Scientific software solutions

Electronic Data Capture

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What is Electronic Data Capture?

Electronic Data Capture (EDC) is the gathering of data collected by humans into computer systems without the need for manual data re-entry. Although automatic data entry has been around for a number of years – who can forget those pencil-based multiple-choice exams from years ago – the constant improvements in front end technology have meant that the functional richness of the process is growing and the benefits are becoming more pronounced.

Data entry can be achieved using a number of mechanisms. Users can enter data directly into an electronic device such as a laptop PC, handheld device, tablet PC, touch screen or tone dialling system. Alternatively they can enter data indirectly using character recognition of manually transferred sheets of paper or faxes, or voice recognition. All these methods result in the data being available for further processing without the need for further human intervention.

The value of EDC is only realised if it is integrated into further business processes. This may mean workflow systems, post processing, automatic reply systems and organised and searchable data stores. These are described below:

Current Usage

EDC is key wherever immediate access to live data collection is important. This covers a wide variety of situations, in many industries. The following examples seek to show just how widespread this is.

In the commercial world EDC is already widely adopted. When you are next doing your supermarket shopping, note how many of the assistants check which items are required to restock the shelves using handheld devices with built in bar code readers. Also, delivery drivers can now record the exact load delivered at a site rather than just what was ordered. This is automatically transferred back to base, allowing the amended invoice to be printed and in the post (or sent via e-mail) before the driver has left site. In other areas, consumer feedback is now gathered via web sites with questionnaires rather than phone conversations or post-back forms.

In manufacturing, increasing amounts of data are gathered electronically. Many assembly lines are dotted with touch screen devices to allow operators to input performance information for immediate analysis and audit trail generation.

Inspectors use hand held devices to record their findings as they travel around the plant without the need to transcribe paper notes when they return to their offices.

The scientific world is starting to realise the benefits of EDC more fully. In the laboratory, Electronic Lab Notebooks are becoming increasingly popular, driven by improved data collection devices such as tablet PCs and better integration with lab instruments. In the field, data is now gathered using rugged hand held devices with bespoke applications, for example, recording habitat or land use information.

Perhaps the area where the most dramatic growth in EDC is set to occur is clinical trials data collection. Here the combination of tight timescales, reduced costs and more accurate analysis of results is driving the investment required to implement EDC in both large and small clinical trials over all phases of drug evaluation. Data collection can utilise many of the methods described above, with tone phone and fax based systems being overtaken by bedside hand held devices and even direct data recording from sensors worn by the subject.

Key Issues

Before discussing the possible solutions to the challenges of EDC, it is important to consider the major issues. Some of the questions that need to be addressed are listed below. As you can see this is a considerable list and serves to encourage a full review of the situation before embarking on an investigation of EDC.

- ❑ What data are you gathering? - Without a clear understanding of the data characteristics you are gathering you should not even start. Is the data structured e.g. a questionnaire - or is it driven by outside activities, e.g. a lab notebook? Is it simple text, dates, numbers or more complex data such as bar codes, drawings, sound, photos or externally acquired data from a measuring device? What is the data to be used for?
- ❑ User Characteristics - The characteristics of the user population need to be considered carefully when investigating EDC. Are the users regular users who will build up skills in the interface or are they one off users who need a simple interface? Are they computer literate or technically unskilled or resistant? What hardware do they have available to them, or will they need new, specific hardware?
- ❑ Portability - Does the data need gathering in a particular location, e.g. outside, shop floor, hospital bedside, patient home? Does the user need to carry the

data-recording device with them or can they enter the data at their desks?

- Connectivity - Can permanent network attachment be deployed, e.g. wire in the wall or WiFi and indeed is it required? Are off-line connections appropriate (dial-up links, docking stations) and if so how are they achieved and how often? Is a public connection allowed (e.g. via the Internet) or must the data be transferred over secure networks? Is two-way communication required or can all communication be initiated from the client end? What is stored locally and what is stored centrally?
- External devices - Does the user need to interact with external devices such as bar code readers or special laboratory equipment? Is this automatically part of the workflow, e.g. reading a bar code then typing in a number?
- Validation - Is validation of input data required? If so how complex is it? Is it limited to simple rules such as field1 must be in the range 1-100, or complex interdependencies (field1 < field2 > field3*0.4)? When is validation performed- immediately a number is entered or at a later time?
- Feedback - Is data entered one way (from the client end to the server) or is feedback required, e.g. to instruct the user to perform an action based on the input?
- Workflow - Is data collection the start of a complex series of steps arranged into a workflow or is it a one off action? Do the data need validating, reviewing, approving and releasing for general consumption locally and centrally? Can further actions be automatically initiated based on the data collection or any other action in the chain?
- Integration - Does the system need integrating with other computer systems? These may be databases, processing systems or additional data collection systems, e.g. the results of an assay or blood test requested at data collection time.
- Post processing. What analysis is performed on the data collected? Is this performed in real time or manually at a later date? What actions result from the processing, e.g. approving or rejecting a drug in a clinical trial?
- Regulations. Does the system have to conform to any externally imposed regulations, such as 21 CFR Part 11, Good Manufacturing Practice, or Good Laboratory Practice? This can have a decisive effect on the approach to the solution.

