IBM

Pharmaceutical Clinical Development

Realising the full rewards of Electronic Data Capture (EDC)

Colin Spink
Life Sciences Industries' Specialist

e business

Contents

Key Topics

- *Explores the opportunity for improving clinical trial processes with Electronic Data Capture (EDC)*
- *Assesses the challenges in planning a successful corporate EDC strategy*
- *Outlines the role of technology, logistics, process and organisational change in implementing a successful EDC solution*
- *Provides a route-map to implementing a company-wide EDC solution.*

Executive overview

Clinical trials play a key role in the pharmaceuticals industry. With a large number of drugs coming off patent, pharmaceutical companies are under pressure to develop and test new drugs as quickly and efficiently as possible. This requires an increase in clinical trials and a reduction in the time cycle of those trials.

The challenge today is to increase the speed with which new, successful drugs can be trialled and approved. Pharmaceutical companies also need an efficient process for eliminating unsuccessful trials earlier, which enables resources to be deployed more effectively elsewhere. Additionally, since clinical trials are a major overhead, improved cost control and effective management of resources are also key corporate objectives.

One of the major barriers to addressing these challenges is the current reliance on traditional paper-based processes for recording patient information during a trial, resulting in a 3–4 month lead-time before information becomes available. Not only does this delay the overall trial process but it also leaves pharmaceutical companies vulnerable to flaws in the trial process that go unnoticed for several months.

As a result of these pressures, analysts expect EDC to become increasingly used in the pharmaceutical sector. However, while pilot studies have been successful, pharmaceutical companies have not yet implemented EDC across the majority of their clinical trials. They are constrained by a lack of strategic planning, the varying requirements of each trial, the relative immaturity and fragmentation of the EDC software market and the need to address both process and organisational change.

Highlights

Organisations like IBM can play a significant role in successful global EDC deployments.

Technologies like EDC will be key for helping pharmaceutical companies reach annual drug application targets, allowing them to remain competitive.

This paper outlines why organisations, despite the clear benefits and opportunities that EDC offers, find it difficult to scale up their EDC pilots. It highlights the need for a more strategic approach to EDC and establishes the key areas that need to be addressed to ensure a successful implementation.

From developing an EDC strategy, through software selection and deployment, to process change and managing organisational change, the paper explains how to overcome the perceived barriers to widespread EDC deployment to gain significant business benefit. It also provides an overview of the role an independent, third party organisation such as IBM can play in a successful global deployment, with services ranging from undertaking a strategic review to providing help desk support for investigators.

Introducing EDC
The huge excitement surrounding genomic developments may have raised media interest in pharmaceutical companies but the financial reality is that, with large numbers of drugs coming off patent, pharmaceutical companies are under increasing pressure to develop drugs ever faster.

Indeed, some analysts assert that to maintain a competitive position, pharmaceutical companies will have to produce four to six new drug applications per year. This is an extremely aggressive target and it is hard to see how it can be attained using current paper-based processes for managing clinical trials.

With approximately 10,000 clinical trials run annually and the increasingly complex nature of clinical trial forms, the pharmaceutical sector would seem a prime area for the introduction of EDC – and indeed there are few companies that have not run an EDC pilot. Yet the combination of stringent regulatory demands and a lack of strategic understanding of the implications of EDC implementations have constrained organisations from attaining real business benefits throughout the majority of their clinical trials.

Highlights

EDC helps reduce invalid data entries and speed up the availability of drug trial information.

In the clinical trial arena, EDC enables doctors to directly record trial data on-site, using preconfigured software instead of the traditional paper form. The software validates the data at the point of entry, communicates it to a central server and raises alert queries arising from data entry.

EDC can be implemented in one of two ways – either by providing a configured laptop to an investigating doctor, or by using the Internet for online data entry into a central system.

The technology's appeal is twofold. Firstly, intelligent software verifies the patient information as it is being input against predefined criteria which ensures fewer invalid patients and an improvement in data quality. Secondly, the information is loaded into a clinical trials database either in real time or near real time, making information instantly available to the pharmaceutical company – Data Managers (DMs), Clinical Research Assistants (CRAs) and management – thereby overcoming the traditional delay period.

