

# Hybrid Hopes

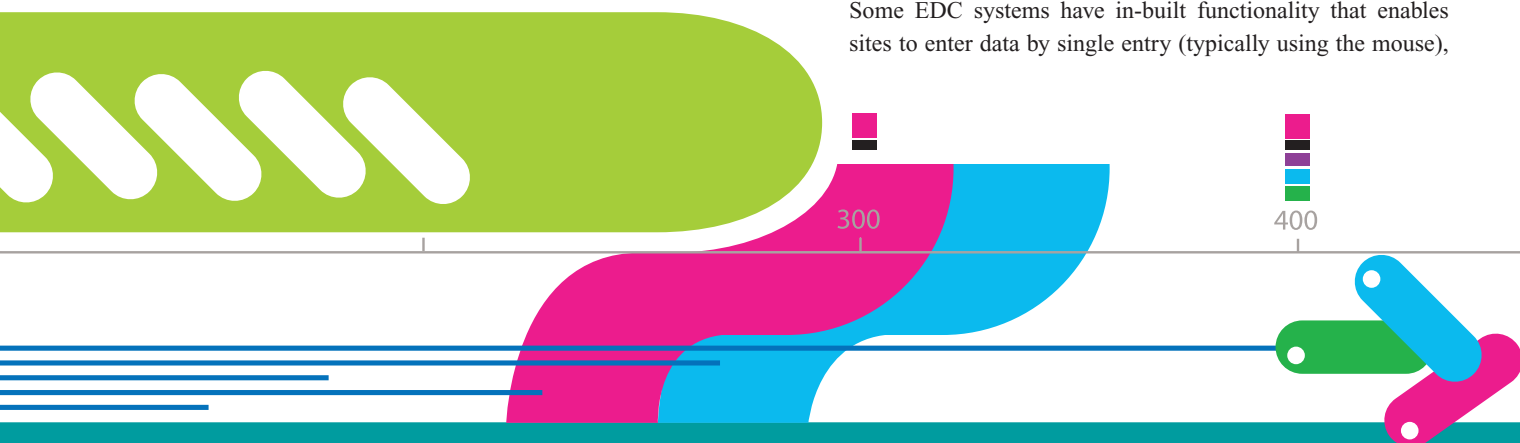
**Paula McHale at Perceptive Informatics explains how to manage paper and electronic data collection in clinical trials effectively**

Is a paperless clinical trial really possible? Of course it is, but is it feasible or practical? Not always. The majority of clinical trials can be conducted with some type of electronic data capture (EDC) tool, and in many cases use a combination of technologies such as EDC, electronic patient-reported outcomes (ePRO), interactive voice response systems (IVRS) or digital pen to collect patient data at sites. These technologies allow for faster collection of data with improved quality, and typically require less data cleaning. Accessing these systems via the internet provides not only immediate visibility of site performance and activity, but also exposure to how the study is running. This insight can help with planning for future studies, managing resources and, at the end of the study, preparation for data locking activities. Web-based technologies give sponsors immediate access to study data that has been outsourced to CROs, which can enhance the partnership and promote better collaboration and teamwork, particularly in situations when only parts of the clinical trial management have been outsourced. In addition, using an eClinical system that connects all the technologies used in your study will save time and provide the best experience for your sites.

But not all trials are able to take advantage of the newest technologies offered, for a variety of reasons including study complexity, the location of sites, site personnel and study design. While the number of EDC studies continues to rise and the majority of new studies use EDC, there are still times when paper data collection is the only way to go for some aspects of a study. Patient diaries and 'quality of life' forms are often recorded on paper and sent to the sponsor to be entered when an ePRO system is not available. When local laboratories are

used because a central laboratory is not suitable for a study, local lab normal data needs to be collected for each lab at every site, sent to be entered, and then merged with the patient's clinical data. Requiring the sites to enter this data into the EDC system themselves is considered an unnecessary burden. In situations such as these, there are often multiple databases designed to collect this information, and all data must be merged and reconciled for analysis. However, with proper planning and technology selection, it is possible to use a single system to collect all data, regardless of the means of collection.

Some EDC systems have in-built functionality that enables sites to enter data by single entry (typically using the mouse),





as well as paper data entry tools that accommodate 'heads-down' paper data entry (typically using the keyboard). Systems that have these features are called hybrid EDC systems. In the scenarios discussed already, this type of hybrid EDC system allows the sites to enter all of their patient data via EDC, and similarly enables the sponsor or CRO data entry personnel to enter the patient diary, quality of life or lab normal data into the same system. Since all data resides in the same database, it is possible to view and report on it as needed.

