

The True Cost of Manual Site Assessments

Quantifying the Costs Involved with Site Technical Assessments

Discover what your current site technical assessment process is costing you and determine its cost-effectiveness



Do you know what your site assessment process is costing you?

Few people truly realize the amount of work that goes into obtaining the information needed for site assessment. Existing manual site assessment methods are often tedious and inefficient, involving long lists of tasks and the heavy use of paper questionnaires and multiple phone calls between site investigators and the clinical staff.

The need for two-way communication in turn results in disruptions in the study start-up process, as huge amounts of time and effort are spent trying to establish contact between the site investigators and the clinical staff. It is estimated that the manual process takes up to 2 weeks and around 7 phone calls to obtain all the information needed.

In particular, many sponsors and EDC vendors expect investigators to answer technical surveys with the same finesse as their IT staff despite the investigators' non-technical background. As a result, investigators often encounter difficulties trying to complete the technical assessment and end up frustrated even before the actual study begins. This leads to a negative impression of the study sponsor, the CRO and the EDC vendor.

Due to the numerous tasks involved in the manual process, significant cost build-ups are incurred. These tasks include:

- Designing the assessment forms
- Approving the forms
- Printing and mailing forms to sites
- Filling out the forms by investigators
- Repeated phone calls between clinical staff and the investigative site to obtain the required information
- Entry of data into a database
- Analyzing results
- Obtaining missing data
- Correcting inaccurate data

Research conducted by Scientific Software Tools showed that for an average-sized study with 100 sites, the cost of performing a manual assessment ranges from **\$375 to \$430 per site!**

To discover the true costs of your site assessment process, read on for more information about the research conducted by Scientific Software Tools (SST) and a detailed break-down of the costs associated with the various tasks involved in manual site assessment.

To establish the costs involved with each task in the manual site assessment process, SST conducted primary research through extensive phone interviews with pharmaceutical sponsors, CROs, EDC vendors and life science help-desk companies to learn about their current site assessment processes. Using information obtained from SST's research and other sources of industry data, a range of the costs and effort involved for each task was determined. The table below lists the various activities involved in a manual site assessment process along with the associated costs and effort required on a per site basis.

Costs per site resulting from:	=	Time spent @	Burdened labor rate (per hour)	+ Other expenses
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Fixed costs

Design of form layout	2 to 4 hours	\$50 to \$80	--
Design of form content	4 to 8 hours	\$50 to \$80	--
Approval of form by project manager	1 to 2 hours	\$80 to \$100	--

Variable costs

Printing of forms and mailing to sites	10 to 30 minutes	\$50 to \$80	Printing costs of \$0.05 per form Postage fees of \$0.60 to \$4.20
Multiple phone calls between clinical staff and investigators	30 minutes to 1 hour	\$50 to \$80	Phone charges of \$0.08 per minute
Manual entry of data into database	10 to 30 minutes	\$50 to \$80	--
Validation of data: <ul style="list-style-type: none"> Verify accuracy of information Check for missing information Correct errors on forms 	30 to 45 minutes	\$50 to \$80	--

Hidden costs

Opportunity cost to investigators	30 minutes to 1 hour	\$120 to \$180	--
Opportunity costs to clinical or IT staff	30 minutes to 1 hour	\$50 to \$80	--
Costs of losing a site @ probability of 1%	--	--	\$80 to \$120

For an average **100-site study**, the **median cost** of performing a manual site assessment amounts to about **\$400 per site!**

Are you aware of the hidden costs involved in performing site assessments manually?

