



5 Critical Factors



For Successful Site Technical Assessment

Discover the factors that contribute to a successful site technical assessment and reap its full benefits

“Check that your site technical assessment process adds value and delivers the benefits it promises to offer.”

“Be aware that site assessment data which is self-reported can contain errors and inaccuracies.”

You recognize the value and importance of performing site technical assessments before embarking on your EDC studies...

But do you know what are the key elements involved for a successful site technical assessment process?

Site technology problems can derail your EDC study and lead to study delays or site failures. Performing a site technical assessment before embarking on an EDC study eliminates the risks of these problems by ensuring that your site computers meet the requirements of the EDC technology employed.

To ensure that your site technical assessment processes help to add value to your EDC studies, it is vital to recognize that there are crucial elements that contribute to a successful site technical assessment. Take a closer look at your current site technical assessment methods. Do you have the assurance that they are able to deliver the maximum benefits possible?

Here are the five critical factors that you should consider when selecting your site technical assessment process...

1. Accuracy

Are you fully confident that your site technical assessment provides you with accurate and precise information?

A recent study made the discovery that 60% of study delays occur due to issues at study sites. For EDC studies, the glitches that crop up at study sites are often technology-related. Even more shocking is the fact that these delays can result in the build-up of substantial costs and losses in potential revenue. It is estimated that \$40,000 is chalked up each day to keep a trial running. And that is not all. A sponsor gives up at least \$600,000 in lost sales for every extra day that a drug remains in a clinical study. As for a potential blockbuster drug, the daily revenue forgone can reach up to a massive eight million dollars.

Under these circumstances, the value of performing a site technical assessment becomes apparent, as this would significantly help to prevent technology-related problems or solve them speedily when they occur. However, it is crucial to first verify that the information obtained from the assessment is fully accurate. This can be a problem if data obtained from the assessment is self-reported, thus exposing the data to problems of human error or a lack of technical expertise.

Performing a site technical assessment that is inaccurate is as futile as not performing any site assessments at all. Clearly, you will be wasting precious time, money and effort if the data provided by your site assessment processes contains errors and inaccuracies.

Besides, inaccurate site technical assessment can lead to numerous other risks. An unsuitable site may be chosen based on the incorrect information obtained, thus creating subsequent technology problems and possibly even site failures as the study progresses.

Key lesson: Make sure that the site assessment process that you use leaves no room for error and provides consistently accurate information.

2. Ease of use

Do your investigators and CRAs see site technical assessment as a chore which is taxing and tedious?

Site technical assessment is often performed by investigators and CRAs at the remote investigative sites and it is important to note that these people do not possess the same amount of technical expertise that your IT staff may have. Getting your site investigators to fill out long surveys asking for highly complex technical information can create a great deal of frustration with the process, resulting in poor productivity and inefficiency. This can end up negating the benefits associated with performing a site technical assessment. Hence, make sure that your assessment procedure is simple and easy to use, even for non-technical personnel such as your investigators and CRAs.

Key lesson: Choose a site assessment process which is high on user-friendliness and ease of use. In this way, you avoid adding to the work burden of your investigators unnecessarily and keep them happy in the course of your EDC study.

3. Speed

Does your site technical assessment get you the information you need quickly without any unnecessary delays?

In selecting a site technical assessment process, you need one which can provide you with the information you require quickly and efficiently. Site technical assessments are intended to improve the efficiency of your EDC studies. It would clearly be counter-productive if the assessment process was slow and time-consuming, resulting in precious time being wasted even before the study begins. Avoid self-reported processes which can present potential hiccups in the form of missing or erroneous data, thus chalking up unnecessary costs by causing the study startup period to be prolonged.

Key lesson: Keep your study startup period short by making sure that your site assessment process gets you the information you need promptly and efficiently.

“Investigators can get frustrated if your site technical assessment process is tedious and complicated.”

“Site technical assessments that take a long time to complete can be counter-productive and impede your study start-up process.”

“Future trials are dealing with an increasing number of sites. Make sure your site technical assessment process is unrestricted by the volume of sites assessed.”

“Avoid ineffective site technical assessments that produce additional delays and costs rather than add value to your study.”

4. Scalability

Is your site technical assessment process able to keep up with your EDC expansion plans and meet your increases in demands?

The switch to EDC is often associated with an increase in the number of clinical trials performed, which in turn gives rise to a larger volume of sites that needs to be assessed. When this happens, it is critical that your site technical assessment process is able to ramp up effectively to meet these intensified demands.

There has also been a shift towards more international studies that are conducted across different geographical locations. Hence, it is important that the site technical assessment process you use is not hampered by issues such as time differences and language barriers.

Key lesson: Find a site technical assessment process that can scale effectively to meet your EDC demands, regardless of whether it is a 10-site or a 500-site study.

5. Cost-effectiveness

Are you satisfied with the value that your site technical assessment provides with respect to the costs involved?

It is essential to make sure that you are aware of the full costs that are involved when selecting your site assessment process. Different ways of performing the site technical assessment should be evaluated to determine their cost-effectiveness. This can be achieved by having a clear understanding of the direct and hidden costs associated with each of the processes. Site technical assessments that are not carried out effectively can become a bane rather than a boon if they end up resulting in additional delays and costs due to inaccurate or erroneous data.

Key lesson: Analyze all direct and hidden costs involved for the different site technical assessment processes to ensure that the most cost-effective process is used.

What's next?

Now that you are aware of the five factors that are critical for a successful site technical assessment, make use of the factors identified here to select the site assessment process which is best for your study or to determine if your current site assessment methods are up to standard.

For additional information, please contact:

Scientific Software Tools, Inc.
1023, East Baltimore Pike, Suite 100
Media, PA 19063-5126, USA

Telephone: 1-610-891-1640
Fax: 1-610-891-8556
Email: vistasales@vistasurveys.com