Possible Solutions

Having analysed the problem, it is now possible to review possible solutions for the use of EDC in a particular situation. Each approach has advantages and disadvantages and indeed, may be used in parallel within the same overall solution. Current innovations, especially in the area of mobile computing, are making the choices wider and the benefits greater. A good architecture removes the storage, processing and workflow decision-making from the front end so that different front-end devices can be swapped without changing the overall structure.

1. PC Client Applications

The easiest method of EDC uses traditional computer based forms to gather data. At its simplest this can be a set of Windows-based forms that lead the user through a questionnaire style interface. This approach, often described as Wizard, has the advantage that the user interface is function rich, easy to interact with and can perform a lot of cross checking and validation. PCs are widely available, laptops can be fairly portable and the user interface is familiar to most users. PCs are also able to connect easily to external devices such as bar code readers, scales, thermometers or even more complex scientific devices.

The problem with this approach is the need for an application to be deployed on each PC. This may require a complex set-up or may have specific pre-requisites (e.g. operating system version) that may not be under central control. This can lead to complex system management challenges. Also, although a laptop is portable, it cannot be carried around when gathering data. PCs are generic devices and so are not specifically set up for the job in hand and if each user requires an extra PC they are expensive.

Despite these concerns, this approach is used by many organisations. Novartis, for example, use a clinical trials system based on PhOSCo (www.phosco.org), which is deployed on each investigator's PC. As with many of the solutions discussed below, connectivity to the local or central data stores and the ability to work offline are issues. In the PC context, significant amounts of data can be stored locally before transfer. This means the data collector can work off-line before uploading the data to a server at a convenient time.

2. Web Based Forms

The Internet offers great possibilities for allowing users to enter data directly into the system via browser-based forms. If deployed over the web these are globally available and users have good familiarity with the technology. No software is required in the client device (except a browser) making system management easy and reducing the need for expensive specialist hardware. A certain amount of validation can be built in and data is available immediately on the server. Responses based on the input, for example, instructions on the next step, can be given immediately.

Internet systems, however, have several drawbacks. The user must always be connected to the network either by phone or LAN connection. This is not always possible in hostile or remote environments. The system is dependent on the performance of the network, which may result in slow responses. The user interface is not as rich or elegant as a client based system, which can make data collection slower and more awkward. If using the public Internet, data security is a major concern and needs special attention.

Despite these drawbacks, web based systems have a major part to play in EDC. They are especially useful where occasional users will not be able to install specialist hardware or software. Even if not used in primary data collection, web based interfaces are very useful for certain parts of the workflow such as reporting, graphing and review and approval cycles. Here managers tend to be permanently connected to a network and there is a reduced need for rapid data entry. Live access to the data collection realises the benefits of collecting data rapidly in the first place.

3. Touch Screens

Touch screens allow users to input data rapidly using bespoke forms. They can easily be incorporated into bespoke hardware systems such as scientific instruments or point of sale devices. Little or no computer literacy is required to operate them and they can be deployed in places where more generic input devices such as keyboards or mice would be hard to use, for example, a factory floor or a public place. System management is easier as the users do not have access to the system configuration data. Data can be sent directly to the server for analysis and action and responses sent immediately to the user if required.

Touch screen devices always require specialist hardware. Despite advances in touch screen technology, complex data entry is still error prone. They are only really useful when the user has a limited number of choices to make and must be used in a very prescriptive manner.

Touch screen systems are best used in specific environments where explicit data collection is needed. They are especially useful where the operators do not have the time or the inclination to sit down and learn complex interfaces and do not have the opportunity to spend a lot of time entering data.

4. Bespoke Handheld Devices

The benefits of handheld devices are significant. They can be carried to the point of data collection so errors are not introduced between recording the data and entering it onto the system. Examples are bedside patient data entry or taking readings from industrial devices running in a production plant.

Bespoke devices are built for one purpose. The advantages of this are that they do not contain unnecessary functions and are tuned for the needs of the user. The interface can be set up exactly for the job required and is often greatly simplified. They can be linked to other input devices, such as bar code readers, thus minimising the chance of incorrect data entry. They can be kept smaller, due to the elimination of unnecessary functions, and can be built to specific standards, for example, for rugged environments.