A variety of business benefits, including improved time to market and more effective management, can be obtained from EDC implementations.

Business benefits

Pharmaceutical companies that have already undertaken pilot EDC implementations will be aware of the benefits that can be attained as a result of data entry at site and data validation at input and the availability of near real time access to trial information.

It is worth recapping those benefits here:

Effective management of clinical trials
Improvements in data validation at the input stage ensure that fewer invalid patients are initially signed up for the trial. This reduces the number of additional recruits required and also reduces the overall length of the trial. Since patient recruitment is one of the most time-intensive and costly phases of clinical development, with about 80 percent of trials delayed one month to six months due to patient recruitment, improvements in first time patient acceptance levels will play an important role in clinical development and cost reduction.

Highlights

EDC can improve the timeliness of patient recruitment and help bring products to market more rapidly.

Immediacy of information enables companies to cancel unsuccessful trials earlier, while efficiently run trials can improve perception in the marketplace.

The Internet can have a further role to play in improving the timeliness of patient recruitment. Pharmaceutical companies are currently experimenting with disease specific Web sites that enable people suffering from a disease to register their interest in trial participation. Additionally, competitive recruitment – with tables posted on a Web site – is ensuring investigators are incentivised to recruit patients to a deadline, or miss out on the opportunity as others run more successful recruitment programmes.

The availability of real time information will also ensure the pharmaceutical company gets an early warning of slow recruitment in a specific trial, enabling it to take action to avoid the trial overrunning.

Improved time to market
In addition to reducing the trial length through efficient patient recruitment, the availability of accurate information in real time also enables the pharmaceutical company to rapidly undertake statistical analysis of the trial results as soon as the last patient has completed the study. EDC also provides easy interim analysis of data during the trial if this is required.

Improved utilisation of resources
This information immediacy also enables a company to pull the plug on unsuccessful trials earlier in the process, ensuring costly resources can be effectively deployed elsewhere.

Improved perception
Investigators, as doctors, are also drug prescribers and as such their perception of a pharmaceutical company can be influenced during participation in a clinical trial. A well run electronic clinical trial that minimises the investigator's administrative overhead will improve overall perception. However, a poorly run electronic trial with inadequate local support and help desk could have a damaging impact on perception.

Improved data quality

On-site checking through data validation at the point of entry and rapid query response makes this possible. While paper-based processes can result in queries being raised up to six months after a patient visit when the investigator is unlikely to remember the information, the speed in which EDC raises queries plays a significant role in speeding up the clinical trial processes and reducing overall costs.

As the figures below demonstrate, the benefits achieved in real world EDC deployments are significant. These results were collected from ten phase three studies, which together involved 6,700 subjects and were conducted over three-and-a-half years. IBM provided consultation, deployment services and support for half of these studies.

	EDC	Paper
Percentage of enrolled subjects that are invalid	7.5%	15%
Cost of raising and resolving a query	$10	$60
Number of queries/subject	0.25–1	5–20
Percentage of data requiring correction	0.05–0.1%	1–2%
Percentage of queries caused by missing data	0%	48%
Percentage of queries caused by inconsistent data	5%	35%
Percentage of queries caused by out of range data	0.1%	8%
Percentage of queries requesting clarification	0%	6%
Percentage of queries due to invalid data	0.05%	0.1%

Note: Query percentages are based upon number of queries raised when using paper

The significant reduction in queries – and the attendant cost reduction in dealing with the remaining queries – provides a guide to the improvements in data quality and clinical trial efficiency. This may lead to a role change for CRAs and DMs.

The obstacles to success

Despite the clear efficiency and time to market benefits outlined above, organisations have not yet successfully extended their pilot EDC deployment to support a majority of clinical trials.

A number of factors combine to challenge the viability of wide-scale EDC implementations – none of which are insurmountable but all require a strategic approach.

Key obstacles include:

Isolated implementation
Taking a bottom-up rather than top-down approach means that EDC is implemented in isolation from other corporate initiatives; the initiative has no clear business plan and, critically, no senior corporate sponsor. Without these, EDC will not deliver the widest business benefits or be aligned with your corporate objectives.

