

# Automated Site Assessments:

## Unlocking the Secret to Better Site Selection Decisions

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Find out how automated site assessments can lead to better site selection decisions for successful EDC trials.

**VISTA**  
Site Assessment Starts Here

**“Comprehensive site assessments can help greatly in the site selection process”**

### **Site selection – the starting point for a successful EDC study**

Investments in EDC solutions are increasing rapidly in recent years, with adoption rates expected to reach 45% by the end of 2007. The push towards automation has partly been motivated by the shift in the industry towards large-scale clinical trials with many international and community-based sites, thus reducing the viability of traditional paper processes.

However, the far-flung distribution of sites has in turn resulted in great uncertainty for pharmaceutical sponsors and contract research organizations (CROs), which now have to face the challenge of managing a geographically-dispersed network of investigative sites. Therefore, to mitigate the high risks involved, companies are starting to recognize the importance of comprehensive site assessments in ensuring that the right sites are selected for a clinical trial.

### **The role of site assessment in the selection of sites for a study**

Before initiating a clinical study, a site assessment is usually mandated by pharmaceutical sponsors as part of their standard operating procedures. This is performed during the site evaluation process, which seeks to gather information about potential investigators and investigative sites before selecting the sites for a study.

In an EDC trial, information is gathered about both the technical and the non-technical aspects of the site. The technical aspect determines if the site has the adequate IT infrastructure needed for the EDC application to run smoothly, while the non-technical aspect evaluates the investigator and site’s suitability based on the study protocol and requirements.

Non-technical information that needs to be collected includes:

- Investigator’s experience and training
- Access to patient populations
- Site facilities and equipment
- Presence of support staff
- Relationship with IRB and relevant procedures

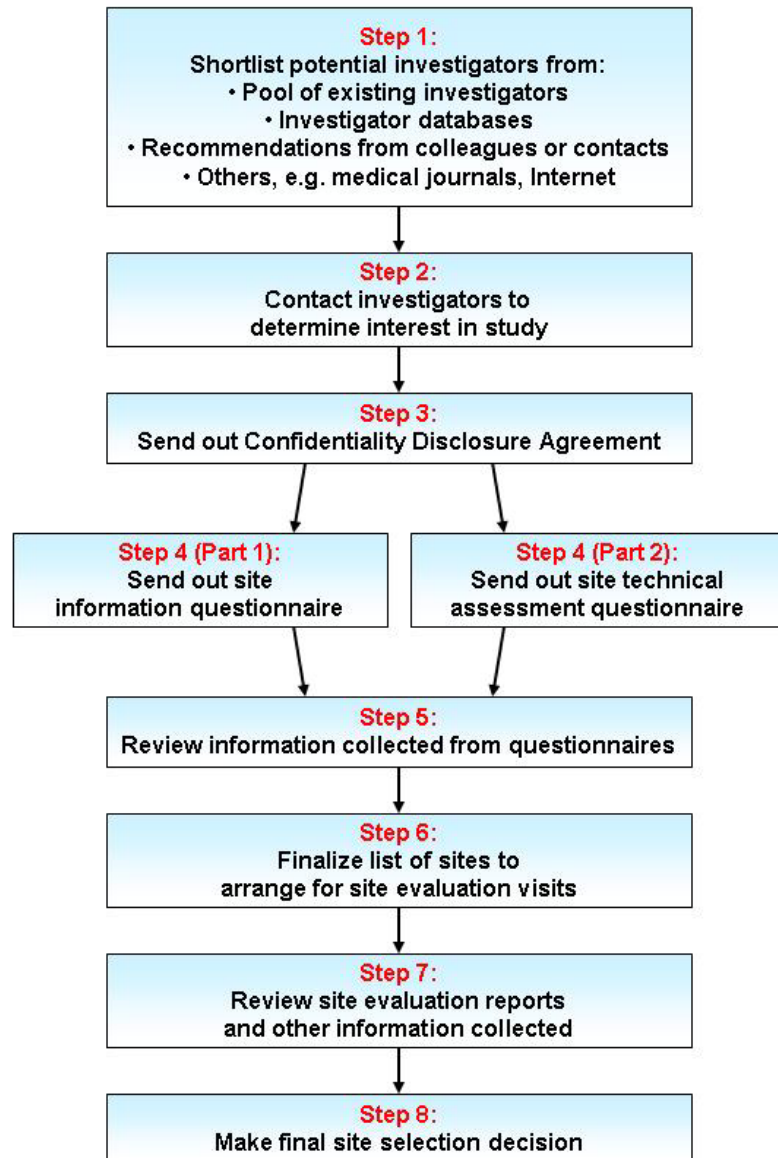
Technical information that needs to be collected includes:

- Type of operating system
- Internet browser version
- Amount of memory and storage space
- Type and speed of Internet connectivity
- Presence of specific software

**“Choosing the right sites avoids running into study delays and site failures and lays the foundation for a successful study.”**

In essence, choosing the right sites lays the foundation for a successful study. By seeking to collect as much information as possible about the sites prior to the initiation of the study, the clinical team is equipped to make fully-informed site selection decisions, thus mitigating the risks of picking the wrong sites and running into study delays and site failures.