These advantages are accompanied by certain drawbacks. Because they are specific, generalising their use is difficult or impossible reducing flexibility or the opportunity for re-use. Most importantly, they do not benefit from economies of scale and so purchase price is likely to be high unless ordered in bulk.

Bespoke devices have specific uses that will continue despite the growth of commodity handheld devices. However, they are likely to remain niche items if current trends continue.

5. Commodity Handheld Devices (PDAs)

Recent years have seen a spectacular growth in the sales of commodity handheld devices such as the Palm Pilot or the Compaq iPaq. Unit prices for these devices, commonly referred to as Personal Digital Assistants (PDAs), have fallen significantly and powerful new features added, such as colour screens and more memory. The number of operating systems is falling and user acceptance is high. PDAs offer a much cheaper alternative to using laptop PCs in many EDC situations.

EDC using commodity PDAs is a fast growth area. High quality interfaces can be produced with built-in validation. Local processing and storage is possible and extra functionality can be added using extra cards to add, for example, networking or mobile phone capabilities. The devices are truly portable and can easily fit inside the pocket of a suit, overalls or lab coat. However, this portability inevitably means that the display area is very limited, which can be a significant limitation to the development of good user interfaces.

Producing good EDC solutions using off the shelf hardware has its challenges. The operating systems are new and can often have problems, especially with connectivity. Both software and hardware are changing rapidly and can constitute a moving target when developing software. If inappropriately designed, the user interface can be fiddly to use leading to input errors, slow data entry or poor user acceptance. The need for extra cards to add functions can quickly make the systems bulky. Battery life is good, but still not infinite and forgetting to put the device on to charge can cause problems.

Despite the challenges, commodity PDAs represent a major growth area for EDC. These systems reduce the investment barrier to using truly portable EDC and will make a big difference to this area over coming years.

6. Mobile Phones

The continual blurring between mobile phones and PDAs again offers possibilities for EDC on the move. High-end phones now have processing capabilities allowing programs to be uploaded and run on them. They can be smaller and more portable than PDAs and are, of course, fully connected. The growth of faster data connection routes such as GPRS and 3G means data upload can be very quick. Photo capture is increasingly common in the more expensive phones. All phones have built-in messaging using SMS. User acceptance is high as few people need to be persuaded to carry an expensive mobile phone.

Using phones for EDC is only appropriate in certain situations. The user interfaces are very small and fiddly and not appropriate for collecting large amounts of data. The connectivity is not always reliable and may not be permitted in certain environments such as hospitals or on aeroplanes. Developing bespoke applications for phones is a new area and again may not be reliable.

In situations where users are required to take readings at specified intervals or to carry out some other action (e.g. take a drug) they can easily be prompted to do so by phoning them up.

Mobile phones are likely to become more prevalent in EDC as their power grows. For situations where remote data entry is required and low functionality is acceptable, they will offer an interesting alternative to PDAs. Devices that can be considered both PDAs and phones, such as the O2 xda, will offer major possibilities in this area.

7. Tablet PCs

The recent release of Tablet PCs offers huge opportunities for EDC. These devices are an interesting mix of laptop PC and PDA that present true portability, an intuitive interface and reasonably powerful processing. Still in their infancy, they are backed by many big players, most notably Microsoft. They offer good connectivity using wireless networking, fast data entry using handwriting recognition and the ability to produce slick systems with good user acceptance.

The drawbacks of Tablet PCs may come from their newness. The marketplace is fairly volatile and likely to change rapidly. The handwriting recognition features may only be useful in some circumstances (for example, free text and diagrams) and more traditional touch screen interfaces used for the bulk of data entry. Developers will have to gain experience at producing optimal user interfaces and users will have to get used to using them.

The size of a Tablet PC, whilst smaller than a laptop, is considerably more bulky than a PDA. However, the increased display area gives much better opportunities for developing effective user interfaces. They are, after all, much more akin to the familiar clipboard and paper pad. The connectivity benefits can only be realised in a networked environment.

The use of Tablet PCs for EDC is likely to evolve considerably over coming years. In many circumstances where fast, complex data entry is required in a portable environment they will prove invaluable.

8. Paper Based Methods

Whilst considering many of the new and exciting methods discussed above, much EDC is still done using more traditional methods. Paper methods rely on forms being filled in by hand and then scanned into a computer, either locally or more usefully via fax. When using the latter, replies can automatically be returned by fax. The system must interpret the paper form and extract data from it, validating at this time. Although very much ‘old technology’ it is, however, very portable, universally accessible and has no requirement for extra local hardware or software (every ward in a global clinical trial may not have a PC, but it will almost certainly have access to a fax machine). Access is full time (24/7) and data entry is immediate at the centre. The original data submissions (fax images) can be retained for audit and regulatory purposes.