Lack of strategy
Without a long-term strategy for EDC implementation across many clinical trials, companies have no clear path for moving from the pilot stage to a successful, company-wide solution.

Lack of process change
EDC is not simply replacing paper processes with electronic processes. It delivers faster, more accurate information that has an implication for existing business processes. Companies have not always recognised that EDC will require process change – and that has an impact on the way they need to communicate and manage the process transformation.

Software immaturity
There is no de facto standard in EDC, so software selection is complex. With around 70 EDC vendors to choose from, assessing which product and vendor is the best choice for your requirements now and in the future is extremely challenging. In addition, even the best software packages may need to be customised to meet specific requirements, or extended to support the significant number of trials that a pharmaceutical company would need to run each year.

Highlights

Pharmaceutical companies must take a strategic approach to the deployment of EDC in order to achieve significant, long-term business advantage.

The strategy should not only encompass today's technology, but also consider future developments that may impact the clinical trial process.

Inability to measure success

Pharmaceutical companies need to establish metrics up-front on their existing paper-based processes to provide a clear comparative position for the deployment of EDC. They must also ensure the collection of metrics throughout the trial.

A Strategic Approach to EDC

Pharmaceutical companies must take a strategic approach to the deployment of EDC to achieve significant, long-term business advantage. This must embrace both a new culture and corporate processes so they can exploit EDC to attain commercial benefit.

A strategic implementation of EDC ensures that it is both implemented in tandem with other corporate objectives and that senior sponsors play a role in instigating the necessary process and organisational change. It also ensures that the EDC technology is integrated into the corporate IT infrastructure to enable rapid access to clinical trials information throughout the company, which drives new business processes.

The strategy should also encompass not only today's technology, but envision how future developments will potentially impact the clinical trial process. Considerations for the future include:

- *Managing by exception will enable CRAs or DMs to focus only on the areas flagged as problems by the software*
- *Direct data entry should remove reliance on paper-based records and eliminate the need for Source Data Verification (SDV). There are regulatory issues associated with direct data entry: source data must be kept and archived at site and it must be possible to differentiate the data that has been entered directly and that which has not. Some companies are encouraging direct entry of data – indeed, a recent survey undertaken by Silico Research on behalf of IBM and others revealed that 22 percent of participants were entering data directly into the EDC system*

Four key areas - technology, logistics, process change and organisational change – need to be addressed for successful deployment.

- *The use of wireless devices – by physicians or patients themselves – is becoming more prevalent and will have implications for usage patterns*
- *EDC software also needs to link into Customer Relationship Management (CRM) solutions to ensure the sales force knows when visiting doctors, whether they are participating in trials, so they can leverage the existing commercial relationship.*

Implementing the strategy

Once a strategy has been agreed there are four key areas that need to be addressed to ensure a successful wide-scale EDC deployment: Technology, Logistics, Process Change and Organisational Change.

Key success factors include ensuring a high level sponsor and addressing each of these areas in unison, not sequentially. EDC pilots are useful in facilitating user acceptance and enabling processes to be trialled. Companies can choose a limited, low-key pilot study to minimise risk although high profile pilot studies will raise awareness of the technology and ultimately bring greater rewards. Additionally, it is important to collect metrics to demonstrate the benefits of EDC. Ideally these should be collected for both traditional paper-based processes and EDC implementations to measure improvements.

Regulatory compliance is essential for success and will influence each of the four key areas.

Regulatory compliance – such as Food & Drug Administration (FDA) compliance is essential and will influence each of the four key areas. Under the FDA compliance requirements, implementation of EDC has to meet 21CFR part 11. Both software and Information Technology (IT) infrastructure need to satisfy specific requirements of 21CFR part 11 and all processes should be documented to ensure they can be audited by the FDA.
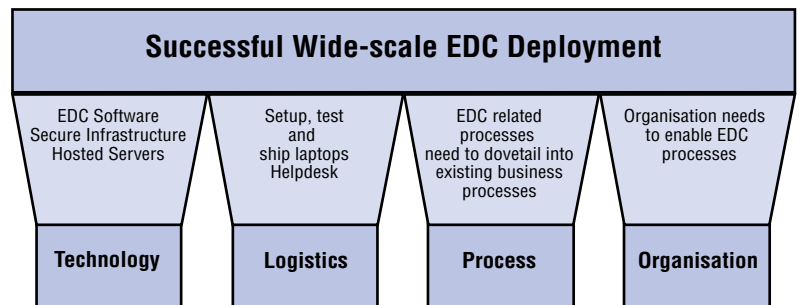
Highlights

It can be beneficial to work with a third party organisation that has experience in implementing EDC projects.