These are the typical steps involved when making a site selection decision:



## Are you enjoying the full benefits of your site assessment?

Currently, most site assessments are carried out manually through three ways. Firstly, the assessment can be performed by the clinical research associate (CRA) as part of the site evaluation visit. More commonly, the site assessment is carried out prior to the site evaluation visit in the form of paper questionnaires that are sent out to investigative sites via direct mail, fax or e-mail. Alternatively, the clinical staff from the CRO or pharmaceutical company who are tasked with site assessment may also call the investigative site and conduct the assessment by phone.

Clearly, performing a site assessment prior to the start of the study can be invaluable in providing useful information for site selection purposes. However, the clinical research team and study investigators often regard site assessment as an onerous task due to the various inefficiencies and delays associated with the process. These inefficiencies can often prevent sponsors and CROs from enjoying the full value that is derived from the site assessment.

The main problem that lies with the manual process is the fact that the clinical team often encounters delays when trying to collect the necessary information from investigators. Some investigators take a long time to complete the questionnaires or forget about them entirely after receiving them. It is estimated that the clinical team can spend up to 1 to 4 weeks waiting for the questionnaires to be returned and often need to repeatedly prompt the sites to return them.

Even after the questionnaires are returned, the information obtained is often incomplete or erroneous. This then leads to further delays as additional information exchanges take place back and forth between the investigator and the clinical staff.

In conducting site assessments by phone, a significant amount of time and effort is often spent trying to establish contact with the site investigators. When taking into consideration the time differences and language barriers involved in the case of international studies, achieving effective communication by phone seems even more unattainable.

In particular, problems are faced when trying to collect self-reported technical data from investigators for the technical assessment. These investigators are often expected to answer the technical surveys with the same finesse as an IT person despite their non-technical background. Although the investigators spend valuable time and effort trying to complete these surveys, they often run into problems and are unable to provide the information required fully or accurately. As a result, the investigators end up getting frustrated even before the actual study begins, and in turn develops a negative impression of the study sponsor and the CRO. Similarly, CRAs who are tasked with performing the site technical assessment during the on-site visit also face similar problems due to their lack of technical expertise.

**“Manual site assessments are often seen as an onerous task due to the associated inefficiencies and delays.”**

**“Investigators get frustrated when performing the technical assessment due to their lack of technical expertise.”**

## VISTA – the new, fast and easy site assessment solution!

Due to the inefficiencies of the manual process, pharmaceutical companies and CROs are recognizing that manual site assessments are no longer effective or feasible in the long run. VISTA aims to overcome these inefficiencies by providing an automated site assessment solution that makes life easier both for the investigators and the clinical team and achieves the full benefits that EDC technology brings.

VISTA automates the site assessment process in two ways. Firstly, VISTA eliminates the need for the clinical team to rely on technical information obtained from personnel at the investigative site who do not have the technical expertise to provide full and accurate information. By automating the site technical assessment, VISTA ensures that the information collected is 100% accurate and free from errors. As a web-based solution, VISTA also allows information to be collected remotely from decentralized sites in a highly efficient manner. The picture below shows an excerpt from a sample report that is produced from the VISTA site technical assessment.

“VISTA is a web-based solution that collects information from remote sites in a highly efficient manner.”

 <b>Computer Report</b> <small>Site Assessment Starts Here</small> for User@VistaSurveys.com									
<b>General Information</b>									
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								
<b>Computer</b>									
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								
<b>Memory</b>									
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%								
<b>Operating System</b>									
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								
<b>Virtual Machine</b>									
Virtual Machines	<table border="1"> <thead> <tr> <th>Java</th> <th>Vendor</th> <th>Version</th> <th>Default</th> </tr> </thead> <tbody> <tr> <td>Java</td> <td>Microsoft</td> <td>5.0.3810</td> <td>true</td> </tr> </tbody> </table>	Java	Vendor	Version	Default	Java	Microsoft	5.0.3810	true
Java	Vendor	Version	Default						
Java	Microsoft	5.0.3810	true						
<b>Browser</b>									
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								

“Non-technical site information can be collected through online questionnaires and captured in a database.”

In addition, VISTA automates the process of collecting qualitative site information through online questionnaires that allow the investigator or study coordinator to enter information into a questionnaire form via the Internet. Automatic prompts ensure that investigators complete all important fields before the form is submitted. All the information collected by the technical assessment and the online questionnaires are then captured and stored in a database to be accessed for troubleshooting and remediation purposes, or when the same site is used for future trials.