Paper based methods still have considerable limitations. Form design is critical to reduce data entry errors and may result in cumbersome forms. There is no data validation until data is submitted and the reply may take several minutes to be resent. Connectivity is error prone as return fax numbers are often wrong or dial out only.

Paper based systems, especially fax, may seem old technology but they can be a considerable improvement over existing off-line systems (manual collection and entry of paper based forms).

9. Electronic Documents

One alternative to paper is provided by allowing users to download electronic documents that are completed using the macros embedded within them, then emailed or uploaded to the server. Current systems have been produced in Adobe Acrobat, MS Word, and MS Excel. This has the advantage that they can be filled in locally, require no additional local software and look like traditional paper based forms. They are also very easily distributed.

The down side is the lack of advanced validation and the possibility the user will not send the forms back. Also, some systems are insecure and allow incorrect data entry, for example, into incorrect cells in the spreadsheet. The documents may require a specific version of the editing software (for example, Office XP rather than Office 2000), which reduces their effectiveness.

Electronic document questionnaires are becoming more popular with the increasing sophistication of macro languages. Given the widespread availability of the client software (for example, MS Office) this is likely to continue.

10. Sound Based Systems

As with paper-based systems, telephones are a universally available device available at no extra charge. Entering data using either touch phone techniques or voice recognition is available to all and can have built in validation. This method is also very easy to use and familiar to just about everyone.

Phone based systems have their problems. Tone phone systems are very slow and frustrating to enter data with and can be error prone. Voice recognition is quicker but more error prone, especially where global data collection is required and users may have different accents or even not speak the base language.

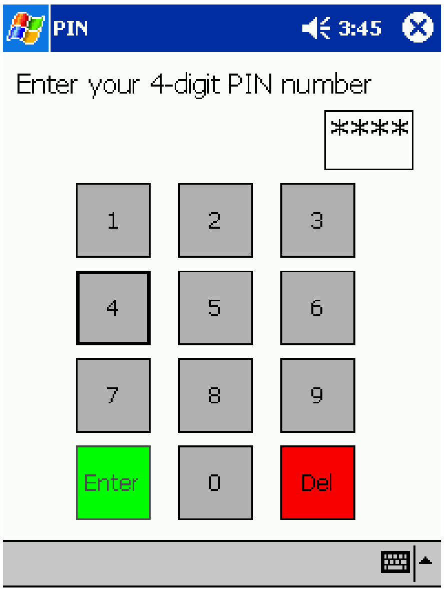
Phone systems are still extensively used for EDC due to their universal accessibility. It remains to be seen whether the newer forms of EDC start to erode their popularity.

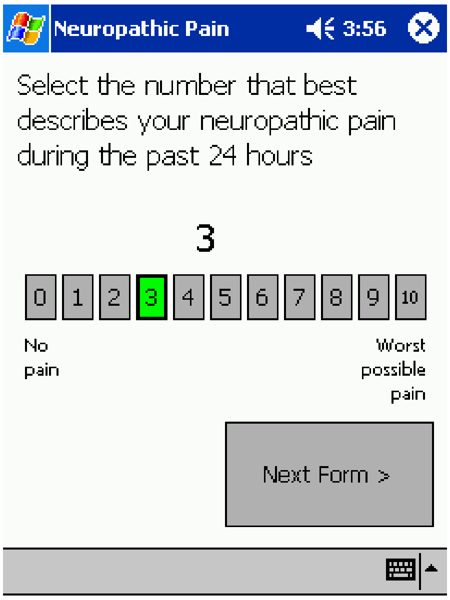
Further Considerations

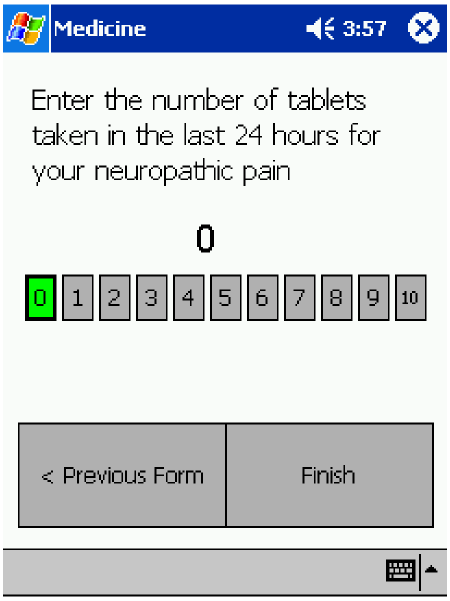
User Characteristics

The choice and design of the solution must take account of the type of person entering the data. Good technical solutions are of little benefit if the users cannot use the system or use it incorrectly. This is especially important where use is voluntary – hard to use systems will not be used at all.

