Site Technical Assessment:

the One Thing that Your EDC Study Cannot Do Without

See how site technical assessments can improve your EDC studies and speed up the clinical trial process

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- **Are you considering using Electronic Data Capture (EDC) for your next clinical study?**
- **Has your attempts with EDC failed to live up to its promised benefits and potential?**
- **Do you hope to improve your EDC study and speed up the study process?**

It is time for you to discover the key element that will help to kickstart your EDC study and ensure its success. As the pharmaceutical industry starts to recognize the value of EDC, a progressive increase in the usage and adoption of EDC is foreseeable.

However, before you make the switch to EDC, it is important to recognize that performing a comprehensive site technical assessment is often the best way to ensure that the rest of your EDC study progresses without a hitch. Read on to discover how site technical assessment can help you realize the full benefits of EDC.

Are your EDC studies delivering on what they promised?

In theory, the promised benefits of EDC are numerous. Errors associated with manual paper entries are eliminated, bringing about improved data quality. Switching to an EDC system is also expected to result in faster trial completion and hence a shorter time-to-market as data is entered and cleaned on an ongoing basis. In addition, non-value added processes such as double entry of data are eliminated as information becomes available in real time.

By moving away from mountains of paper to a much cleaner electronic system, cost savings are also achieved. On-site monitoring costs are expected to decrease significantly by up to 75% due to a reduction in frequency and duration. EDC also cuts down on other data management and query costs. It is estimated that the use of EDC can result in cost savings of about 25 to 30% per study.

"The promised benefits of EDC do not always materialize. Site technology problems are common, resulting in frustrating study delays."

However, site technology problems can prevent these much-coveted benefits from materializing. For instance, the ability to enter data efficiently is affected if the site is facing poor connectivity or slow page turns, causing the study progress to be impeded significantly. These technology problems usually occur when the site's infrastructure does not meet the requirements of the EDC software due to hardware or software inadequacies at investigative sites.

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"Performing a comprehensive site technical assessment minimizes site technology problems and facilitates in computer remediation."

Realize the full potential of EDC with site technical assessment

To realize the benefits of EDC, it is important to minimize the probability of technology problems occurring at your investigative sites. This can be achieved by having a detailed understanding of your sites' computer infrastructure.

Performing a site technical assessment prior to the start of an EDC study provides you with a complete profile of the computer infrastructure at your study sites. This ensures that the hardware or software installed on your site computers is compatible with the requirements of your EDC system, thus preventing the occurrence of site technology problems. As the study progresses, having a base-line report of the computers at investigative sites can also help to speed up the remediation process if troubleshooting is required.

The need for a comprehensive site technical assessment has become even more pressing due to the increased decentralization of investigative sites. Pharmaceutical sponsors and CROs are now dealing with larger-scale studies that involve thousands of sites. These studies are also taking place on an international level and becoming more community-based. It is estimated that 40% of sites are located internationally and 60% of clinical trials are now being conducted at community-based sites.

Dealing with a complex and geographically diverse network of sites has created a great amount of uncertainty, making it harder to track and manage the computer infrastructure that exists at these sites. As the pharmaceutical industry experiences an upsurge in the usage and adoption of EDC, it has become even more important for pharmaceutical sponsors and CROs to have assurance that the EDC software that they use can function effectively at their chosen sites. This can only be achieved by performing a rigorous site technical assessment before the start of each study.

If you are a pharmaceutical company or a CRO, here are some reasons why site technical assessment is important:

- *Helps to avoid study delays and site failures*

Technology problems often happen in the course of an EDC study. Firstly, your EDC software may not function optimally if your site computers do not have the adequate infrastructure that is needed. For instance, poor connectivity or the absence of applications such as Java can lead to difficulties in using the software and uploading study data. The presence of malware or adware can also result in performance issues and cause a breakdown in your study.

These problems result in unexpected study delays and site failures, causing needless costs to be incurred. The costs involved are sizeable, amounting to about $40,000 for each extra day that a study is kept running, and between $8000 and $12000 for a lost site. Hence, it is crucial to minimize the risks of these occurrences by choosing sites that are compatible with your EDC software. It is also important to verify that your site computers possess the necessary security tools to be protected from malware or adware. This can be achieved by performing a thorough and accurate site technical assessment to ensure that the best possible sites are chosen for your EDC study.

Seen & heard:
"100% of our investigators claim that they have a PC that supports the study but only 80% end up qualifying with our EDC software!"

- *Aids in site provisioning*

Performing a site technical assessment identifies exactly what each site needs in terms of its computer infrastructure, thus allowing you to make informed decisions on the type of provisioning required. Proactively provisioning sites that lack any necessary requirements helps to prevent study delays due to time wasted trying to resolve problems that occur due to inadequate infrastructure.

Accurate site provisioning also ensures that your investigators are fully equipped for a smooth study experience. Given the difficulty involved in recruiting sites, it is vital to keep your investigators satisfied as this encourages participation in future trials. Inadequate hardware or software infrastructure causes your investigators to experience problems with the EDC application, thus translating into a poor user experience and investigator frustration.

Seen & heard:
"Anyone embarking on a major roll-out would like to know exactly what hardware is available ahead of time."

- *Facilitates future troubleshooting*

Technology problems can crop up as your study progresses, resulting in exasperating delays and investigator dissatisfaction. Performing a site technical assessment before the study begins provides a baseline report on the site's technology infrastructure. This is highly valuable for troubleshooting purposes as comparing assessment reports of site infrastructure before and after the problem occurred often helps to determine the cause of the problem, thus helping to solve it quickly.

Seen & heard:
"If my support team could see what's on the machine, they could determine the problem quicker and with more certainty."

If you are an EDC vendor, here are some reasons why site technical assessment is important:

- *Minimizes problems with EDC software technology*

The EDC vendor often bears the brunt of the blame when technology problems crop up at an investigative site. Performing a site assessment beforehand will allow you to determine which sites possess infrastructure that is compatible with your EDC software. If necessary, you can then alert your clients about potential problem sites that may not work with your technology, thus minimizing the probability of software problems arising during the study. This allows your clients to then make informed decisions on site selection or provisioning to ensure a smooth study experience.

Seen & heard:

"We face problems with our sites because they are chosen for us. But when these sites run into trouble, it is our fault as the EDC vendor."

- *Helps to provide a full-service solution*

In the crowded EDC market, it is no longer sufficient for an EDC vendor to remain competitive by merely providing the EDC software technology. Demonstrate your commitment in minimizing technology problems by performing a site technical assessment before the start of each study. This sends a clear signal to the sponsor that you proactively seek to ensure the success of the study by verifying that the sites used are compatible with your EDC software.

- *Part of sponsors' mandate*

Pharmaceutical sponsors usually emphasize performing site technical assessments as part of the standard operating procedures. A particular thin-client EDC vendor which never used to perform site technical assessments was confronted with the possibility of losing a key sponsor when the sponsor's request for proposals mandated that site assessments be carried out before they proceeded with the study. To stay ahead of your competition and differentiate yourself, offer site technical assessment as a part of your EDC solution.

Final tip:

Now that you recognize the importance of site technical assessment, make sure that the assessment process which you choose is able to obtain all the data you need efficiently and provide you with a comprehensive and accurate report about your sites' infrastructure.

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