

# EDC PAST, PRESENT AND FUTURE

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It is no exaggeration to say that electronic data capture (EDC) is a practice of the new millennium; the introduction of technology into the collection and cleaning of clinical trial data has gained real momentum since 2000. Quintiles has embarked on 300 studies facilitating EDC since the turn of the century; 130 of these have since been locked. While early EDC studies were small and generally limited to Phase I and II trials, today 48 percent of these studies are in Phase III, a figure which demonstrates the confidence now placed in EDC. In total, Quintiles has run EDC at more than 19,000 trial sites worldwide, covering more than 310,000 subjects.

These figures—and in particular the number of locked studies—place Quintiles in a privileged and unique position in the industry. Complete studies provide a clear insight into the value of EDC across the entire trial process, from initial build to close-out. Until a trial's final outcomes can be evaluated, it is impossible to assess the difference EDC has made over the life of the trial. Quintiles continues to improve its trials management practice based on experience from each new study and it

is clear that in start-up, study conduct and close-out, EDC can benefit clinical trial sponsors and CROs alike. Correctly implemented and managed, EDC delivers accurate and up-to-date information, offering researchers the opportunity to analyze ongoing data, respond sooner to findings and derive clear and accurate conclusions from the final results.

#### Quintiles defines EDC as follows:

- > EDC is a service enabler, not a technology solution.
- > EDC enables access to real-time, clean, visible data; it facilitates the opportunity to improve the trial process, increase communication and create efficiencies in drug development as a whole.

In many ways, EDC has introduced technology to the pharmaceutical sector as a possible method of achieving efficiencies, rather than as a result of the industry looking to resolve a problem. For this reason, it is necessary to constantly challenge the use of EDC technology—to ask why it is being used and what benefits are intended to be realized.

Ultimately, however, EDC is not just about implementing a technology, nor is it just about introducing a more efficient front end to clinical research. EDC initiates a change in processes to ensure a clinical trial is run efficiently from start to finish, and changing processes in this way requires an alternative approach to service delivery. EDC will be truly adopted on an industry-wide basis only when the suggestion of implementing a paper-based trial begs the question: How do I do that?

There is much to be gained from EDC, but executing it is not easy. Even after implementing EDC, the temptation to continue or return to paper-based processes is very strong. Meeting the challenge involves asking trial personnel to abandon procedures that may have been followed for some people's entire careers and to put their faith in something new. That level of confidence can only be based on experience; therefore, it is worth sharing some of Quintiles' experience in order to promote confidence among others in this optimal use of EDC.

## THE PERFECT TRIAL

Trial sponsors often give many reasons for not implementing EDC during a clinical trial. For some time there has been the perception that a trial with less than eight patients per site is not appropriate; the small number of participants doesn't support the financial overhead involved in setting up the project.

Interestingly, although low patient numbers is a disincentive to EDC, so too is a high number of users. The argument runs that a new data collection system affects the people involved in a clinical trial, and each of those people requires training and ongoing support to get the best out of the system. Again, financial barriers—training and supporting remote sites in the use of the technology—have made CROs and sponsors less than enthusiastic

## Quintiles EDC Experience 2000-2007

Phase	Number of Studies	Number of Sites	Number of Subjects
Phase I	87	179	4,141
Phase II	53	1,759	17,161
Phase III	128	13,047	152,807
Phase IV & Registry	23	3,086	163,464
<b>Total</b>	<b>291</b>	<b>18,071</b>	<b>337,573</b>

about introducing a new methodology. Moreover, if a trial site is gathering only a few items of data from each patient, surely a complete EDC system is a little excessive?

Conversely, some trials are presented as being too complex for the use of EDC. These are trials that typically involve detailed monitoring requirements and heightened safety issues. In some cases, creating and managing an EDC system to match these requirements would be far too difficult and costly. Training and support costs once again place the idea out of consideration. In fact, complex trials place stress on personnel regardless of how they are conducted, and EDC in itself does not increase their complexity or contribute to an individual's stress level. However, until EDC becomes second nature to trial personnel, fear of the unknown will continue to play a large part in the industry's reluctance to implement change and EDC will continue to seem out of reach.

In fact, EDC is appropriate to use in each of these cases. Designed and implemented correctly, EDC offers simplicity rather than complexity. True, some of the technology can appear complicated, but frequently the extra features and functions technology providers deploy in order to differentiate themselves in the marketplace can obscure EDC's valuable streamlining benefits. One should not be dazzled by the "bells and whistles" of an EDC system, but concentrate on its central purpose—to facilitate real-time, clean, visible data. Some technology providers already know that creating increasingly complex systems to deliver more functionality is counterproductive. The required solution does not need to carry out complete data management functions; it simply needs to collect information accurately and efficiently.

It's also important to note that EDC is not a one-size-fits-all solution. Just because one EDC solution appears complex and offers functionality over and above the scope of most trials doesn't mean every solution will. When designing the trial and implementing EDC within that trial, the process of capturing data—and the technology through which the data is captured—should be kept as simple as possible and only supply what the trial team needs so they can focus on what they know.

## THE TRUE COST OF TRIALS

Cost often is cited as the reason why EDC cannot be used for trials and yet the overhead involved in running paper-based systems now seems to be accepted without question. The paper-based method of collecting and collating data costs money, but because this way of working is well-established, these costs are no longer examined.