Occasional users will not have time to learn complex input forms. They require simple forms with simple options. A series of questions, one per screen, is a good way to get the data required. This is especially important when gathering data from technically inexperienced or resistant groups, for example, elderly patients. This becomes more important where the users are based away from local support, for example, at home or on the road.







Regular users will require efficiency when entering data. This is vital where data collection is a large part of their daily work and may be seen as a burden if it takes too long. This is especially important where users are familiar with paper-based systems (laboratory notebooks, manual patient records), which are quick and flexible.

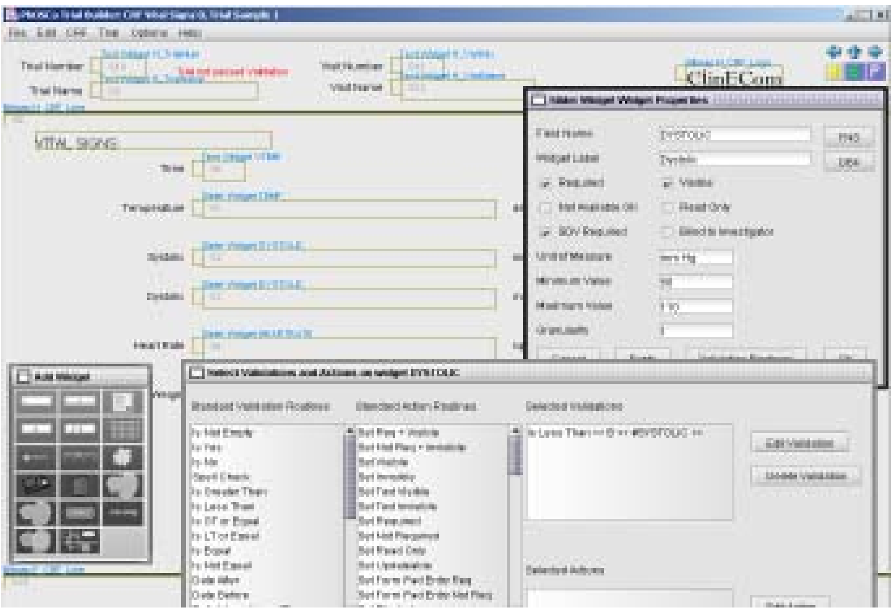
Whatever the target user group, interface prototyping and investigation is vital when designing these systems. The best judges of the usefulness of the interface are the people who will use it.

Form Design

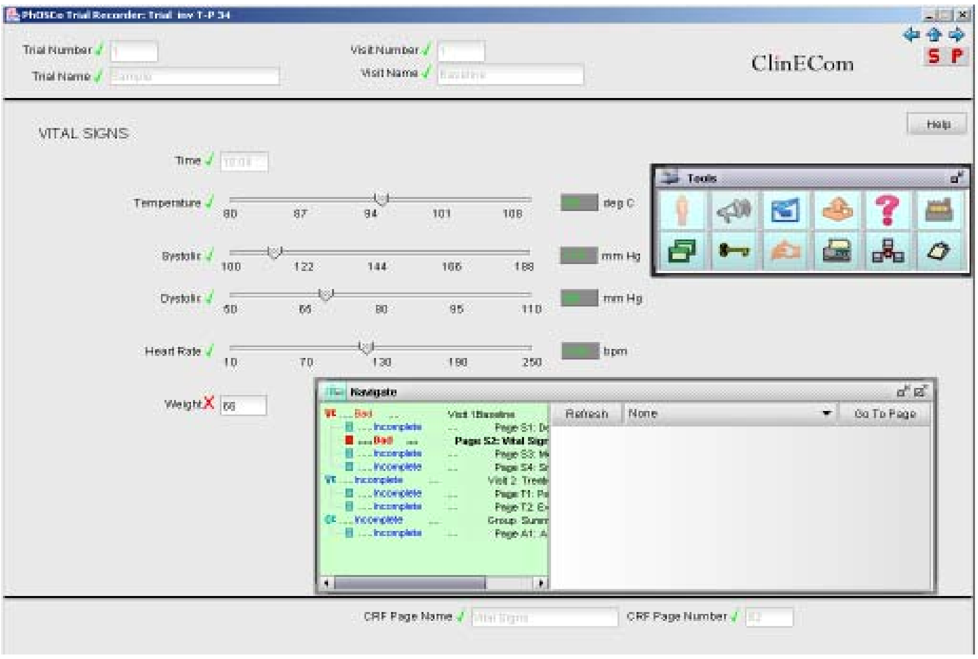
Form design in EDC solutions is very important however the system is implemented. This can be critical where poor form design skews the results and invalidates the data. The different format of the data collection medium compared to traditional paper based methods presents both designers and users with challenges – smaller screens, different forms of data input and user resistance. Trying different approaches with real users and getting external validation should both be investigated before agreeing a particular solution.

