

Automated Feasibility Studies:

Optimizing the Site Feasibility Questionnaire for Maximum Benefits

Discover how automation can help you enjoy the full value of performing a feasibility study for your clinical trials



“A detailed feasibility study contributes to a successful clinical trial through better trial design and study execution.”

“One of the biggest challenges of initiating a new study lies in the recruitment of an adequate patient population.”

Are you aware of the risks involved as your clinical trials increase in size and scope?

There are many risks involved throughout the life cycle of a clinical trial, such as failures in recruiting an adequate patient population or meeting planned study timelines. These risks become all the more pronounced as sponsors start to undertake large-scale international trials with unfamiliar sites that span across multiple geographical locations.

Increasingly, study sponsors and contract research organizations (CROs) are recognizing the value of performing a comprehensive feasibility assessment in mitigating the risks involved with a clinical trial. In particular, a detailed feasibility study is critical for the planning and conducting of successful large-scale global clinical trials. A feasibility study helps promote better trial design and study execution, thus ensuring that trials avoid unnecessary study delays by meeting their planned schedules and patient recruitment targets. When performed well, sponsors and CROs have found that a feasibility study is invaluable in contributing to the success of a clinical trial and produces many significant benefits.

Plan for your clinical trial’s success with feasibility studies!

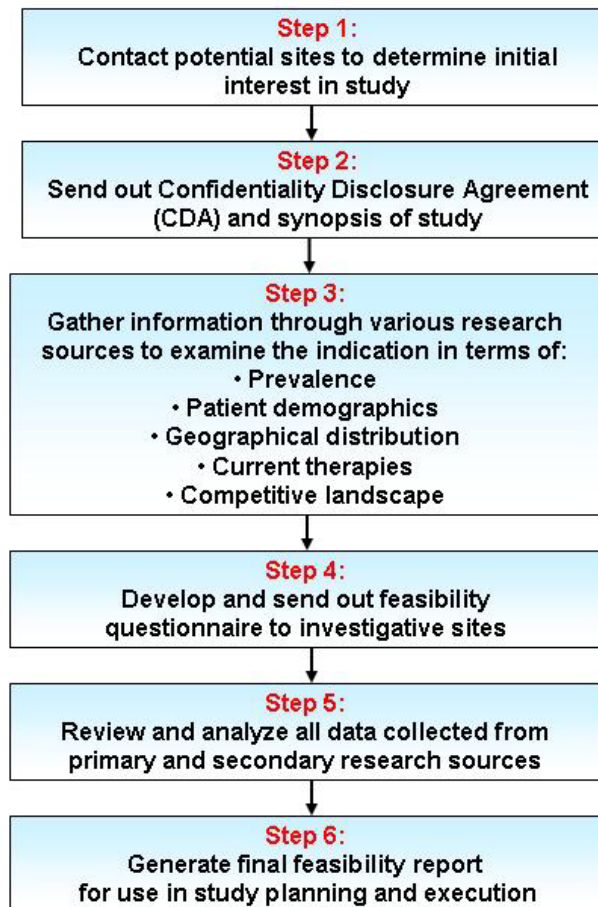
A feasibility study is typically performed as part of the planning process before the initiation of a new study. The study consists of a series of analyses based on detailed research and data about similar trials that have been completed in the past. This then provides the basis for the formulation of a sound strategy that will help to ensure a smooth execution of the trial.

Given the challenges involved in selecting the right sites for a study, undertaking a feasibility assessment at an early stage in the site selection process is highly valuable in helping sponsors and CROs choose the best possible sites for the study. One of the biggest difficulties of initiating a new study lies in the recruitment of an adequate patient population for the study, especially in the cases of large Phase III studies. It is estimated that on average, Phase III trials run for 30% longer than what was scheduled by the clinical team, with the most common reason for the delay being caused by problems with patient recruitment. In addition, 30% of a clinical trial’s timeline is spent recruiting study participants.

Hence, to minimize potential delays that may occur as a result of problems with patient recruitment, it is important to make sure that only sites with access to suitable patient populations are selected. This can be achieved with the help of a detailed feasibility study, which seeks to identify ideal trial locations for the study based on the indication and the inclusion/exclusion criteria for the study.

A large amount of data and metrics needs to be collected for the performance of the feasibility study. These include patient demographics, geographical distribution of indication, enrollment periods of individual sites, patient retention rates and recruitment methods and results. The set of information is then analyzed and reviewed by the clinical team for use in the planning and execution of the study.

Here are the typical steps that are involved for a feasibility study:



Examining the role of the feasibility questionnaire in a feasibility study

The feasibility questionnaire is a critical component of the feasibility study, as it is the main tool used to collect information from potential sites. Hence, it is essential that the questionnaire is well-designed to ensure that the questions relate back to the study design and take into account any potential issues that may arise during the course of the trial.