To some extent, the break-even point—when it becomes economically viable to conduct a trial using EDC rather than paper—exists only because the cost of managing paper-based studies is largely ignored. In addition to the expenses of sourcing, marking up and transporting the paperwork, there are additional costs of data entry and storage. At the same time, trial personnel will always view the status quo as the cheaper option compared with a new technology-based system. For this reason, the concept of the break-even point is likely to remain until the number of EDC studies equals or outweighs the number of paper-based studies. This is something of a catch-22 situation, but it seems clear that the cultural barrier to introducing EDC is far greater than the financial one.

## CHANGE MANAGEMENT

If true efficiencies are to be realized in the data collection process, the introduction of technology alone will have little, if any, beneficial effect. The potential of EDC lies in the adoption of better processes rather than just good technology. This is not about how CROs or sponsors can use technology at trial sites, but rather taking the holistic view across the entire trial process and asking how it can be done better.

While paper-based trials are conducted based on practically the same model, EDC processes are unique in their creation and execution. This is both a strength and a weakness of the process. It is a weakness because, in general, there will always be some resistance to or suspicion of change. It is a strength because through building and adopting an effective EDC service delivery solution, it is possible to earn the buy-in of all those involved.

Each new project should be given as much time as required for development rather than a standard time frame with the hope that everything can be completed by an arbitrary end date. Put simply, no two projects are the same, so why manage them in the same way? Each project requires its own unique level of resources in terms of time and expertise. Collaboration and team ownership are necessary disciplines for successful adoption and comprehensive service delivery.

## MULTIPLE VENDORS, SINGLE PROJECT MANAGER

When an EDC system is established, the original paper-based process is broken up and rearranged into new steps. Some steps from the original process may disappear entirely, others may change little. In all likelihood the responsibility for certain steps or specific tasks may change between personnel and even organizations. Work previously carried out internally may now be completed externally. The work of remote site management will certainly change with the introduction of new practices and with the move towards off-site processes. Not all companies will slice this process up in the same manner, which may lead to inconsistencies, overlaps and gaps if working with multiple service providers.

The resulting arrangement of a new EDC solution may involve multiple vendors and multiple service providers (all with their own flavor of optimal EDC process service delivery), rather than all tasks being conducted in-house or through one single supplier. If separate suppliers are providing EDC service, this can lead to confusion among mixed functional groups such as data management, clinical operations or even the EDC vendors themselves. Remember, the approach to EDC is slightly different from company to company and experience levels among providers may differ considerably.

One role that always changes when EDC is implemented is that of the EDC trial's project manager. This person is accountable for the execution of that study and he or she needs to understand the process from start to finish, how that process is being broken up and which organization or individual is responsible for each part of the process.

The project manager plays an essential role in coordinating multiple vendors and service providers because when companies are brought together to work toward a common objective, there are potential gaps and overlaps between these organizations' work. This, in turn, can lead to inefficient practices jeopardizing the accurate and clean data promised by EDC. A clearly identified project manager ensures the various parties concerned are coordinated correctly and are aware of each other's

expectations and requirements. Experience here is vital, as you can not spot risks if you do not know what to look for.

When new systems and protocols have been established, it is essential that they are followed and understood by everyone involved with the trial. Part of our work as trial partners is to ensure this happens. Since EDC provides real-time data, it is possible to tell early in the progression of the project whether the new processes are delivering data as required by the study. If the project is not progressing in line with defined and measurable expectations, either the process does not work or it is not being followed correctly. In the latter case it becomes apparent very quickly that EDC is not being adopted and we can act to address this appropriately.

## THE WAY AHEAD

The use of technology in clinical trials will increase. With the health sector experiencing increased IT investment, technology is being pushed into new sites and even onto the patients themselves. Electronic patient records, electronic patient reported outcomes and similar initiatives will grow in use and become more integrated with one another. New functions and features will grow on existing systems, offering greater accuracy and reducing the time spent on low-value activities.

To this extent, EDC is no different. At Quintiles, we are developing new data reporting and reviewing services along with improved safety services. We will continue to improve our usage of real-time, clean, visible data and work to drive more value from this data according to our customers' requirements.

However, these new technologies promise a simpler place in which to work. The problem is that as more and more technology and solution providers deliver more diverse systems dedicated to specific tasks or situations, there is a danger that organizations will become swamped and confused by the available solutions. We must not introduce "e-overload" as this is a huge risk to beneficial change.

As technology increases, there should be a decrease in the number of contact points for users who need help and support with their IT solutions. One step toward this is our intention to provide a single point of contact for our sites, no matter what their query or request might be. We can not only ensure the appropriate support is always delivered, but also make the gateway to that support a known, familiar and accessible one. In this way, sponsors, CROs and sites can continue to benefit from the products and services of multiple vendors without the headache of trying to find the right help desk when the need arises.

## CONCLUSION

With EDC, technology is not the solution, but the enabler. In order for any technology to be effective, it cannot be implemented without consideration of the context in which it will be used, the processes it will be used alongside and the results required. Throughout the development and implementation of a system we must ask these questions: How is this technology improving the start up process? How is EDC improving data management? Does the solution ultimately mean better clinical trials? Does it improve the life of the people working at that remote site?

By placing excellent service delivery at the heart of all innovation we can be sure any introduction of new technology will deliver value to the industry. EDC provides the opportunity to make trial processes operate more efficiently and it helps to deliver more accurate results. While this approach benefits trial sponsors in the form of quicker trials, lower costs and reduced time to market, there also are benefits from clinical and data management perspectives—more reliable and accurate management of research studies.

Quintiles recognizes the challenges EDC adoption can bring to organizations, and we are convinced of the benefits a service-driven approach can deliver. We will continue to learn and update our practices, ensuring that our focus on EDC adoption and service delivery continues to improve and thrive with the technology push.

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