A robust, secure technology infrastructure is essential – consider a hosted service that delivers guaranteed performance levels.

To achieve this level of compliance it can be beneficial to work with a third party organisation that has gained experience of implementing EDC projects that meet the required compliance standards.

The four foundations of successful EDC

Successful Wide-scale EDC Deployment			
EDC Software Secure Infrastructure Hosted Servers	Setup, test and ship laptops Helpdesk	EDC related processes need to dovetail into existing business processes	Organisation needs to enable EDC processes
Technology	**Logistics**	**Process**	**Organisation**

Technology

Creating a robust, secure infrastructure is essential. While initial EDC pilots may be hosted on existing IT equipment, as the roll out increases to support perhaps hundreds of trials annually, the pharmaceutical company will need to invest in additional hardware and network services. While this can be done internally, one option is to buy a hosted service that will deliver guaranteed performance levels globally.

In addition to the global scope of clinical trials, the provisioning organisation will need to be able to support the dynamic clinical trial environment.

Security is also a critical issue. The FDA lays down guidelines for the management of clinical trial data, which demands high levels of information security. In addition, with both external and internal users accessing the same database – particularly when using online systems – there are security protocols that have to be addressed.

The Silico Research study referred to above questioned investigators and those conducting clinical trials on their view of EDC. Security was raised as a key issue, with 35 percent of respondents citing confidentiality concerns and 37 percent security concerns with the software. Therefore, in addition to ensuring that the technology and infrastructure is secure, it is essential that an organisation communicates its commitment to delivering high levels of security to allay the fears of trial participants.

Highlights

Making the right software choice is key and requires an understanding of the different products available.

With around 70 software providers in this area, making a long-term viable software choice is undoubtedly a challenge. Over the next five years the market will consolidate, resulting in both players and software products disappearing — potentially leaving your EDC implementation unsupported. Making the right software choice is key and requires understanding of not only the different products on the market, but also links back to an organisation's strategic deployment of the technology.

Software products are split between off and online solutions, either located on a laptop or using existing Web browser software to enter clinical information online directly into the clinical trial database. In addition, there are a growing number of hybrid solutions that support both off and online deployment.

Your organisation's choice of software will obviously be dependent on how you plan to deploy EDC, which indeed may vary according to clinical trial type, size and geography. There is no right or wrong approach, but advice will be required to ensure the solution meets your business needs.

Integration with existing systems is another important consideration.

Additionally, EDC software's integration with existing systems is a key consideration. Examples of relevant existing systems include:

- *In-house clinical data repositories such as Clinical Data Management Systems (CDMS)*
- *Safety systems*
- *Randomisation systems and drug supply systems — to optimise use of what is often a limited supply of the clinical trial drug.*

The software is also evolving rapidly — although it is often hard to distinguish real product from demoware. Working with an independent third party can help to ascertain both existing product functionality and attain a realistic view of product developments and how these can impact upon future EDC expansion throughout the organisation.

Logistics

Consistent global support is an essential element of the successful deployment of EDC. Simplicity is key to widespread user adoption, which means that laptops must be preconfigured — with the right local number for Internet dial up, for example. The key is to minimise the distraction for the investigator, enabling them to concentrate on inputting data rather than wrestling with technology.

This support must encompass not only the initial roll out of technology, but also help desk support for the investigators using the laptop or web browser solution. A below par help desk can seriously compromise the success of an EDC implementation.

However, many of the EDC software providers are small companies without the resources to provide support for more than a few clinical trials. In this case, a third party with a broad global reach and experience of the pharmaceuticals industry can provide both initial deployment and help desk services. As with any help desk, it is essential to create a Service Level Agreement (SLA) that supports the specific needs of investigators globally.