The form below shows a sample online questionnaire that is sent out to potential sites.

### Personnel for Study

**PRINCIPAL INVESTIGATOR**

Name:

Accreditation:

Medical Specialty:

**EXPERIENCE**

Have you had any past experience in conducting clinical studies?  Yes  No

	Indication	Sponsor	Phase	Year
1	<input type="text"/>	<input type="text"/>	<input type="text" value="Select phase"/>	<input type="text"/>
2	<input type="text"/>	<input type="text"/>	<input type="text" value="Select phase"/>	<input type="text"/>

Are you board-certified in any therapeutic area?  Yes  No

If yes, please state which area:

Have you ever been audited by the FDA?  Yes  No

If yes, please explain:

### Patient Enrollment

Please provide an estimate of how many subjects with the stated indication do you see at your institution every month:

Please provide an estimate of how many subjects with the stated indication will you be able to enroll over a year:

Please provide an estimate of how many subjects potentially meet the inclusion/exclusion criteria for this study:

Do you have a computerized patient database?  Yes  No

**FOR YOUR PAST 3 STUDIES, PLEASE DESCRIBE**

	Indication	Enrollment Goal	Actual number screened	Actual number randomized	Actual number completed
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Are you currently conducting or planning to conduct, in the next 6 months, a competing study for the same indication?  Yes  No

How will patients be allocated if they meet eligibility criteria for more than one study?

**“VISTA streamlines the study start-up process and benefits both the clinical team and the site investigators.”**

**“Automating the site assessment process improves investigator satisfaction by providing a better study experience.”**

To further speed up the assessment process, VISTA also offers automated fax and email reminder systems to routinely prompt sites if they fail to adhere to the planned timeline for completing the assessment. This reduces the burden of the clinical staff in trying to establish communication with sites to get them to provide the information required.

### **Why choose VISTA?**

There are many benefits to be reaped from automating the site assessment process. Lengthy paper questionnaires and phone calls, along with the complicated questions and tasks of the technical assessment, are eliminated. Automation also allows the clinical team to avoid experiencing delays in getting the information they need back from the sites, which can reach up to 1 to 4 weeks in the traditional manual process.

Clearly, the parties that benefit the most from VISTA are the clinical team and the site investigators, both key stakeholders in a clinical study. VISTA collects all necessary site information, both technical and non-technical, in a single setting. This ensures that the clinical team no longer needs to maintain multiple points of contact with investigators by sending them a host of different assessment surveys, while investigators do not have to endure the hassle of submitting the same information on multiple occasions, while benefiting from the greater convenience of providing information online.

In addition, by minimizing the need for human involvement in the technical assessment, investigators and CRAs are able to effortlessly obtain 100% accurate technical information about site computers at their own convenience without the need for any technical expertise.

The accuracy and completeness of the technical assessment information collected by VISTA can be channeled towards making informed decisions about site selection and provisioning, thus ensuring that the rest of the trial runs smoothly without any technical problems. In the event that provisioning is required, the study team is also able to come up with precise forecasts of the costs of upgrading, provisioning and connectivity needs for the investigative sites.

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. Manual site assessments often 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. In contrast, VISTA improves investigator satisfaction significantly by reducing their administrative burdens and providing a better study start-up experience.

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. Automating the site assessment process also eases the workload of the clinical team, who can then focus their time and energies on other tasks that need to be completed during the study start-up process.

#### **VISTA: better site assessments for better site selections**

By automating the site assessment process, VISTA provides better-quality site information, thus improving the clinical team's ability to select the right sites for the study. With VISTA, the time spent on gathering site information is also significantly reduced.

As industry trends move towards an intensified usage of EDC, it is important to ensure that the sites you pick are well-equipped to handle the requirements of the technology and the study. A detailed and well-performed site assessment undoubtedly contributes to the success of the study and brings about significant cost and time savings.

VISTA's site technical assessment solution is able to provide quick and accurate information to aid in identifying sites that are technologically well-equipped for the EDC software used. The combination of the technical assessment with the online questionnaires that collect qualitative site information thus ensures that the clinical staff are provided with comprehensive site reports that provide them with all data points necessary to make informed decisions about the selection and provisioning of their investigative sites.

As you ramp up your EDC studies, it is important that your site assessment process is able to effectively facilitate your site selection process and keep up with your increased demands. Do away with inefficient manual processes that result in unnecessary and costly delays for your clinical studies. Before embarking on your next EDC study, start thinking about how automating the site assessment process can help to add value to your EDC study and ensure that you choose the best sites for the success of your study.

**"Automating the assessment process contributes to better site selection decisions for successful studies."**

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