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EDC: Are We There Yet?... Maybe Not

EDC Today is an independent publication on current information and issues in Electronic Clinical Systems (ECS) strategies and technologies for the Biotechnology and Pharmaceutical (Biopharma) industry. Each month we examine topics related to ECS theory, technology, practice, or implementation.

EDC Management recently presented at a major conference a session on the use of both EDC and paper in the same clinical trial. The feedback at the session was tremendous, and it appears that many people in the audience still do not fully embrace EDC.

In this issue, we examine some of the feedback from the presentation, and some recent publications to assess the current state of the EDC industry, and whether or not EDC is living up to its promises. Our take on the situation is that there are conflicting opinions about the acceptability of EDC, and there appears to be some hope that something better is on the way.

Introduction

Our conference presentation stated that there are still compelling reasons to use paper CRFs for clinical trials in spite of the fact that EDC can provide greater efficiencies over using a paper-based process. This paper briefly summarizes some of the reasons for using paper CRFs, one of which is still poor Internet connectivity for some sites.

This paper then presents some of the feedback received from the audience. Of the many questions asked, the question “Isn’t EDC just pushing data entry to the site” is still being asked. Beyond that, there are still questions about 21 CFR 11, electronic signatures, and source documentation. From this feedback, it is clear that some people are still not comfortable with EDC.

Some thoughts pulled from recent publications will then show the conflicting opinions in the industry. It appears that EDC vendors want to believe the time is ripe for widespread EDC adoption, while other people believe more fundamental problems continue to exist.

In the next issue of
EDC Today:

Translating Study
Materials

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The paper concludes by urging biopharmas to continue their efforts to optimize and innovate their clinical data processes in hopes of achieving better data collection efficiencies. Over time EDC vendor consolidations will continue to occur and, perhaps, better eClinical offerings may make their way into the market. Until then, Biopharmas should make their best efforts with the technology and software applications that are available.

Reasons for Using Paper CRFs

If EDC can provide better efficiencies than collecting clinical trial data using paper CRFs, why would we want to consider using paper? Ultimately, the answer to this question is that sponsors do not believe all of the investigator sites that need to participate in a clinical trial can use an EDC application.

Often sponsors running a multi-center clinical trial need to involve investigator sites that are “EDC incapable.” Three potential reasons for a site being “EDC incapable” are as follows:

1. Poor Internet connectivity
2. Technology export restrictions/difficulties (sending computer hardware/software to some countries is not allowed/feasible)
3. Computer-phobia

Why would a sponsor still want to use one of these sites? The reasons include:

1. High enrollment requirements
2. Difficult enrollment requirements
3. Highly skilled sites (medically)
4. Remote location of disease population

In many cases it is possible to work around a site that is EDC incapable, especially in the case of computer illiterate or phobic sites. In such cases a biopharma could supply personnel to the site to perform EDC related tasks. On the other hand, it may be difficult to circumvent technology shortcomings. Poor or nonexistent Internet connectivity or export related issues may force one to resort to paper CRFs.

A halfway solution of using a Fax-based data capture application may prove beneficial for some EDC incapable sites. One CRO that EDC Management is aware of uses Datafax with success even with remote and isolated sites. Their contention is that it is easier to get a fax machine installed and hooked up than to get good Internet connectivity.

Session Feedback

The presentation audience had quite a few questions and lively input especially when the topic of discussion was the pros and cons of using both EDC and paper CRFs. Among the major points raised were issues of having the site do entry, what constitutes source documentation, if using workbooks instead of CRFs is helpful, duplicate entry of data (once into the hospital Electronic Medical Record (EMR) system, and once into the EDC system), uncertainty about 21 CFR 11, and various shortcomings of the EDC applications.

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A general consensus is that paper CRFs are still much easier for sites to use. One attendee mentioned that she took the CRFs into a break room, spread them out on a table with her source documents, and filled out the forms. She found this much easier to do than sitting at her desk and keying the data into the EDC system since she did not have room to comfortably lay out all her documentation.

The issue of duplicate entry of data was an indication of the desire of sites to use EMR, or at least it reflects the desire of site management to have electronic records. Comments from the audience stated that data is entered initially into the EMR system. The EMR records were then printed out. The print outs were then used to key the data into the EDC system. EDC Management has been a proponent of integrating EMR and EDC, but realizes the huge barriers that need to be overcome for such an integration to be commercially feasible.

Further comments revealed that hospital IT staffs are often extremely sensitive about providing Internet connectivity. Hospital data is regulated by privacy concerns, and IT staffs take these regulations seriously. One attendee indicated that the investigator had one network connection in his office, into which he needed to plug multiple laptops from different sponsors (Editor's note: the IT staff probably should have installed a network switch or hub for this investigator).

Having the site do data entry is still seen as a burden, especially if the data needs to be entered into an EMR. Plus, different EDC packages are often used by the same site for different studies. As a result, the data entry is often more time consuming than sites would like it to be.

Finally, the issues with source documentation and 21 CFR 11 indicated that there is still a general uncertainty at the sites (and for sponsors) as to what exactly is needed. We believe the FDA needs to come out with further clarifications and guidance before widespread comfort with EDC will exist.

Thoughts from Current Publications

Clearly the audience in a presentation on using both EDC and paper CRFs in the same trial will exclude devoted EDC disciples that want to avoid paper CRFs. As a result, it is necessary to examine some current publications to gain a more balanced take on the status of EDC.

There are authors who believe that EDC is poised for explosive growth. Likewise there are authors that believe EDC cannot deliver all that is needed and a more comprehensive solution is needed.