The Silico Research survey also highlighted the need for improved training, both to enhance overall IT literacy and deliver focused EDC software training. Within this training programme it is important to deliver the right training at the right time and place that, where possible, uses familiar data. A customised course supported by excellent training documentation provides significant improvements to user acceptance levels.

Process

As most pharmaceutical companies have now discovered, a successful pilot EDC deployment cannot automatically be scaled up to support the majority of clinical trials. To address the problems highlighted above, organisations need to introduce process change to support the software and to ensure the use of software interfaces with existing organisational processes.

Highlights

A number of internal processes – form design, procurement, data entry and education – need to be addressed to ensure a streamlined operation for when the project scales up.

For example, the EDC software packages do not, on the whole, provide a way of centrally entering lab results data into the clinical trial – a limitation that creates the need for a 'work around' solution. While this can be handled manually in small pilot trials, the process becomes costly and burdensome when scaled to support larger trial numbers, undermining the cost benefit arguments and creating potential delays in the faster clinical trial process.

Areas to address include:
- *Design – the traditional design and approval of the paper based-study form can be replaced by a totally electronic process by designing the form and validation checks straight into the EDC software and using electronic workflow processes to handle review and approval. Additionally, depending on the functionality of the software it should be possible to reuse all or part of the form in further trials. Demographics and adverse events are examples of pages that can be standardised*
- *Set Up – the process of deploying laptops to investigators will be a new one to a pharmaceutical company embarking on EDC and needs to include laptop procurement, configuration, ISP procurement, testing and shipment*
- *Initiation – investigator training needs to be addressed, as does the process of enabling an investigator to change the system password on receipt of a laptop. Education could be provided with online training, group training or one-to-one training from CRA. The choice is dependent on both the functionality of the software and existing user skill levels*
- *Study Conduct – the preferred data entry process should be considered. This can be either on paper first, from patient notes or directly onto the system. Ownership of queries is also important as is defining a timeframe for query resolution. It is also worth considering incentivising the investigators to enter data in a timely manner and to respond to queries within the specified time frame to avoid clinical trial delays*

- *Reports – controlled access to reports is key since inappropriate access could result in the 'unblinding' of a trial, which could compromise results. The reporting policy also needs to include the process for requesting additional reports*
- *Archiving – rather than the traditional 'third copy', investigators will need a record of their trial data. This could be provided with a CD, but additional access to archives may also be required. Additionally, country specific and legal requirements need to be taken into account*
- *Service Level Agreements – where activities are provided from outside the business, either by IT support or a third party, SLAs need to be realistic and in place.*

Organisation

It is equally important to address the impact of EDC on the existing organisational structure. The introduction of a global EDC strategy has huge change management and cultural change implications. Throughout this process of change, it is essential that business and IT functions in the pharmaceutical company work towards clear, common objectives.

The impact of EDC on the existing organisational structure needs to be looked at, ensuring that business and IT functions work toward clear, common objectives.

EDC may require role changes for certain employees. For example, the traditional role of the Data Manager will change, providing an opportunity for broadening that specific role within the clinical trial process, perhaps to encompass configuring EDC software for the studies they are responsible for. Furthermore, as monitoring by exception becomes the norm, it is likely that the CRA and DM roles will merge, creating a completely new role within the clinical trial process.

One of the most significant shifts is that the tasks required to support a clinical trial are now loaded to the front of the process. While in the past, the design, approval and creation of the database and validation checks could be carried out in parallel with patient recruitment activity, they are now required to be ready from day one. This front loading will require additional resources to be deployed initially to avoid delay.

Organisational changes that increase teaming and parallel working will support front loaded processes and increase the speed of trial deployment.

Additional role changes will include CRAs and pharmaceutical partners such as Clinical Research Organisations (CROs).

Successful organisational change will not just ease the process of EDC deployment, it will proactively exploit the real time availability of highly accurate data. The scale of the changes, the inter-departmental impact and potential impact on the drug development process mean that visible board level commitment is essential for successful implementation. A company-wide deployment of EDC attempted by a single department would be unable to address the wider changes in job role and process required to ensure it becomes part of that organisation's culture.

