



# Better Feasibility for Global Clinical Trials

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W W W . P R A I N T E R N A T I O N A L . C O M



# Better Feasibility for Global Clinical Trials

## Introduction

**T**oday's clinical trial landscape is littered with trials that fail to meet their planned timelines and patient accrual. For any large Phase III program, a global footprint will be necessary in order to stay on schedule and recruit enough patients, so understanding where to go and what benefit each region can bring will be critical to successful planning and implementation.

By planning ahead and developing a draft protocol synopsis along with a formal feasibility assessment prior to finalizing the protocol, timelines and patient accrual, it is possible to devise a more realistic timeline and budget for your clinical research program. A carefully constructed and implemented feasibility questionnaire will help you determine where to hold your trials, based on patient and investigator availability and interest in local regions, among other factors. With these tools, you will also gain early feedback on your study design so you can refine it before you launch your study program.

You will realize benefits from having performed a thorough feasibility throughout the course of your clinical research program. You will quickly learn that feasibility is not a luxury item or merely "nice to have." It is a necessity to conducting successful global clinical trials.

## Ten Tips for Feasibility Success

### 1. **Research emerging countries**

Take a good look at the countries where you plan to conduct your feasibility. Assessing feasibility can be a meticulous process, so research is key to using your time and resources wisely. First you should know the local patient populations. Take advantage of supporting data that has already been compiled through such resources as IntrinsicQ, IMS and pharmacist databases, covering segments of the US and EU markets. Also check the literature and prior FDA or SBA approvals. Who else has run similar studies in those areas? What countries did they choose and how well did their sites accrue? Does existing data support the need for a global study?

### 2. **Determine your comfort zone**

How necessary is it to keep the study details confidential? Are you comfortable that the investigator you are questioning will honor your need for confidentiality? How much will maintaining a confidentiality shield delay your timeline or create a barrier to completion of your feasibility process? Do you need to issue a blinded questionnaire to protect proprietary information?

### 3. **Consider what you need to assess**

Build a questionnaire that will give you answers to:

- Do the medical standards of care match the protocol?
- Does the trial design fit into the local standard of practice?
- What ethical or cultural issues should you consider?
- Are there reimbursement issues?
- For which drugs will you be required to pay?
- What are the supportive care standards and who pays?
- Are diagnostic and follow-up services available, such as PET, CT or MRI scans?
- Are infusions or administrations of drugs needed?
- Will care be handled on an inpatient or outpatient basis?
- What follow-up care issues need to be addressed?

### 4. **Design it well**

The most important step is to design your feasibility questionnaire well, because a poorly designed tool will lead to useless data. The questions should support the study design and also anticipate potential issues. You need to balance your questions so that you ask enough to draw clear, informative answers without soliciting extraneous data that will be collected later anyway during a pre-study site visit.

### 5. **Test and refine**

Use a control group to test your feasibility instrument. As with any questionnaire, a usability test before implementation will give you feedback to inform your revision process. The result will be questions that are precise and easy to answer and that provide useful information.

**6. Be informative**

Potential study sites will want to know all they can about your study program up front. By providing the study synopsis as an addendum to your feasibility questionnaire, you will receive more meaningful, better informed answers to your questions.

**7. Plan your approach**

Will you be administering your survey from a central location or regionally? Keep in mind the effects that local language, culture and relationships can have on participation. Do you have a centralized fax service you can use? Another route is to set up a designated website with varying levels of access.

**8. Nurture goodwill**

Show that you value the time and knowledge of the sites you survey. If your study intent is uncertain use a ballpark feasibility approach as a precursor to a full feasibility assessment. Keep your feasibility program relationship-driven to optimize your response rate, and to further increase your returns, offer some form of payment or reward. The goodwill you extend now will pay off later during the execution of the studies.