In spite of the value which is derived from conducting a feasibility study, sponsors and CROs are often still relying on manual methods of delivering the questionnaires and collecting information, which can lead to unnecessary inefficiencies and delays that negate the benefits of the study. It is estimated that the clinical staff can spend anywhere from 1 to 4 weeks waiting for the paper questionnaires to be returned from potential sites. This significantly contributes to the costs of conducting a feasibility study, which ranges from \$50,000 to \$250,000.

Typically, paper questionnaires are mailed, faxed or emailed to potential sites to request for more information about the sites' patient populations, recruitment strategies and other facilities that they may possess. However, attempting to collect information from investigators can be frustrating for the clinical team, as busy investigators often take a long time to complete the forms and return them, and some even forget about the questionnaires entirely. It is estimated that in order to obtain a 20 to 40% return rate on your survey, the number of questionnaires that need to be sent out is 3 to 4 times the number of responses needed. As a result, the clinical staff often end up spending additional time and effort contacting the sites through multiple phone calls, emails and faxes in order to ensure that they return the forms promptly.

The information collection process becomes even more challenging as feasibility studies usually involve a large number of sites spread over dispersed geographical locations. Apart from the time wasted on trying to get the sites to return the forms within the scheduled timeline, the clinical team also has to grapple with other problems such as missing information, illegible handwriting and the tedious task of manually entering data into Microsoft Excel or other databases.

Therefore, to reap the full benefits of performing a feasibility study, it is important to start considering automation as the key to overcoming the inefficiencies of the manual process. This ensures that site information is collected and processed expeditiously, thus shortening the time and hence, money spent on the feasibility study.

“Trying to collect information from busy investigators can be time-consuming and tedious for the clinical team.”

“Automation can help to shorten the time and money spent on a feasibility study.”

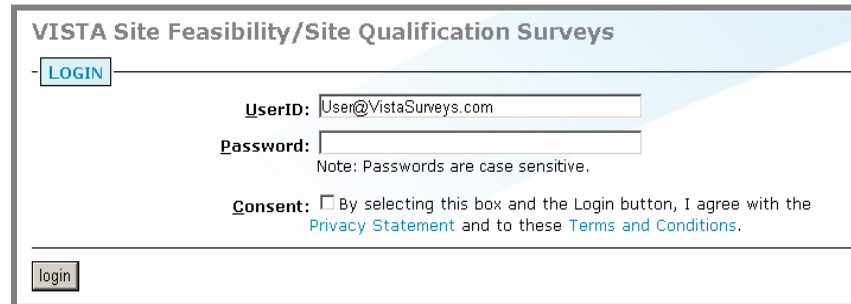
“VISTA makes use of online survey capabilities and other technologies to streamline the feasibility study process.”

See how VISTA optimizes your feasibility questionnaires through automation!

VISTA is a web-based service that uses a combination of online survey capabilities and other technologies to facilitate the collection of information for site feasibility studies. This streamlines the feasibility study process by ensuring that sponsors and CROs obtain the necessary information needed to complete the study quickly and effectively.

VISTA directs investigators to a customizable login page, where they can then access the website by entering their unique UserID and Password, as shown below. VISTA allows each participant to self-register or study administrators to pre-register participants and provide them with their login information.

Figure 1: Login page for VISTA



VISTA Site Feasibility/Site Qualification Surveys

LOGIN

UserID:

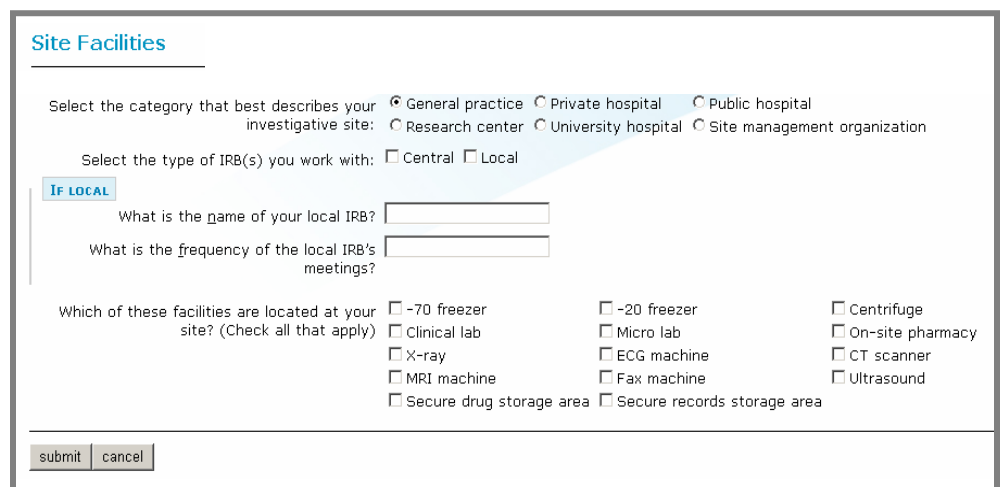
Password:

Note: Passwords are case sensitive.