Successful EDC Deployment

A technology that requires a strategic implementation will also require work with experts in the field who understand both the pros and cons of software choice and implementation and the business challenges associated with deployment and cultural change.

IBM has more than five years' experience working on EDC projects and can deliver end-to-end solutions from initial design and implementation to the global roll-out of e-clinical solutions, including EDC internal implementations or outsourced implementations.

The first step must be a strategic review that assesses how EDC will be implemented across the organisation, with objectives defined and clear sponsorship allocated. This will include software review and choice and subsequent gap analysis to define areas of process and organisational change.

Maximising the value of EDC – an end-to-end method

Implementation Plan		
Therapeutic Teams	Management Systems / Laboratory Data / Medical Term Coding / Safety Reporting / EDC Software Application / EDC Software Application / EDC Software Application / Trial Setup / Trial Rollout/Logistics / Helpdesk/Support / Hosting and Secure Infrastructure	Statistical Analysis / Submission

Global Reach
Local Support
Scalable
Experience
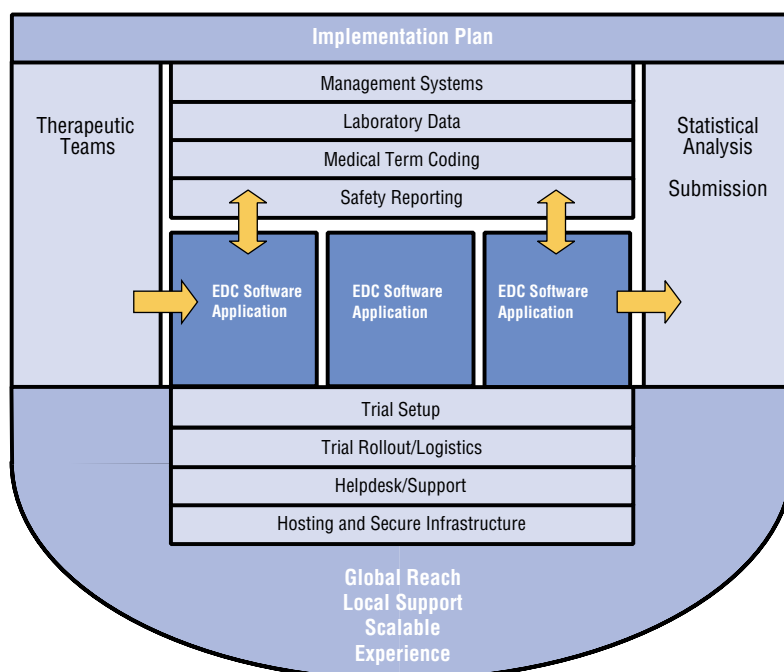
There are a number of options available for companies wishing to overcome the problem of working with immature software products.

Software Review

There are a number of options available for pharmaceutical companies wishing to overcome the problem of working with small, unproven suppliers with functionally immature products in the EDC marketplace.

Companies can:

- *Develop a system in-house*
- *Further develop existing, open source software*
- *Buy source rights*
- *Form a consortium to develop or further enhance a system*
- *Establish a close relationship with an existing vendor*
- *Invest in a vendor.*

IBM can help guide and support companies through these choices. It has also gained broad experience working with a variety of EDC software applications, including over three years' experience with PhOSCo open source software, an EDC solution which has been deployed worldwide by a leading pharmaceutical company.

EDC Process Review Workshops

EDC Process Review Workshops help clients plan the detail of their EDC usage. Run by facilitators with extensive EDC and pharmaceutical experience, the exact format of a process review workshop will vary with need, but typically IBM will facilitate a two-day workshop with the attendees from all the departments likely to be affected by the use of EDC.

The output from the workshop is usually:

- *A high level process flow for the business's use of EDC*
- *A high level description of each of the processes*
- *A provisional owner for each process*
- *A change management review outlining desired roles, required responsibilities and training needs*

Follow-up activities are often smaller focused workshops to detail each of the process steps. Role definitions can be distilled from the process descriptions and then used as input to optimise the organisation for use of EDC.

Trial Set-up

IBM has performed this activity for about 20 trials. From experience, IBM practitioners understand what design features work well, how much flow control should be included, which data checks should be included and which are likely to be superfluous when using EDC.