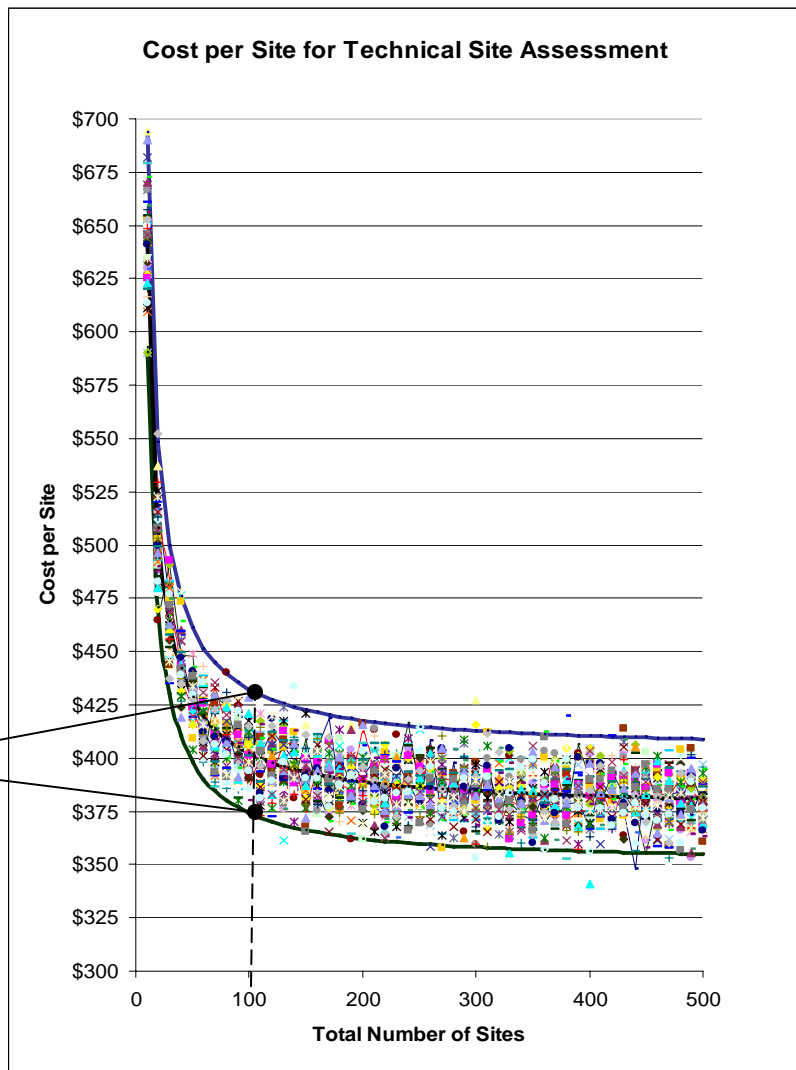
- Loss of **potential revenue for your investigators** from meeting with fewer patients.
- **Slower study start-up process** as your clinical staff spends unnecessary time on manual assessments.
- Risk of **study delays and site failures** as data collected manually is prone to errors and inaccuracies.

Do you know?

- The loss of a site incurs a cost of \$8,000 to \$12,000.
- Even at a low probability rate of 1%, this amounts to \$80 to \$120 per site.
- Performing an accurate site assessment is a small price to pay to ensure that the best sites are chosen for your study.

For further analysis, a Monte Carlo simulation was performed to account for the range in the costs identified for the tasks listed in the previous table. Randomly generated figures that fell within these determined ranges were used to obtain a distribution of the cost per site of performing a technical assessment as a function of the total number of sites. The values obtained are plotted in the graph below.

The middle line on the graph corresponds to the median cost per site of performing a technical assessment while the top and bottom lines on the graph represent the upper and lower confidence limits for the cost per site at a 95% level of confidence. Hence, the cost of performing a technical site assessment falls within these limits 95% of the time, with only 5% of companies experiencing costs that are higher or lower than those shown on the graph.



For an average-sized study of 100 sites, it can be seen from the graph that the cost of performing a manual site assessment ranges from **\$375 to \$430 per site!**

An accurate site assessment ensures that the best sites are chosen for a study, thus mitigating the risks of study delays and site failures.

By automating the site technical assessment process, VISTA shortens the study start-up process by up to 2 weeks.

From the analysis above, it is evident that considerable costs are involved in performing a manual site technical assessment. The major problem that lies with these methods is that they are notoriously slow and tedious. Errors and inaccuracies are also common as the information obtained is self-reported. In view of these inefficiencies, manual processes are clearly not cost-effective and detract from the value of your clinical studies.

Improve your site assessment process with VISTA!

