can auto-generate the data collection forms (supporting submission formats). They have seen decreases in study set-up time of 70 percent, 80 percent, or more, and the audit trail information is in a standard format, making it easy to review and archive.

**SUCCESSFUL IMPLEMENTATION**

Several factors come into play when implementing electronic data capture tools as well. The following list is not necessarily exhaustive, but it is a good place to begin.

**Leadership.** Implementing EDC requires change management; processes and jobs must change. There are always those who welcome new ways to achieve their goals and those who are more comfortable with the way they have always done their work. Strong leadership, management skills, and positive, open attitudes are essential to a successful implementation.

**Planning.** The planning part of a project is often short-changed because of timelines, but it is an extremely important stage. The current process should be mapped out, then revised according to the new process using EDC. That also helps prepare for a means to measure the impact of the EDC. Too often, the baseline for comparison is inadequate, which makes it impossible to determine the success of an EDC implementation.

**PRISM denotes a helpful set of steps for the new EDC process. The steps are:**

- **Planning**
- **Resourcing with “can do” personnel and a good leader**
- **Implementing according to the plan (with contingency planning included)**
- **Supporting standards adequately, and**
- **Metrics collection to measure success.**

**eClinical trials.** Ensure that the EDC system fits into a pure eClinical trial environment. That is, make certain that it supports data interchange standards, allows the collection of eSource data, and is positioned to fit into a continuum of primarily electronic processes and applications for an entire clinical trial.

**VISION FOR THE FUTURE**

The last consideration, but certainly not the least important, is that those who implement EDC, and especially eClinical trials, should articulate a vision for the future. That vision should include a view of health care information technology. During the coming decade, governments around the globe will increasingly emphasize the use of electronic health records, and will encourage consumer participation in maintaining medical information.

Understanding why investigative site personnel still have reservations about EDC and why the number of investigators is declining may rest on a couple of observations about current conditions.5 For example, 70 percent of active research sites are using more than one EDC application. A significant percentage use three or more at the same time; all too often a single sponsor has multiple systems. Each system requires a different login, a separate password, different requirements for entering the data and resolving queries, and each has its own instructions for using the system. The varied requirements for data entry, layered with regulatory requirements, make it cumbersome to do clinical research without dedicated research staff at the sites.

Furthermore, there is currently no link between the data entered for the

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**ABBREVIATIONS USED IN THIS PAPER**

- CDISC Clinical Data Interchange Standards Consortium
- CSUCT Computerized Systems Used in Clinical Trials
- EDC electronic data capture
- eSDI Electronic Source Data Interchange
- ODM Operational Data Model
- LAB Laboratory Data Model
- SDTDM Study Data Tabulation Model

The CDISC Clinical Research Glossary (v.4) and its glossary of Acronyms, Abbreviations, and Initials (v.4) can be downloaded from the organization’s website, [www.cdisc.org/glossary/index.html](http://www.cdisc.org/glossary/index.html). Check back from time to time, because those documents are always under review, and a version 4.5 is being prepared.
clinical research and that entered for health care. Site personnel may have to transcribe and enter and reenter data two to four times. With electronic health records coming, it is important for us to facilitate the means to enter data once for multiple purposes and to link health care and clinical research records to streamline the processes for the site personnel. It is also important to factor in the trend to encourage patient-reported outcomes and patient-entered data.

Several ongoing initiatives are aimed at defining the means for linking health care and clinical research records in the context of the existing regulations. Those include a Discussion Document by eClinical Forum and PhRMA in the review process (“The Future Vision of Electronic Health Records as eSource for Clinical Research”), the CDISC eSDI Document (www.cdisc.org) the CDISC Single Source Proof-of-Concept Project, a profile for Integrating the Healthcare Enterprise (IHE)—www.cdisc.org/single_source/about.html, and several other pilot projects.

Although regulations may change in the future, it is not going to occur in the short-term. We cannot wait for changing regulations to be a driving or even an enabling force. Those who wish to ensure that research remains an important factor in the development of electronic health record systems should become involved in influencing the future of those systems and related certification requirements and standards. The need to link pre-approval biopharmaceutical product safety assessments with post-marketing safety surveillance necessitates improving the harmonization of the health care and research worlds.

It’s Time

The value of moving toward an electronic environment for clinical trials is clear. When making the move, however, it is important to select tools that are well-supported, flexible, and positioned to adapt to future trends. Such a systematic approach can prevent repeating work, archiving legacy systems, and the need for purchasing new systems in the near future.

Vendors and applications poised for the future are those that support data interchange standards, that can readily exchange data with other technologies and partners, and whose plans include links with electronic health records at the appropriate time in the future.

Electronic health records vendors are now exploring ways to support regulated clinical research. Some may develop applications that can do that inherently. Others may partner with EDC vendors that have already developed tools with robust data management capabilities, integrated data standards compliance, and comprehensive methods to support the applicable regulations. The development of sophisticated integration profiles that can support such partnerships are under way.

Providing a means to capture data once for multiple purposes can be of enormous benefit to site personnel. That can also provide value to biopharmaceutical sponsors, particularly if it encourages investigators to do more research, enroll more subjects in trials, and produce higher quality data. The time to move to eClinical trials has come.

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References

5. www.cdisc.org/eSDI/forms/eSDI.pdf.