## PLAN FOR THE UNEXPECTED

Planning for the unexpected can keep a study on track and minimise any delays. For example, you might decide to use EDC for your study, but discover that some of your sites are unable or unwilling to use it. These situations are often due to connectivity and firewall issues, which can cause a lack of interest in using EDC because of a previously unfavourable experience. Selecting a hybrid EDC system for your study will present options for collecting some patient data via paper and other data electronically while storing all data in one database. Using this kind of unique system has many advantages, specifically in the areas of cost and study management. With hybrid EDC systems there is no risk associated with using EDC because sites can switch data collection methods at any time during the study. Sites that opt not to enter their own data into the system can use paper case report forms (CRFs) to record their data, and the paper forms can be sent to the sponsor or CRO to be double-data-entered into an EDC system. Using such a system yields the benefits of electronic data collection, including viewing patient data via the internet and obtaining study metrics through a study portal, while providing the utmost flexibility for sites. However, conducting a study in this manner is only possible if the hybrid EDC system possesses full paper data entry tools and allows the flexibility for sites to easily switch to or from EDC as needed throughout the study.

## GUIDELINES FOR SELECTING A GOOD HYBRID EDC TOOL

Not all systems are created equally. Careful analysis must be carried out to determine if an EDC system has the functionality that is necessary to conduct a study in this manner. It is imperative that the system has standard clinical data management system (CDMS) features in order to accommodate paper CRF processing. Without any configurable features, paper data entry will not be successful.

### Heads-Down Data Entry Features

Data entry personnel are well-practiced at entering data via the keyboard and should have the ability to configure hot-keys that allow them to determine which functions each key will control on the keyboard. This will minimise any learning curve and allow individual users to interact with the system in a way that is most familiar to them.

In a typical paper study, some CRFs are entered twice, and others that contain a lot of text are usually entered just once with a full QC against the paper CRF to ensure accuracy. Therefore, the ability to configure each study to require either single data entry or double data entry is essential.

When double data entry is performed, it is common for a junior employee to input the first entry, while a different, usually more senior, staff member does the final entry. Data reconciliation must be performed and any discrepancies between each round must be clear.

Conflict management tools determine if the same user is permitted to perform both rounds of data entry, or if it is necessary to have different users perform each round of data entry. To ensure data quality, security features must be available to configure these settings.

### CRF Tracking Tools with Reporting for Missing Page Reports

Standard EDC systems have no need to track paper CRFs and data clarification forms (DCF) because, normally, all data is entered directly into the system. However, if paper CRFs are used in a study, it is necessary to be able to track the CRFs that come in for entry. This means a hybrid EDC system must include a utility to track and report on all CRFs received.

In addition, the ability to report on those CRFs that have not been received is of equal importance.

### Printable DCFs

Standard EDC systems do not accommodate for printing DCFs because all discrepancies are managed within the system. When looking for a hybrid EDC system it is critical that it has the ability to print DCFs in a configurable and adjustable format to be able to mimic your standard DCF template.

It should enable multiple printing options to meet the needs of any scenario including identifying which DCFs to print, printing in a batch, or printing one at a time as needed. It should also be possible to reprint DCFs without resetting the original date in the system in case a shipment gets lost and DCFs need to be reprinted and shipped again.

As with the need for CRF tracking, there is a need for DCF tracking and reporting tools to identify which paper DCFs have not been collected.

## HYBRID SYSTEMS VERSUS HYBRID 'PROCESSES'

In approaching hybrid systems, it is critical to distinguish between hybrid processes and hybrid systems. Using a standard EDC system that does not have hybrid capabilities to enter paper CRFs means relying on manual processes to manage and clean the study data. If no double data entry feature is built into the system, one has to rely entirely on the QC of the data against

the original forms, depending on the phase of your study. This will not only take much more time but will also cost a lot more money. Since standard EDC systems do not have DCF printing capabilities, when a standard EDC system is used with a hybrid 'process' it will not be possible to print DCFs without manually typing them up. It is very important to remember that if these features are not built into the system itself, it is only a hybrid process and not a hybrid system.

## STUDY CHALLENGES

Even with a state-of-the-art hybrid EDC system there will be additional hurdles to overcome to ensure a successful and

### About the author



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and technological experience in healthcare and drug development, including 15 years in a CRO environment. Previously she worked at ClinPhone, where she served as the lead Product Director for its EDC solution. In August 2008, ClinPhone was acquired by Perceptive Informatics. Paula has worked with multiple leading EDC systems and has extensive experience in the area of clinical trial management. She also has expertise in data management and quality systems regulations for clinical trials. **Email:** paula.mchale@perceptive.com

smooth study. Regardless of how good your hybrid EDC system is, there will continue to be certain issues that will have to be tracked outside the system. While technology requirements are the most critical, they are not the only important factor to consider. Technology facilitates the two data collection means, but the human aspect of managing the study is just as important. Being proactive and ready to process data both electronically and with paper will ensure success.

Unless the system has the ability to distinguish between sites that are collecting data via EDC and those that do so via paper CRFs, one must keep track of that information outside of the hybrid EDC system. Since these systems allow some CRFs to be entered via EDC and others by paper, it will be necessary to have a way to track those forms which need to be sent in and those which need to be entered at the site. Additional reporting will be required to track adequately the progress of your paper sites as well as EDC sites that are collecting some data on paper forms.

## CONCLUSION

With the advancement of technology, there are fewer hurdles when running an EDC study than ever before. But, regardless of the improvements that have been made over the years, there will continue to be situations where paper is better suited for part of a study than EDC. When these scenarios occur, using technologies that can manage both means of data collection can help to realise the full benefits of technology.