VISTA is a web-based service that quickly and accurately captures and reports on your site's technical infrastructure, thus shortening your study start-up process significantly. Automating the site technical assessment process with VISTA produces substantial cost savings. Here are the ways in which VISTA helps you obtain the maximum value from your site technical assessment process:

- **Accuracy**

A site technical assessment is crucial in determining if your site is qualified for an EDC study, and also helps to provide important information for site provisioning. Basing your site selection decisions on erroneous or inaccurate site assessment information can be a costly mistake. An EDC vendor experienced this first-hand when follow-up business was lost after a key investigator complained about the extensive problems he faced with the EDC package due to the lack of accurate site assessment information.

In contrast to manual processes which are prone to errors and inaccuracies, VISTA provides comprehensive site technical assessment reports that are 100% accurate. Poor site selections due to inaccurate site assessments can result in study delays or even site failures after the study begins. Performing an accurate site assessment ensures that the best sites possible are chosen for your study and also aids in provisioning decisions if necessary. Given that the cost of a lost site ranges between \$8,000 and \$12,000, an accurate site assessment process is worthwhile in mitigating any possible risks of losing a site.

- **Speed**

Clinical trials and the drug approval process are an extremely costly affair. Hence, there is great pressure to shorten the clinical trial process and speed up the time-to-market for new drugs. In performing a manual site technical assessment, the study start-up period is usually prolonged by up to 2 weeks due to the extensive list of activities involved. Given that a sponsor loses about \$600,000 in potential sales for every extra day that a drug remains in a clinical study, such delays in the study start-up process can translate into significant losses in terms of potential sales.

VISTA eliminates such delays by performing site technical assessments within seconds to minutes. The time used by your clinical staff to perform site technical assessments manually can be better spent on completing other tasks, thus speeding up the study start-up process.

Eliminate investigator frustration by providing your investigators with a user-friendly process like VISTA.

VISTA scales effortlessly regardless of the number of sites and has the flexibility to allow investigators to perform the assessment at any time they choose.

VISTA collects all site assessment information needed in one setting by combining online surveys with the technical assessment.

- ***User-friendly interface***

In the manual process, investigators often waste precious time and effort grappling with complicated questionnaires that involve highly technical questions and tasks. Investigators typically run busy practices as well, and the time they use to complete these assessments is equated with lost revenue that could have been obtained from meeting with patients. It is also common for the less tech-savvy investigators to encounter problems when performing the technical assessment manually, thus resulting in the need for a fair amount of technical support. This creates a great deal of frustration with the manual process.

VISTA is specially designed to provide ease of use for non-technical users, thus ensuring that site technical assessment is no longer a frustrating and tiresome chore. Using VISTA, investigators only need to spend several minutes performing the assessment, and can quickly and easily obtain all the information needed with a few clicks of the mouse.

- ***Flexibility for investigators***

The manual process relies heavily on two-way communication between the clinical staff and the investigator. As a result, investigators often have to accommodate to the schedule of the clinical staff. On the contrary, VISTA allows investigators to enjoy the flexibility of performing the technical assessment at any time they choose, thus ensuring minimal disruption to their busy schedules.

- ***Scales effortlessly for both large-scale and international trials***

As large-scale megatrials become increasingly common, manual processes are often inefficient in meeting with the rise in demand. The shift towards more international studies also creates additional problems, as these manual processes are unable to effectively handle issues such as time differences and language barriers.

The beauty of an automated solution like VISTA is its ability to scale effortlessly regardless of the number of sites involved and their geographical locations. As the volume of trials escalates, the cost of using VISTA also decreases significantly due to the economies of scale reaped, which are far less pronounced for manual processes.

- ***Eliminates the need for multiple contact points***

Apart from performing the technical assessment, investigators are also required to complete a host of other surveys to qualify their sites for the study. VISTA offers the unique feature of incorporating these qualitative surveys together with the technical assessment. This eliminates the use of paper completely and allows your clinical staff to obtain all the information that they need in one setting. Your investigators also benefit from greater convenience as they no longer have to face the hassle of dealing with different surveys from multiple points of contact.

Concluding thoughts:

When deciding on your site assessment process, make sure that you are fully aware of all the costs involved. Choose a process that is cost-effective and adds value to your EDC study to ensure that you enjoy the maximum benefits of performing a site assessment.

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