**9. Expect results...realistic results**

To obtain a 20-40 percent return rate on your survey, you have to plan to send three to four times the number of questionnaires as the number of responses you need. For instance, for 300 questionnaires sent out, you might receive 100 responses, which would represent 30-40 actual sites. Therapeutic indication, drug class, patient/physician needs and name recognition are other factors that will influence the response rate. You can realistically plan on a 6-8 week process for your global feasibility program. Keep in mind that self-reported accrual rates are not necessarily accurate and may be inflated by at least 50 percent in the US, although somewhat less so in other world regions. However, standard-of-care data, medical data and regulatory and ethical data are generally reliable.

**10. Check your results**

It is best not to take all the data you receive on face value. Use registry data as a cross reference and analyze your feasibility results further by checking the literature, prior history accounts, previous experience and other resources. As you move forward with your protocol development, keep in mind that trial timelines and assumptions cannot be based solely on feasibility results.



# Sample Feasibility Study Questionnaire

Please fax back the following pages to: [Name of local Company contact] at Fax [local fax #]

## Contact Information (please complete or correct)

Investigator Name: \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_ E-mail \_\_\_\_\_

What is your main field of expertise? (please tick only one)	<input type="checkbox"/> Specialty 1 <input type="checkbox"/> Specialty 2 <input type="checkbox"/> Specialty 3 <input type="checkbox"/> Specialty 4 <input type="checkbox"/> Other (please specify): _____
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Investigator Signature	Date
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## Part A: Patient Recruitment and Study Start

1. How many patients with [ <i>disease indication</i> ] do you see at your institution per month?	_____ Patients per month									
2. Now, please carefully review the attached Study Synopsis.  Based on the specified inclusion/exclusion criteria and study procedures, please estimate the number of eligible patients that you might see per month.	_____ Eligible patients per month									
3. What percentage of these eligible patients do you expect would be willing to sign an Informed Consent Form and participate in this study? ( <i>tick only one</i> )	<input type="checkbox"/> 0-20% <input type="checkbox"/> 21-40% <input type="checkbox"/> 41-60% <input type="checkbox"/> 61-80% <input type="checkbox"/> 81-100%									
4. Do you have capabilities to perform the required study procedures at your site?	<table style="width: 100%;"> <tr> <td>Procedure 1</td> <td><input type="checkbox"/> Yes</td> <td><input type="checkbox"/> No</td> </tr> <tr> <td>Procedure 2</td> <td><input type="checkbox"/> Yes</td> <td><input type="checkbox"/> No</td> </tr> <tr> <td>Procedure 3</td> <td><input type="checkbox"/> Yes</td> <td><input type="checkbox"/> No</td> </tr> </table>	Procedure 1	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Procedure 2	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Procedure 3	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Procedure 1	<input type="checkbox"/> Yes	<input type="checkbox"/> No								
Procedure 2	<input type="checkbox"/> Yes	<input type="checkbox"/> No								
Procedure 3	<input type="checkbox"/> Yes	<input type="checkbox"/> No								



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5. What is your primary treatment choice for patients with [disease indication]? (Tick only one)	<input type="checkbox"/> Treatment A <input type="checkbox"/> Treatment B <input type="checkbox"/> Treatment C <input type="checkbox"/> Other (specify) _____
6. Can you recommend other investigators potentially interested in this study whom we should contact? Name and contact information:	

### Part B: Summary

I am interested in participating in this clinical trial

I am not interested in this clinical trial due to:

- Lack of suitable patients
- Subject eligibility criteria are too difficult
- Disagree with the study design
- Protocol procedures are too difficult
- Ongoing competing studies in my institution
- Other (please specify): \_\_\_\_\_

Please use this space for any additional comments you may have related to the study protocol or your interest in this trial.

FOR MORE INFORMATION ON FEASIBILITY FOR GLOBAL CLINICAL TRIALS, PLEASE CONTACT KENT THOELKE, SENIOR VICE PRESIDENT & HEAD, THERAPEUTIC EXPERTISE AT [THOELKEKENT@PRAINTL.COM](mailto:THOELKEKENT@PRAINTL.COM).



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