

Is Being “Thin” Everything?

Finding out the Truth about EDC Thin Client Solutions

Find out why site technical assessments are an integral part of your EDC study even when using a thin-client EDC application



Having the misconception that using a thin-client EDC software eliminates the need for site technical assessment can have costly impacts on your study.

If you think that all you need for your thin-client EDC software to work is “any old browser on any old computer”, think again.

Many study sponsors or EDC vendors make the costly mistake of assuming that the use of a thin-client EDC application eliminates any potential limitations that investigative sites may possess in terms of computer infrastructure. It has often been taken for granted that all that is needed for a thin-client software is a browser and an Internet connection. As a result, the importance of site technical assessment for thin-client EDC studies is frequently disregarded, and looked upon as a redundant expense.

The reality, however, is usually much more problematic. For a thin-client application, connectivity issues and slow Internet speeds can still result in a frustrating user experience for site investigators. Technology problems can also surface as the study progresses, resulting in time-consuming and tedious efforts in troubleshooting and remediation. As a result, EDC vendors claiming to offer thin-client solutions often end up discovering that certain technical requirements are still indispensable for a smooth and problem-free study.

In a recent report done by the Clinical Trial EDC task group comprising industry experts from various leading pharmaceutical companies, it was recognized that performing a robust site technical assessment to determine the investigative sites’ hardware, software and telecommunications capabilities is essential in supporting a thin-client EDC application. Read on to see how site technical assessment can add value to your EDC study and keep your investigators satisfied with your thin-client solution.

Are you aware of the risks involved even when dealing with a thin-client EDC application? Here are 5 questions that you should be asking before embarking on a thin client EDC study:

1. Are your sites’ Internet speeds fast enough?

In a thin-client application, data is stored on a central server and accessed through a secure browser connection. Hence, the effectiveness of a thin-client application hinges on the sites’ basic ability to connect to the Internet. However, having an Internet connection alone is not enough. Study data travel repeatedly back and forth from the site to the Web server before being entered into the central database. Hence, for a good user experience, the speed of your sites’ Internet connection is critical in ensuring that the data entry process can be completed efficiently.

Slow Internet connectivity can give rise to problems such as delays in loading pages and entering data. This is especially common for sites that are using dial-up modems rather than faster alternatives such as DSL or a cable modem. A tedious data entry process can cause investigators to become exasperated with the entire study. In fact, some of these “thin

clients” have been so problematic that some investigators are even charging a premium if they cannot get the eCRFs to refresh on the screen quickly enough.

The latency of your site computers can also determine the rates of data entry and uploads. Latency is directly related to the distance that a packet of data has to travel before reaching the central server, and hence there is a higher possibility of experiencing network lags for faraway sites due to the further distance traveled. Server and traffic delays on the Internet can also slow down this process. As more international sites are used due to the global ramp-up of EDC, it becomes even more critical to check that these sites possess a high-speed Internet connection.

Site technical assessment reduces these risks by obtaining key information such as the connectivity and page turn rate of your sites beforehand, thus allowing you to choose your sites wisely. Having this information provides you with full confidence about whether your sites are equipped with the necessary infrastructure for a smooth study experience. By accurately identifying and selecting sites that meet the requirements of your software, the probability of future technology problems occurring as the study progresses is minimized. If a key site is identified as having a slow connectivity rate, high-speed Internet can also be installed to ensure that a smooth user experience is provided.

Lesson 1: Verify that your sites’ Internet speeds are fast enough for your thin-client EDC application to work smoothly.

2. *Do your site computers have the necessary plug-ins for your thin-client software to function effectively?*

Your sites may possess the connectivity speeds that are required for fast and efficient data entry. However, some thin-client applications may not be as “thin” as they claim to be and may require various plug-ins such as Flash to work optimally. In other cases, the thin-client application may only support certain browsers such as Internet Explorer and not work on others like Firefox. To make things even more complicated, you may find that your thin-client application only works optimally with specific versions of a particular browser or a plug-in.

