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THE CHANGING FACE OF ELECTRONIC DATA CAPTURE: FROM REMOTE DATA ENTRY TO DIRECT DATA CAPTURE

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For the last 10 years remote data entry (RDE) has been the great white hope of the pharmaceutical industry in achieving three main aims: cutting clinical trial duration time, saving resources, and improving data quality. But where is it? Who is using it? RDE has failed to meet the three aims. The time of the RDE paradigm is past and the future will be shaped by new study site technologies which more and more are able to provide much of the required clinical data directly without the need for the transcription to paper and then reentry to another system. Direct data capture (DDC) from machines such as patient record systems, MRI machines, ECG and EEG technologies, laboratory measurement equipment, and an increasing range of other previously manual data providers will enable error-free and resource-efficient data capture. The substantial reduction and possible elimination of errors will allow early locking of the database and therefore, potentially earlier product launch.

Key Words: Direct data capture; Remote data entry; Clinical data management; New technology; Human-computer interaction

INTRODUCTION

TRADITIONAL DATA MANAGEMENT, that is, the collection of clinical trials data by the use of paper case report forms (CRFs); delivery by a courier or postal system; manual coding; data entry—single, double, or quadruple; computerized consistency and missing data checks; and manual creation and processing of data request forms (DRFs), has functioned, one may say adequately, since the advent of new drug clinical testing. So why is there a need for change? There are three commonly given reasons:

1. To cut clinical trial duration in order to realize "faster time to market (FTTM),"
2. To reduce resource use or use skilled resources more efficiently, and
3. To improve data quality.

Competitive pressures and market pressures are greater now than ever before and will only continue to increase.

WHY REMOTE DATA ENTRY?

The three aims that remote data entry hoped to achieve are closely linked to each other and to that which computers do best, repetitive tasks of calculation and organization of large amounts of information. All of the data control tasks that are executed after data have been returned to the sponsor and entered into a computer have these two aspects. Doing these tasks at the site on paper CRFs takes

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a great deal of time and misses many of the common mistakes. It is, therefore, relatively inefficient. Computers can include built in front-end error checking on electronic case report forms (eCRFs) that can check for inconsistencies in the data and prompt for important data that are missing. Missing data, illogical data, and illegible data can be the reasons for a great number of unnecessary DRFs. If these errors are trapped and removed at the source, a large reduction in DRFs can potentially be achieved. With this reduction comes a reduction in the resources used to remove the errors from the data. The trial monitor or clinical research associate can devote more time to center and investigator management tasks and source data checking instead of looking for mistakes on CRFs. It is well known that the DRF loop extends trial duration because until all DRFs are signed off the database cannot be locked. Each day saved in the number of days required to lock the database is potentially a day earlier that the product can be on the market because locking the database and breaking any blinding codes is a central milestone in a trial. With daily sales of some drugs being over $1million per day worldwide and potential benefits from a patent perspective, from the company finance viewpoint this is significant.

WHERE IS RDE?

With all of these benefits and incentives, where is RDE? The pharmaceutical industry has been waiting 10 years for a universally successful RDE system to be developed. For 10 years there have been in-house dry runs and pilot studies and a few studies that managed to use real data. Approximately half of the pharmaceutical companies have tried RDE and of those, half again have continued to use it (1). That means that three quarters of pharmaceutical companies are still using paper. In a survey of investigators, the majority said they would use the RDE systems that they have tried again and an even higher number said they think that the new technology is better than paper (2). If the majority of the users think that a new technology is an improvement but a minority of the suppliers are supplying that technology something is wrong. There are potentially many reasons for this but the primary reason is that the RDE design and development process within the pharmaceutical industry has failed. Technology project failure is not unique to the pharmaceutical industry. Analysis of the reasons for information technology (IT) project failures shows that expectation failure is one of the greatest problems (3). This expectation failure is brought about by lack of correct user involvement in the design and development phases of the project. This has been the case with remote data entry systems.

EXPECTATION FAILURE

Error-free data was an expectation but it was never a realistic one. There may well be fewer errors if front-end data checking is used effectively, but with RDE error free is never likely. There are two main categories of error, systematic and random. IT may introduce a new type of error, that is, typing errors. These could be systematic or random. Somebody must still take the source data and enter them into the RDE system. It may be the originator of the data or it may have been transcribed onto paper first and a second person then enters it. Any or all of the transformations can introduce errors of either kind.

Paper and pen is a simple “technology”; once one has learned to read and write no more learning is required. With remote data entry systems, however, each system is unique, requiring investment in time and effort for each new system. One does not forget how to write but investigators and other staff can forget the subtleties of distinct RDE systems or confuse two if they conduct two RDE supported trials simultaneously. IT is often expected to be more convenient than paper because it can hold the details on many hundred patients that otherwise would require mounds of paper. This may be true but on the flip side, PCs are nowhere near as portable as a sheet of paper and a pen. ECRFs take longer

to fill in than equivalent paper CRFs and that too can make an IT solution less convenient in the investigator's view.

