



Make the Right Choice:



Deciding on the **Best Site Technical Assessment Process** for your Study

Get a complete evaluation of the different site technical assessment processes available to choose the one that is best for your EDC study

As clinical studies start to take place on a larger scale and involve more international and community-based sites, uncertainty about the infrastructure of these investigative sites becomes a very real problem. For EDC studies, performing a rigorous site technical assessment before the start of each study reduces the ambiguity that is present by ensuring that your site computers meet the requirements of your EDC technology. This prevents the occurrence of site technology problems and also helps to speed up the remediation process if troubleshooting is required.

However, even though you recognize and appreciate the importance of performing a site technical assessment, your attempts at doing so may often be plagued with problems that create more woes rather than add value to your EDC study.

Are you finding that your site technical assessments:

- Take up too much time and money?
- Produce unwanted study delays?
- Provide inaccurate and incomplete information?
- And most of all, result in a great deal of frustration for your investigators and clinical staff?

You no longer have to accept these problems as part and parcel of the site assessment process. If performed effectively, site technical assessments can, in fact, offer many advantages that will help to improve your EDC studies.

Read on to discover a fresh new solution which helps you complete your site assessments smoothly and efficiently without any of the problems mentioned above.

Are you still relying on antiquated and inefficient manual processes for site technical assessment?

Currently, most site technical assessments are carried out manually. This can be accomplished in three ways.

Firstly, site technical assessment can be performed as part of the pre-study site visit by the clinical research associate (CRA), who fills in a paper-based survey when visiting the site.

More commonly, the site technical assessment is completed before the pre-study visit in the form of a paper survey questionnaire, which gets sent out to the investigative site via mail, fax or e-mail. Study staff may also call up the investigative site and conduct the assessment by phone.

“If performed effectively, site technical assessment can offer many advantages that will help to improve your EDC studies.”

Here is a typical example of how site assessment gets done using the manual paper method:

- **Day 1** → Clinical staff sends a paper survey to site investigator. Questions asked are highly technical, such as type of operating system, Internet browser version, Internet connection speed, the presence of a firewall or whether cookies are enabled, among many others.
- **Day 2** → Clinical staff calls to check if investigator has received the survey. Investigator cannot be reached.
- **Day 3** → Clinical staff calls again. Investigator is seeing patients.
- **Day 4** → Clinical staff manages to contact the investigator and reminds him to fill in the survey.
- **Day 6** → Investigator looks at the 7-page long survey and sees a whole load of technical jargon that he does not understand. Leaves the survey aside and goes home.
- **Day 7** → Clinical staff has not received the survey from investigator. Calls investigator and leaves a voice mail.
- **Day 10** → Investigator tries to fill in survey but does not know how to obtain his computer's connection speed. Calls clinical staff but they have left the office.
- **Day 11** → Investigator calls clinical staff and reaches their voice mail.
- **Day 12** → Clinical staff calls back. Instructions to obtain connection speed are too confusing. Investigator gets frustrated and hangs up the phone.
- **Day 14** → Clinical staff receives survey from investigator. Survey contains missing information and errors. Clinical staff pulls hair out and begins process to contact investigator all over again.



Excluding further delays due to errors or missing data, the total time wasted: **2 weeks** and counting...

“The main problem that investigators face when completing manual site technical assessment surveys is a lack of technical expertise.”

“The huge amounts of time and effort expended in performing site technical assessments manually lead to significant cost build-ups.”

Is this your sad reality?

The inefficiencies depicted above are unfortunately a common occurrence in the pharmaceutical world. The main problem that lies with the manual process is the fact that most sponsors and EDC vendors expect investigators to answer these technical surveys with the same finesse as their IT staff despite the investigators’ non-technical background.

Investigators waste valuable time and effort trying to fill in these surveys and end up becoming frustrated even before the actual study begins. This in turn leads to a negative impression of the study sponsor, the CRO and the EDC vendor.