Performing a site technical assessment helps you to clearly identify if your sites are lacking in any way in terms of computer infrastructure. You are thus equipped to make informed decisions on site selection and the type of provisioning required. Choosing to provision reactively only when technology problems occur can cause the study to be interrupted for a significant period of time, resulting in expensive study delays. This also causes the pharmaceutical sponsor to appear unprepared and disorganized. Rather than make last-minute efforts to correct problems

when they arise, sites that are lacking certain requirements should be provisioned proactively before the start of the study.

Lesson 2: Make sure that your thin-client software does not need specific browsers or additional plug-ins to function effectively.

3. *Are your sites' firewalls correctly configured to allow access to your EDC software?*

A computer firewall controls the traffic that passes from the Internet to the internal computer network by monitoring traffic on different network ports. The presence of firewalls on your sites' computers can prevent the passing of data to and from the server, thus creating uncertainty about whether your sites will face problems in accessing your EDC software. Often, sites run into difficulties when using a thin-client EDC software as the necessary ports are not opened, thus preventing the sites from accessing the IP addresses that are needed to run the EDC software.

Performing a site technical assessment allows you to check that your sites' firewalls are properly configured to run your EDC software. You can thus verify before the start of the study that your sites have the correct ports opened to allow access to the IP addresses needed for the EDC software. The sponsor or EDC vendor can then accurately pinpoint the sites which do not have the required ports opened and make the necessary arrangements to configure their firewalls appropriately. This helps to eliminate the chances of your sites running into technical glitches after the study begins.

Lesson 3: Reduce the occurrence of technical glitches by making sure that your site computers' firewalls do not impede the performance of your thin-client software.

4. *Are your sites well-maintained and secure from malware or spyware attacks?*

It is important to note that due to the geographical dispersion of your investigative sites, computers that are used for the study are typically owned and maintained by the investigators. However, these computers may not be maintained for weeks, months, or even years, and are thus highly vulnerable to malware and spyware attacks, causing their security to be severely compromised. Breakdowns in your sites' computers due to these attacks result in the need to set up and install the necessary infrastructure again. This in turn causes your study to be significantly delayed and leads to the accumulation of unnecessary costs.

As studies start to take place on a larger scale and involve more community-based and international sites, study sponsors and EDC vendors are experiencing greater uncertainty and apprehension about the technical infrastructure at their investigative sites. A site technical assessment will help you to verify that the sites you choose have a robust security system and are regularly maintained before embarking on a study. This is crucial in ensuring that your site computers are well-protected and secure from attacks by malware or spyware.

Even after your sites are selected, it is important to consistently check that the site computers are well-maintained. Studies can run for a long period of time and the computers used may not be maintained or updated regularly. Periodic site technical assessments can help to check for the latest updates and eliminate the risks of any security breaches by ensuring that security patches are installed.

Lesson 4: Keep your site computers protected from malware or spyware attacks by checking that they have a strong security system that is well-maintained.

5. *Are your troubleshooting and computer remediation processes solving your technology problems in a timely and effective manner?*

It is not uncommon for technology problems to crop up in the midst of an EDC study. When this occurs, the study becomes delayed, resulting in investigator frustration and mounting costs. The troubleshooting period can be time-consuming and aggravating if comprehensive information about the site's computer infrastructure is not readily available. Site technical assessments can play a key role in improving the troubleshooting process by comparing assessment reports of site infrastructure before and after the problem occurred. This significantly facilitates the troubleshooting process by helping to identify possible causes of the problem, thus solving it quickly.

Lesson 5: In the event that troubleshooting is required, make sure that you are able to resolve technical problems quickly to minimize study delays and added costs.

EDC vendors! Do not jeopardize your business and risk losing business by neglecting the importance of site technical assessment.

On a final note, it is crucial to be aware that many sponsors often mandate site technical assessment as part of their standard operating procedures (SOPs). Sponsors are now recognizing that site technical assessment plays a key role in mitigating the technological risks associated with performing an EDC study. A lot of these risks can be reduced if a thorough site technical assessment is performed before embarking on the study. This ensures that your site computers possess the critical conditions that will allow your thin-client application to function smoothly and efficiently. By minimizing the chances of technology problems occurring during your study, the user experience for investigators is also improved, thus increasing the sponsor's appeal for future studies.

Final tip:

Using a thin-client EDC software does not free your sites from the need to meet with certain technical requirements. Do not expose yourself to unnecessary technological risks by neglecting the importance of site technical assessment!

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