Consent: By selecting this box and the Login button, I agree with the [Privacy Statement](#) and to these [Terms and Conditions](#).

Upon logging in, the investigator or study coordinator is presented with the questionnaires that they must complete. VISTA is able to fully customize the questionnaires based on the requirements of each study. Here are some sample online site feasibility forms created in VISTA:

Figure 2: Site facilities



Site Facilities

Select the category that best describes your investigative site: General practice Private hospital Public hospital
 Research center University hospital Site management organization

Select the type of IRB(s) you work with: Central Local

IF LOCAL

What is the name of your local IRB?

What is the frequency of the local IRB's meetings?

Which of these facilities are located at your site? (Check all that apply)

<input type="checkbox"/> -70 freezer	<input type="checkbox"/> -20 freezer	<input type="checkbox"/> Centrifuge
<input type="checkbox"/> Clinical lab	<input type="checkbox"/> Micro lab	<input type="checkbox"/> On-site pharmacy
<input type="checkbox"/> X-ray	<input type="checkbox"/> ECG machine	<input type="checkbox"/> CT scanner
<input type="checkbox"/> MRI machine	<input type="checkbox"/> Fax machine	<input type="checkbox"/> Ultrasound
<input type="checkbox"/> Secure drug storage area	<input type="checkbox"/> Secure records storage area	

Figure 3: Personnel for study

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:

Figure 4: Patient enrollment

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 provides smooth communication between the clinical team and the investigative site, thus improving study start-up.”

VISTA offers significant cost and time savings over the manual process!

Smooth communication between the clinical team and the investigative site is crucial to the success of your feasibility studies, and VISTA achieves this by automating the flow of information during this process. By eliminating inefficient and redundant manual tasks, VISTA speeds up the study start-up process, thus resulting in considerable cost and time savings for all stakeholders involved.

Your clinical team no longer needs to deal with mountains of paper and engage in tedious back and forth communications with investigative sites. This reduces frustration for investigators, while the ability to submit information instantly via the Web also increases convenience. Finally, providing a satisfactory study start-up experience allows the sponsor and CRO to maintain a good relationship with their investigators. This ensures that valued investigators stay inclined towards participating in future trials.

Here are the benefits that are derived from automating your feasibility studies with VISTA:

1) Avoid manual inefficiencies by harnessing sophisticated technology

- Online format eliminates delays and hassle of regular mail
- Automated email/fax reminder system improves response rates from investigators
- Data is automatically captured and stored in a central database upon submission

2) Relieves unnecessary burdens of investigators and clinical staff

- Web-based format increases convenience of submitting data for investigators
- Improves speed and ease of collecting site information for clinical staff as they receive information from sites in a much shorter time
- Exporting of data to Microsoft Excel or other systems saves time and effort spent on double data entry

3) Comprehensive

- Questionnaire forms are fully customizable to collect all information needed based on the unique requirements of the study
- Automatic prompts minimize missing information by ensuring that important fields are not left blank

4) Security of data

- Transmission of information is protected via a SSL link

5) Technology-independent

- Data is presented in XML format for easier integration with other e-clinical trial systems

“Overcome manual inefficiencies and experience the full benefits of your feasibility studies with VISTA!”

In conclusion, it is evident that conducting a feasibility study before the launch of a new clinical trial is the best form of preparation to mitigate any possible risks during the trial and help in ensuring its success. However, the inefficiencies and delays involved with the use of manual paper-based processes in these feasibility studies can often cancel out these benefits.

As a result, the clinical staff and investigators end up wasting precious time and effort on the information collection process. It is estimated that the clinical staff spend 1 to 4 weeks to obtain the information required from investigative sites for each feasibility study, and make use of numerous paper questionnaires, multiple phone calls, emails and faxes.

VISTA offers a better solution by automating the information collection process, making it much faster and easier for the clinical team to gather the information they need for improved feasibility decisions. This allows the feasibility study to be performed more efficiently, thus shortening the study start-up process and reducing unnecessary costs. Start automating your feasibility studies today and break away from inefficient manual processes to experience the full benefits that performing a feasibility study offers!

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