The need for two-way communication between site investigators and clinical staff also contributes to breakdowns in the process, as huge amounts of time and effort are spent trying to establish contact between the site investigators and the clinical staff. Some investigators completely forget about the questionnaires after receiving them while on the other end, clinical staff can spend up to 2 weeks waiting for the surveys to be returned.

As for phone assessments, it is found that an average of seven phone calls is needed before the information required can be obtained. When you consider the time differences and language barriers involved in the case of international studies, achieving effective phone communication seems even more unattainable.

Even after the surveys are returned, the information obtained is often incomplete or erroneous due to the investigators’ lack of technical expertise. This then leads to further delays as additional information exchanges back and forth between the investigator and the clinical staff takes place.

Do you know how much this is costing you?

Few people truly realize the costs involved with the manual site assessment process. In reality, the true number of activities and the associated direct and hidden costs are mind-boggling.

“Based on Scientific Software Tools’ internal research, the direct and hidden costs associated with the manual process averages \$375 to \$450 per site, depending on the number of sites.”

Here are some of the activities that are involved in the manual process:

- Designing the site technical assessment survey for individual studies
- Distributing the survey to all the investigative sites
- Making repeated phone calls back and forth between clinical staff and the investigative site to obtain the required information
- Filling out of the survey at the investigative sites
- Data entry of survey results into a database
- Analyzing survey results
- Correcting inaccurate data
- Obtaining missing data

Due to the inefficiencies of the manual process, these activities often result in time delays, leading to mounting costs that are not readily apparent. In addition, given that investigators only get paid when they start recruiting patients, the time wasted on site assessment can result in a significant amount of opportunity costs.

These are some of the hidden costs associated with the manual process that you should consider:

- Delay in study startup – The manual process takes about 1 to 2 weeks to be completed and a sponsor loses about \$600,000 in potential sales for every extra day that a drug remains in a clinical study
- Further delays due to missing or erroneous data can result in:
 - Additional losses in potential sales
 - Costs incurred by helpdesks or IT personnel in providing technical support
- Opportunity costs for investigators in spending time to complete site assessment surveys
- Opportunity costs for study staff tasked with site assessment
- Potential loss of site due to inaccurate site assessment – The cost of a lost site ranges between \$8000 and \$12000

Clearly, these manual processes are neither cost-effective nor efficient, and may end up frustrating both your investigators and your clinical staff. This can ultimately create more problems rather than add value to your EDC study. As the pharmaceutical industry starts to ramp up its usage and adoption of EDC, it is not hard to foresee that these manual processes will no longer be able to keep up, especially as the industry moves towards bigger trials that occur more frequently on an international level.

“Manual site assessment processes have become too slow and inefficient to provide any significant benefits.”

“Given the inefficiencies associated with the manual processes, there is a pressing need to look for a better solution that is able to keep up with the rising usage and adoption of EDC.”

There has to be a better solution!

Before you lose hope about the entire site assessment process, allow us to offer you a much easier and more painless approach.

VISTA – a new, sophisticated web-based solution for efficient site technical assessment

VISTA solves the problems associated with current manual methods by automating the site technical assessment process. The VISTA technology quickly and efficiently captures and reports on the following set of information from remote computers:

- CPU
- Operating system
- Browser version
- Storage
- Memory
- Display
- Hardware
- Software
- Network
- Connectivity
- Bandwidth
- Security
- Plug-ins

See how simple site technical assessment is with VISTA:

- **Day 1** → Site investigator is informed by clinical staff about the need to perform a site technical assessment and is directed to a secure website link.
- **Day 1, 5 minutes later** → Investigator logs into the website and clicks on a few buttons. Within seconds to minutes, a comprehensive report containing all the hardware and software information required is produced. Clinical staff gets an email of the assessment report immediately.



Time taken: 5 minutes!

“With VISTA, site technical assessment is completed within seconds to minutes, thus shortening your study startup time by 2 weeks.”

“VISTA helps to significantly improve your investigators’ satisfaction with your EDC study thus increasing their willingness to participate in future trials.”