Any system designed will almost certainly need updating at some time. This is especially true where one EDC exercise is only required for a small number of cases, but that many such exercises are likely, for example, in Phase 1 Clinical Trials. This makes it important to be able to alter the system to design new forms without the need for system changes or costly third party support.

Design systems should allow you to maintain libraries of frequently used forms (for example, vital signs). They should allow you to apply validation rules, screen layout, help systems and workflow. They should also allow you automatic deployment to user platforms without the need for a complex rollout mechanism.



An example of a form designer used to produce the following user interface



Without an effective form customiser, companies can easily find themselves locked into an expensive and unsatisfactory relationship with a supplier. However, such flexibility comes at a cost that can only be justified if required.

Input Validation

One of the major benefits of EDC is that data entry can be validated immediately rather than some time later, when it is too late to re-collect the data. Most of the systems described above have some form of validation. Individual fields can be validated against fixed or flexible boundaries or permitted dictionaries of values. They can also be validated against other fields, for example patient weight must be no more than +/- 10% of the previous occasion it was recorded.

Validation can also occur at form level or at entire data series level, for example, printing a warning message if the value is more than 2 standard deviations from the mean of previously collected values.

Workflow – Immediate Messaging

Often when data is entered into the system, the user requires instructions as to what to do next. This can be based on some simple logic using the input values or on a more complex analysis of the data. An example of the latter is active learning used to steer clinical trials. Depending on the input data, the user can be advised on which dose of the trial compound to give the patient in order to gain most information from the treatment. This can reduce trial time by up to 30%. This sort of facility requires complex analysis but is only possible with live data entry.

Immediate messaging can also be used to activate support if there is a problem or opportunity. Problems can be trapped and dealt with immediately if an alert is sent to support personnel. Also, it is possible to track what is going on and discuss this immediately with the user which presents a real opportunity to, for example, encourage further use of the system.

Immediate messaging is only possible if the interaction device is attached to the decision-making facility. This may be performed on a central server accessed, for example, by fax, Internet, on a local off-line laptop or Tablet PC. However performed, the decision-making engine must be able to respond back to the user immediately.

Workflow – Subsequent Activities

As data is collected live it can be passed on to other parts of the organisation immediately. Collection of shelf contents in a supermarket is useful for staff tasked with filling the stores, but it can also feed directly into the central ordering facility that automatically requests replacements. Data collected in a laboratory may need approval before it is released for general consumption.

Integration into further workflows is only useful if data is transferred automatically and immediately to the next point in the chain. If data must be transferred manually (for example, manually attaching a document to an e-mail) it may either not be done or may be delayed. Workflows should also be two way, allowing feedback to the user of the results of subsequent activities. Because the data is collected so much quicker, decisions can be made using it without waiting for it to be passed back.

Off-line vs. On-Line Data Collection

One of the key driving forces behind decisions on technology is the connectivity of the data collection device. On-line systems such as client-server PCs, WiFi networked PDAs, web browser systems or fax-based systems are always in contact with the server. Data is never saved locally, it is always sent through to the server. The data is immediately available for further processing and responses can be based on all other collected data. Messages can be sent back to the user immediately (for example, via on-screen messages or faxes sent to the user). These types of systems are always preferable, but limitations may make their use impossible.

Off-line systems first gather data locally then send it in to the central server at a later date. These may be required where continuous connection is impossible, such as in hospitals and in remote outdoor locations. Off-line systems allow the data to be reviewed prior to dispatch. Depending on the power of the data collection system, they can allow a great deal of validation and decision making locally. Data transfer is, however, delayed and may not occur if it is forgotten. Also, complex logic may be required to ensure the local and central systems are in step if both are permitted to edit the same data. Local data storage is required which may be quite large and could, for example, easily be beyond the capabilities of a PDA

Post Processing

Because the data is available centrally much more quickly than using traditional methods, post processing can be performed at a much earlier stage. This may include statistical analysis or decision-making tools, or confirmation that the recorded data is within some specific targets. When adopting EDC it is important to consider how to benefit from the timely gathering of the data to make decisions earlier.