One aspect of pure IT is data transfer. The commonly expected scenario is to collect the data, connect the computer up to a phone line, and send the data regularly at a convenient time when the system or phone line would not be in use. That is fine if one can get an external phone line from the study site, but this is not always as easy as expected. Also, if one can get a phone line, can the modem be connected to it and will the exchange cope with data transfer? In many cases, for temporary installations the answer to these questions is no. Furthermore, is it really necessary? Will any of the three aims of data management discussed at the beginning of this paper be achieved by transferring the data electronically instead of sending it on a diskette with a courier? The critical path process is patient inclusion and therefore, speeding up data delivery will not provide any benefit. Only when patient inclusion is so rapid that the data are not processed rapidly enough will data delivery become critical.

A NEW PARADIGM

Technologists, on data management's behalf, have tried to develop one system for all trials, all environments, and all types of data. Trials vary greatly. The environments within each trial vary, the types of data collected can be diverse, and the users of such systems are far from identical. A system more tailored to each need may produce more realistic expectations. Paper may well be appropriate in face-to-face contact with patients in the consulting room. Psychologically, a computer is often seen as a barrier especially if used by an inept operator. A simple spreadsheet is a good way to capture repetitive tabular data. Export to databases or SAS is quick and simple. Best of all would be the direct capture of data, direct data capture.

More and more equipment for study center data is becoming computer based. The EEG and ECG that printed out on paper can now be captured on a computer so that the investigator can save it in the patient record file. Data from patient diaries can be captured electronically, and medical history and concomitant medications may in the future come from a "Patient Smart Card" (4). MRI, X-ray, and ultrasound machines are controlled by computers and can readily provide computerized output of both machine parameters before picture sequences and after with evaluation parameters and results. These developments provide an opportunity to escape the paradigm of "data entry" and experience something computers do better than their human counterparts, communicating with one another effectively.

It is possible to imagine a future where the clinical trial system will take all or most of its input from measuring instrumentation. This will fulfill the aims which RDE set out but failed to achieve. Trial duration will be shortened because there will be fewer and even no errors. Therefore, resources required will be reduced.

This will, however, require a multitude of interfaces to each medical device type from each manufacturer or some standard to be adopted by manufacturers. The challenge for pharmaceutical companies in the coming years will be to try and influence the development of such systems before it is too late. Providing access to all the data produced by medical equipment is a potentially contentious issue, if not on other grounds, for security and confidentiality reasons. For a given clinical trial only a subset of the data is probably required and therefore, some extraction utility would need to be built in.

TOWARD PROPER IT DEVELOPMENT

Doctors are not techno-phobics; many and perhaps the majority, interact with a computer on a daily basis. They enter patient data into a hospital database or into other systems and do not want to enter it again into several other systems. To ensure that investigators are not overburdened by all the new technology a cooperative partnership between spon-

sor trial teams, technologists, and study site staff is required to clearly identify the factors of user, environment, and task.

These are the cornerstones of the discipline in computer science known as human-computer interaction (HCI), defined as "an understanding of task, user, and environment in order to design a system that can be used effectively in the context in which they are placed" (5). HCI can raise the likelihood that new technology will benefit the sponsor and the user by considering all the necessary factors in a holistic and systemic manner throughout the development process and provide feedback on the success or otherwise after implementation.

THE FUTURE OF THE DATA MANAGER

What will data managers be doing in the future? They will be more focused on what their title implies, management of data. This includes data coordination, collection, and integration, not the sole destroying task of removing errors that everybody admits should not be there in the first place. The data manager will need to be familiar with medical equipment technologies and visit the study sites to discuss DDC issues. Cross patient and range checks will still be required because where manual recording is appropriate or the technology goes wrong it is possible for errors to creep in. CRAs will be able to become center managers or coordinators and not form checkers and processors as they currently are. These future roles are more exciting and challenging than present roles.

CONCLUSIONS

A proactive approach to the collection of patient and clinical trials data, in which the pharmaceutical industry is the driver and not the follower, is now required. The industry must take the initiative and work with patient record system vendors and hospital equipment manufacturers to ensure that they provide the necessary functions to allow the direct extraction of data by nontechnical operators into a form usable by the sponsor. For the new paradigm to benefit both sponsor and investigator, IT professionals need to recognize that the development process for new systems has changed due to greater user awareness. It is no longer acceptable for the IT department to tell the users what they need. The cooperation between systems developer, trial team, and investigator must be a much closer partnership if the real and substantial advantages of the changing data management environment are to be realized.

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