“It is crucial for CROs and EDC vendors to provide a good user experience for the investigators, as this leads to positive feedback to the sponsor.”

“Do not underestimate the importance of choosing the right investigative sites as this helps to ensure success for your EDC study.”

It’s that simple?!

Well, the good news is that VISTA is really that simple. By automating the process, VISTA makes site technical assessment much faster and easier for both investigators and clinical staff.

Your clinical staff no longer needs to waste valuable time trying to obtain the information they need about investigative sites, while the frustration that investigators experience in filling in manual surveys is eliminated.

Given the difficulties involved in finding good investigators for clinical trials, it is highly crucial that investigators are kept happy and provided with a favorable study experience. As seen previously, manual site assessments consume a significant amount of investigators’ time but do not provide any associated compensation in return. As a result, valuable investigators are often antagonized by the inferior study start-up process, resulting in an aversion towards participating in future trials.

With VISTA, investigator satisfaction is improved significantly. Any resistance to EDC is also combated by shortening the study startup time and ensuring that the rest of the trial runs smoothly without any technical problems.


Switching to an automated process also helps to reduce your investigators’ administrative burdens, causing them to become more predisposed towards participating in future trials. This shortens the recruitment time for new trials, which in turn reduces a drug’s time-to-market.

For CROs and EDC vendors, providing a favorable experience for investigators, especially in the study start-up process, in turn results in positive feedback to the sponsor, thus increasing the probability of repeat business in the future.

VISTA – site assessment starts here!

Start off your EDC study on the right note by selecting the best investigative sites for your study. This is the first and most crucial step which paves the way for the rest of your EDC study. Choosing the wrong sites can be detrimental, as your study may be undermined by costly study delays and site failures as a result.

VISTA performs efficient site technical assessments to provide quick and accurate information that aids in your site selection process. The comprehensive nature of the VISTA report guarantees that you are equipped with all data points necessary to make informed decisions about the selection and provisioning of your investigative sites. Below is a sample of a VISTA report:



Computer Report
for User@VistaSurveys.com

General Information

Study	Demo
Date	Tue Apr 27 10:26:32 EDT 2004
Domain	VISTASURVEYS
Computer Name	VISTA
User Name	JohnD
Administrator Rights	false
Primary Owner Name	John Doe
IP Address	63.135.105.178

Computer

Model	Dell Computer Corporation Dimension 4300
Processor	Intel(R) Pentium(R) 4 CPU 1.60GHz
Number of Processors	1
Current Clock Speed	1.60 GHz

Memory

Physical Memory	255 Mb
Available Physical Memory	11.0%
Page File Size	1,001 Mb
Available Page File	79.1%
Virtual Memory	2,048 Mb
Available Virtual Memory	93.6%

Storage

Name	Type	File System	Total Space	Free Space
A:\	Removable Drive		empty	
C:\	Local Fixed Disk	NTFS	40 Gb	83.8%
D:\	CD-ROM Drive	CDFS	29 Mb	0.0%

Operating System

Name	Microsoft Windows 2000 Professional, Service Pack 4 (Build 2195)
Language	English (U.S.)
System Drive	C:
Windows Directory	C:\WINNT
Is Thin Client?	false

Virtual Machine

Virtual Machines	Vendor	Version	Default
Java	Microsoft	5.0.3810	true

Browser

Name	Microsoft Internet Explorer 6.0 (6.0.2800.1106)
Updates	SP1 Q813489 Q330994 Q822925 Q824145 Q832894 Q831167
Connection Type	LAN Proxy RAS Configured
Connection Speed	108 Kb/sec
Proxy	none
DOM Version	6
Cookies Enabled	true

Components

Name	Installed
Acrobat 5	true
Flash 7 (v3 v4 v5 v6)	true
Media Player 5.2 or higher	true
Quick Time	
MSXML 3.0 2.6 2.0 1.0	true

Scripting

Name	Installed	Enabled
JavaScript 1.3	true	true
VBScript 5.6.8513	true	true
ActiveX	true	true

Display

Display Adapter	16MB ATI Rage 128 Ultra
Resolution	1024 by 768 pixels, True Color, 75 Hertz

Monitors

	ManufacturerType
	NEC-MitsubishiNEC MultiSync FE7715B

“The comprehensive and accurate VISTA report provides you with a complete picture of your sites’ computer infrastructure.”