Integration with other Data Collection Processes

Whilst EDC is an important part of the data gathering process, it is not the whole story. Additional data may come from corporate databases, external data feeds or hardware devices that feed into the system. For example, consider a sample of material being submitted for assay. This fact is entered onto the system along with the barcode of the packet containing the sample. The sample is then dispatched to the lab for specific analysis. The results must be fed into the system and matched up to the original request. Full integration of the EDC, workflow and LIMS systems in this way can significantly reduce turnaround time and errors.

When planning fully integrated systems of this nature, it is important to allow for the very different forms of data gathered in each cycle. Devices such as mass spectrometers can gather large amounts of data that may not fit in with the simple data structures of an EDC system without further processing. Also, lab data may need to be specially integrated with the data structures of a fixed EDC system.

Regulation

Many EDC solutions must be deployed in environments regulated by government agencies. These agencies have a good record for ensuring that companies produce secure and reliable systems, but the rapid growth in electronic systems is making it difficult to keep up. Widespread use of technologies, such as electronic signatures, is not advanced and thus proving an EDC system can be difficult.

The US Food and Drink Administration (FDA) cast a long shadow over companies wishing to exploit EDC in the pharmaceutical sector. Although the accompanying 21CFR Part 11 regulation appears to be in the process of simplification to stimulate development in this area, many organisations are being held back by the FDA's unclear stance. This is an area that needs consideration at the start of any investigation of EDC but should not be allowed to impede it.

Benefits of Electronic Data Capture

The descriptions above demonstrate the wide benefits of EDC. The following list is a summary to help show how an investment in an EDC solution can quickly be repaid.

- Remove slow human input and data transfer stage - The manual re-entry of data recorded on paper is expensive and unreliable. EDC removes this step altogether.
- Immediate validation of input - Immediate validation of data entry and transfer trap errors early and help to eliminate them.
- Data can be gathered in an easily processed form - Data entry is quick and efficient and tuneable to the user population.
- Instant access by co-workers - As soon as the data is on the system, other staff in the organisation can see it and use it.
- Data is searchable and easily categorised - This is especially important when compared to paper records such as lab notebooks.
- Feed into workflow - Subsequent processing can proceed immediately the data is received.
- Quick decision making - A critical benefit is that a decision point in a project can be reached much more quickly, saving both time and money.

Case Studies

The following demonstrate how EDC has been used in practical situations and how this has been a major benefit to organisations. The following short descriptions show ways in which it is being deployed and some of the benefits.

Clinical Trials using Adaptive Learning

To ensure they are statistically valid, clinical trials need large numbers of subjects (patients). This is especially true of Phase 2 (Dose calculation) and Phase 3 (Effectiveness) trials. Advanced statistical techniques can be used to steer the trial to ensure the maximum information is extracted from the minimum number of subjects. The software allocates a dose of target compound or placebo based on the patient condition and the gaps in the system's knowledge.

To ensure this happens effectively, the information must be fed into a central system where the calculation occurs. The response must be then sent back to the investigator. For conditions where immediate treatment is vital this must occur very quickly, potentially from anywhere in the world. The results of the treatment must also be fed back quickly to ensure the knowledge base is kept up to date for further treatment allocations.

A major pharmaceutical company approached Tessella to provide a system to exploit these techniques. A phase 2 trial was to be deployed globally in around 200 centres. The equipment in these centres was highly variable, and the lowest common denominator was a phone and fax system. The decision was thus taken to use fax based data submission and dose allocation responses.

Tessella developed the fax handling software using an off the shelf Optical Character Recognition (OCR) package that decoded the incoming faxes and sent responses back again. We also developed a flexible database and a management reporting and administration suite. The statistical calculation engine was provided by Duke University in the USA. The entire system was supported 24 hours per day by a Tessella team.

The clinical trial ran for 18 months, gathering data from approximately 1000patients. Using the advanced analysis, 300 fewer patients were required before the end conditions were reached. The EDC approach also meant that the last patient form was received only a few weeks after the end of the trial allowing further investigation decisions to be brought forward significantly.

The use of EDC had other benefits beyond the adoption of advanced statistics. The trial manager was able to maintain a much better picture of the progress of the trial and control progress accordingly. Also, he was able to react to events more quickly, for example, phoning investigators who had submitted subjects, to encourage them to submit more. This and the benefits above led to a saving of over $3 million.

This technique is now being generalised for other trials. Tone phone and PDA front ends are being prototyped, and in some cases, deployed.

Macaulay Land Use Research Institute

The Macaulay Land Use Research Institute (MLURI) is a multidisciplinary-based research institute located in Aberdeen, Scotland. They carry out research into the physical, environmental and social consequences of land use. Their research station in Hartwood, Lanarkshire carries out research on the grazing ecology of sown swards and the development of sustainable management systems. This involves the collection of botanical information from a field.