On the positive side for EDC is Procera senior partner John Murray who says:

Overall, Procera's 30,000 ft. view is that the industry is finally, truly changing. "We think an inflection point has arrived," says Murray of electronic data capture. "People are going to start going 100 percent electronic. It's a no-brainer. People are going to get their processes aligned. It's taking off. There is a huge growth spurt that is about to occur."¹

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Murray is not the only one who believes this. Beth Herskovits, News and Online Editor, Pharmaceutical Executive says the following:

Drug makers are finally putting their money where their mouths are with electronic data capture (EDC)--the technology that is supposed to drive clinical trials into the digital age.

Although companies have been increasing their EDC investments by about 6.5 percent a year, they're about to shift into high gear, with tech spending set to accelerate 13.3 percent this year and climb to 14.7 percent per year through at least 2011.²

What is interesting, however, is that in the same article, Herskovits quotes Chris Connor, a senior research analyst with Health Industry Insights, as saying:

While many drug companies had been test-driving EDC models over the past four years, full implementation has occurred only in fits and starts. In addition to the high price of the systems, drug makers had to contend with a large number of small vendors--each with its own electronic system that was incompatible with any other. That meant a constant retraining of investigators and duplicated data.

"This was a market of pilot studies--and each pilot study was autonomous," Connor said. "Every one became a one-off, and it was very hard to get economies of scale. It was harder than they expected it to be."³

The question is, is using EDC really getting easier? Connor says that pharmaceutical companies have persisted and are starting to see the benefits. Hugh Donovan, the general manager of the clinical trials business division of Siemens Medical Systems, also believes that EDC's time has come, but still believes there are shortcomings. In his excellent article in Applied Clinical Trials, he states:

The speculated benefits of EDC are many, including improved quality, faster access to data, reduced effort, and faster database lock. So if this is the case, why has it taken more than 20 years for Remote Data Entry (RDE)/EDC to gain acceptance? Whatever the reasons, be they technical, process, and/or cost related, the uptake has been slow and there are still drawbacks—the primary one being re-entry of data by the site staff.⁴

This certainly matches one of the comments provided by the presentation attendees mentioned above. In this same article Donovan describes several efforts to integrate hospital medical record systems, and EDC systems:

In a nonscientific survey conducted on the ACT Web site, 71% of 407 respondents felt that electronic health records (EHR) and EDC would merge within the next five years—a very short time frame when one considers the comparatively slow adoption of EDC. Of those that disagreed, it is reasonable to speculate that the primary reason was not a belief that it will not happen but rather that it will not happen within five years.⁵ (Editor's note: EHR as used by Donovan is conceptually the same as EMR used in this article).

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Likewise, a white paper authored by eClinical Forum and PhRMA entitled "The Future Vision of Electronic Health Records as eSource for Clinical Research," recommends the integration of EMR and EDC, but acknowledges there are difficulties. In particular, they say:

The expansion and government-encouraged use of electronic medical record (EMR) systems in hospitals and physician offices means that patient data are increasingly being entered and maintained electronically. At the same time, clinical trial sponsor-supplied electronic data capture (EDC) systems are often used by healthcare professionals for entry of some of the same patient data as well as trial-specific data. Unfortunately, the data in most existing EMR systems cannot be used directly for clinical research purposes because of the variability of the data and systems and because the systems and infrastructures are not governed by clinical research regulations. Conversely, the sponsor-maintained EDC system is not appropriate as the only source for patient data as clinical research is not the main process flow for a healthcare practice, and research regulations prohibit the sponsor from having jurisdiction over the source data. In practice, this same information is often hand-written on patient charts prior to entry into the EMR and/or is printed to paper for hand-transcribing from the EMR into the EDC system. Sometimes, information first collected in the EDC needs to be backfilled to the EMR or patient chart in order to satisfy regulatory obligations. It is anticipated that this duplication of tasks and associated costs will grow with the increasing use of electronic data sources.⁶

It is conceivable that the integration of EMR and EDC could be the technological breakthrough that Biopharmas are looking for to efficiently collect clinical trial data.

Conclusion

So, what does all this mean? Clearly, from both the presentation attendees and from current publications, EDC adoption continues to rise. What is not clear is how quickly it is rising, and whether or not its adoption will become completely widespread. There are still issues that one must contend with, whether they are site data entry issues, software/EDC vendor issues, or EDC process issues.

Biopharmas should continue to push for better ways of collecting clinical trial data. However, it is not necessarily imperative that paper CRFs be abandoned. In fact, we continue to see paper CRFs being useful for certain specific trials and situations.

However, we do believe that processing paper CRFs can be made more efficient. There is room for improvements in collection forms, whether they are paper or electronic. There is also room for more care in completing forms.

Finally, we believe there is a technological solution beyond EDC. Integrating EMR and EDC may be one promising approach, but there may be others as well. EDC Management continues to push for standards such as CDISC. These standards will contribute to the eventual feasibility of the interoperability of computer applications that perform different functions.

In the meantime, Biopharmas cannot wait for the ideal application but need to continue to innovate and improve.

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Who's behind the research?

Our lead researcher, Kirk Mousley, PhD received BS and MS degrees in Electrical Engineering from MIT and a PhD in Computer Science from Lehigh University. He has been the President of Mousley Consulting, Inc. since its founding in 1993 and has directed the company's efforts in the areas of clinical database design, data editing/cleaning, document management, and submissions.

Karl Mousley received his BS in Mechanical Engineering from Rose-Hulman Institute of Technology and a MS in Computer Science from Villanova University. He has been a senior member of the technical staff at Mousley Consulting, Inc. since 1993. Among his significant accomplishments are the investigation, evaluation, and implementation of new computer technologies for clinical data management systems and developing strategic plans for integrating these technologies into current systems. He has extensive experience preparing Standard Operating Procedures (SOPs).



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