Apart from performing the site technical assessment, VISTA also offers the option of incorporating fully customizable qualitative surveys for any extra information that needs to be obtained according to the requirements of your study. Here is an example of a qualitative survey that can be integrated into the site technical assessment process.

VISTA Computer Survey for Scientific Software Tools, Inc.

Site Survey

SITE INFORMATION

Have you participated in an Electronic Data Capture (EDC) study before?
 Investigator: Yes No
 Study Coordinator: Yes No

Do you have a computer to use for this study? Yes No

Are you using the study computer now? Yes No
Please run VISTA using the study computer.

Will this computer be available for the entire study? Yes No

Does your site have a dedicated line available for visiting CRA/Study Monitors to access the Internet? Yes No

TECHNICAL SUPPORT INFORMATION

Do you have an Information Technology (IT) team to support the study computer? Yes No
If yes, please complete the following:

IT CONTACT

Name:
 E-mail address:
 Telephone:
US or International format with optional extension, "x1234"

“Do away with paper surveys completely by integrating your qualitative surveys with your site technical assessments.”

In this way, you no longer need to maintain multiple points of contact with your investigators by sending them a host of different surveys, while your investigators also get to benefit from greater convenience by entering all the necessary information in one setting. This can also help in mitigating the risks involved in the selection of investigators. For instance, these surveys might be useful in determining the investigator’s experience with past EDC studies, thus ensuring that the investigators you choose are comfortable and proficient with the use of EDC.

VISTA also makes it easy to perform recurring assessments of your site computer infrastructure as your EDC study progresses. This is highly valuable for troubleshooting purposes when technology problems crop up as the study progresses. Comparing the baseline report of the site’s technology infrastructure before the study with the assessment report after the problem occurred can aid in pinpointing the cause of the problem and solving it quickly. Periodic assessments also ensures that your investigative sites are well-maintained by determining if the antivirus software is kept up-to-date, or if critical security patches and updates to the EDC software have been regularly downloaded.

“Choose a site assessment process that is able to scale effortlessly as you ramp up your EDC studies.”

It is evident that long-term trends will move towards the intensified usage of EDC on an industry-wide level. As you ramp up your EDC studies, it is important that your site assessment process is able to keep up with your increased demands and meet your needs effectively. Providing consistent global support is also becoming increasingly important as trials start to include more international sites. In this aspect, manual processes are often hampered by issues such as time differences and language barriers due to the need for two-way communication between investigators and clinical staff. In contrast, VISTA scales effortlessly and allows investigators to perform the assessment at their own convenience at any time anywhere around the world.

Let’s see how VISTA measures up in comparison with existing manual processes:

Manual processes

- Self-reported manual process
- Prone to errors and inaccuracies
- Complicated and highly technical
- Slow and tedious; takes up to 2 weeks
- Requires two-way communication

- Unable to scale effectively to meet demands as EDC volume intensifies
- Significant costs involved

VISTA

- Automated process
- 100% accurate
- Extremely user-friendly
- Fast; completed within seconds to minutes
- Can be used at any time at investigator’s own convenience
- Scales effortlessly regardless of volume

- Cost-effective; less expensive than manual methods processes

Are you making the right choice?

It is clear that when performed effectively, site technical assessment can bring about significant cost and time savings. Before you embark on your next EDC study, think carefully about how you want to carry out your site technical assessments. Don’t put up with slow and inefficient manual processes which end up producing study start-up delays and additional costs any longer. Add value to your EDC study and discover how VISTA can help you achieve the full benefits of site technical assessment.

“Make the right choice and add value to your EDC study by choosing VISTA.”

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