Originally, MLURI's Point software was used to record botanical information. The program was written in Pascal and had been run for many years on Husky Hunter handheld devices. The Hunters have now been replaced with Husky Fex21 machines, which are handheld PCs running Pocket PC.

Tessella was asked to migrate the Point application to the new platform, making use of the Pocket PC Graphical User Interface (GUI).

Tessella developed Point2 for the new Husky Fex21 devices using Microsoft eMbedded Visual Basic, part of the eMbedded Visual Tools suite which is designed specifically for creating applications for Pocket PC devices.
The new Point2 application for the Husky is a significant improvement over the old application that ran on the Hunter machines. Point2 stores the field data as a text file, which can be easily transferred to a desktop computer for further analysis. The text files can be saved to the device's ROM or to a storage card if installed.

The provision of a GUI makes the application much easier and quicker to use. Now, instead of having to enter data into the system via the keyboard, MLURI researchers can use the stylus to interact with the various elements of the GUI. This stylus is the portable version of the mouse and facilitates quick data entry, no matter how unfavourable the physical environment.

Unlike the desktop PC, portable computers can vary significantly in terms of processor platform, memory capacity, and input/output strategy. As a result, designing applications to run on a spread of vendors' hardware can be challenging. This is partly addressed by the eMbedded Visual Tools, which can provide a framework for developing for a selected target platform.

Clinical Trials

(Source: Bio-IT World)

Sylvia Collins, Novartis Vice president has implemented EDC clinical trial solutions at two major pharmaceutical companies. Whilst at Bayer, she worked on the adoption of EDC solutions and by 1995 100% of trials used EDC. Time between the last patient visit and database lockdown was reduced from an average of 12 weeks for paper-based systems to just 4 weeks. Now at Novartis, Collins says that the lag time has reduced yet further and she can anticipate a time when it is reduced to just 1 day.

Novartis has taken the important step of bringing the ownership of the product in house. Based on the popular PhOSCo product, the system is continually being developed. It is deployed on 3000 laptops worldwide and had been deployed on 150 trials within 18 months. Database licence savings alone have been over $50 million. The configuration and deployment of the clinical report forms takes around 9 weeks but Novartis hopes to improve this considerably.

Implementing a system of this scale was a major challenge, according to Collins. Strong leadership, change management and broad authority were required. Most importantly it needs to be pushed forward as a business development, not an IT development.

The PhOSCo product is available for purchase, on a per trial or corporate basis, and is supplied with full Java source code for customisation and integration.

Mobile Data Entry and Invoicing

Bottled water delivery companies often incentivise their delivery drivers by offering bonuses based on persuading customer to take more than they ordered. This is very successful but creates a paperwork headache as the invoice cannot be printed and posted until the driver returns to base and indicates how many bottles and cups were actually delivered, rather than the number ordered.

One of Tessella's customers, a world leader in bottled water delivery, is developing a system for providing drivers with PDAs connected via mobile phone cards to base. Once a delivery has taken place, the driver enters the amount actually sold onto their PDA. This is sent back to base using the GPRS card and is passed into the Oracle Financials database. The invoice can then be printed and posted before the driver is back at the depot, improving cash flow and reducing credit times significantly.

The system has other benefits. Routing information can be passed to the PDA so the driver has the system in the vehicle. Also, emergency delivery information such as extra deliveries or cancellations can be sent to the cab, allowing for extra sales or removing wasted journeys.

What the future holds for EDC

Electronic Data Capture is set for rapid growth over the next few years. For example, EDC use in clinical trials has moved from 12% to 24% in just two years. Many current developments are expected to fuel the growth and will enable companies to achieve large returns on investment in a short timescale.

A leading stimulation to growth will be the reduction in price and increased sophistication and power of small handheld devices. This will include laptop PCs, PDAs and especially tablet PCs, which are expected to make a significant contribution in this area.

An aspect of technology that will also drive growth in EDC is improvements in connectivity. Increased use of GPRS and 3G mobile connections and wider access to WiFi will make communicating with central resources especially easy. Also, more and more devices will have connectivity built in with wireless cards delivered with the system.

These developments are only useful if accepted by the users. A general wider acceptance of technology and especially hand held devices will make take up easier and acceptance more straightforward.

Increased integration with other forms of data collection will be lead by the widespread adoption of RF Tags. This will enable the easy combination of human and automated data collection in a simple, single system.

Software improvements will also continue. User interface design will improve, but so will customisation and form design, and integration with other business systems as EDC becomes a mainstream part of the business rather than an interesting add-on.

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