Study Rollout

IBM has deployed laptops to over 1,000 sites in more than 30 countries worldwide. Study rollout also includes personalisation of the laptop and testing prior to shipping to the end-user, typically via the country representative of the client Pharmaceutical Company. IBM maintains an asset register to track the configuration and location of each laptop, which ensures effective systems support.

Helpdesk Support
IBM provides full helpdesk support to four continents. The hours of coverage are designed to meet each client's specific need.

Hosting and Infrastructure
IBM currently hosts the servers for a number of clinical trials. In addition, IBM can provide Virtual Private Network (VPN) access to the servers. IBM is able to scale this provisioning from a small number of trials to the hundreds of trials that a large pharmaceutical company might initiate each year.

IBM has also advised on how to meet EDC infrastructure requirements while assuring levels of security. In addition, IBM can help plan what EDC server functionality will be required in order to minimise the effort involved in supporting large numbers of EDC server instances.

Project Support
In addition, IBM's Supporting Therapeutic Teams service underpins an individual Therapeutic Team wishing to use EDC for one or more of their studies and requiring impartial EDC knowledge. IBM has performed this role for a client using the PhaseForward application InForm, but the service is software independent. Activities undertaken in this role include:

- *Providing an overview of EDC to the Therapeutic Teams: what it is, why and how it is used*
- *Assisting the Therapeutic Team with defining how the EDC application should be configured and which validation checks should be run in the EDC application*
- *Consolidating information required by the EDC vendor (e.g. application options, sign off authorities, users and sites)*
- *Defining how the EDC functionality should be used (e.g. Who should add notes and why, what to do if data is missing, who and when to freeze data etc)*
- *Assisting the client in determining the coding and laboratory data loading process.*

- *Defining the mapping specification between the EDC and CDMS applications*
- *Modifying the InForm generic training documentation to be specific to the client process and terminology*
- *Building and maintaining a documentation archive of EDC-related activities for subsequent archive by the client.*

IBM's end-to-end solution includes:

- *Trial set up*
- *Provisioning infrastructure and hosting servers for EDC applications*
- *Working with clients to define business processes for use with EDC through workshops*
- *Helping Therapeutic Teams to deploy studies using EDC*
- *Assisting clients in determining their infrastructure and security needs for use with EDC*
- *Documenting EDC related projects so that they are FDA audit-ready*
- *Help desk support*
- *EDC Software configuration.*

IBM's technological knowledge and EDC experience also enables it to assists clients in:

- *Requirements definition and package selection*
- *Using wireless technology with EDC*
- *Investigator portals*
- *Using On Line Analytical Processing (OLAP) technology to benefit from the immediacy of EDC generated data.*

IBM

Conclusion

The move towards electronic clinical trials is just a matter of time. With pharmaceutical companies increasingly submitting trial data electronically, it is inevitable that the FDA will eventually demand all information be provided in this format – although no date has yet been set.

With that is mind, and the proven business benefits that EDC can deliver, undoubtedly the successful pharmaceutical company of the next decade will have harnessed EDC across the majority of clinical trials.

The key to such success will be a strategic implementation of the technology. By working with an experienced organisation, such as IBM, who can guide and assist you in the four key areas of technology, logistics, process and organisational change, based on a well defined EDC strategy, EDC can become an integral part of the clinical trial process, delivering significant cost and time to market benefits.

About the Author

Colin Spink has been a member of IBM's Life Sciences Group (formally Pharmaceuticals Group) for eight years. For the past five he has worked with clients on EDC projects with trials in up to 200 sites.

During this time, Colin has gained wide experience of working with different EDC software solutions, both on and offline, and has run workshops to enable pharmaceutical companies to successfully deploy EDC to support corporate strategy. Colin's experience and expertise, alongside that of IBM's Life Sciences Group, is playing a key role in supporting leading pharmaceutical companies in their move towards e-clinical trials.

For more information

To learn more about Pharmaceutical Clinical Development visit:

ibm.com/solutions/lifesciences/

To learn more about IBM Global Services, contact your IBM sales representative (or Business Partner if applicable) or visit:

ibm.com/services