

Feasibility Tips for the Expert Research Sites

By Christian Burns

When it is time for Sponsors and CROs to determine which sites are right for their studies, a feasibility questionnaire is a site's first opportunity to make an impression and to decide on whether the study may be a good match. In this whitepaper, Christian Burns, Cofounder of BTC, discusses strategies that sites often overlook when submitting their feasibilities.

I. Communication and Early Steps

One of the most important tactics to start off a positive relationship with a sponsor/CRO during the feasibility process is to ensure your site has clear communication and opens a dialogue. Have your site's main point of contact attempt to start a direct relationship with the appropriate person distributing the feasibility. Create an open, honest dialogue and establish clear expectations on whether your site can be an asset to the upcoming or ongoing study. If a sponsor has a difficult time getting a response from your site right off the bat or you submit the feasibility late or respond to them after the deadline— they will have a negative first impression of the organization of your site.

For trial opportunities, you need to have a dedicated point of contact with the sponsor in order to facilitate a clear line of communication. Once the CDA or feasibility is introduced, take a look at your past metrics and data to see what other studies you have conducted with a similar indication or patient population. A great way to keep organized with this is through a master spreadsheet outlining historical metrics and data.

Make sure to store historical metrics with at least these basics:

- Number of patients contracted
- Number of patients enrolled
- Enrollment period
- Any notes regarding outcome/difficulty

Ask yourself if this is a study that you're qualified for. Remember its okay to say no, just make sure you get back to them within the allocated timeline or make sure to ask for an extension ahead of time!

II. Ask Questions

Completing a feasibility questionnaire is a great way to learn more about the study opportunity and determine if it will be a good fit for your site. It also provides an open line of direct communication with the sponsor, in addition to providing you with the opportunity to have an honest conversation with them. Lastly, it will establish clear expectations about what your site can offer and how your team can be an asset on the study.

Before you complete the feasibility make sure you ask the right questions to the sponsor to ensure you understand initial expectations and can be sure your site is in line with them. These questions can include but are not limited to:

What specialty is required of the PI?

If your site has done dermatology studies before, but the trial requires a Dermatologist, you will want to confirm with the sponsor which specialty is required to be sure you are submitting the appropriate physician.

When is the first patient expected to enroll?

Knowing when the first patient is expected to enroll will give you information regarding your own timelines - you can allocate your resources and make sure you won't have competing studies enrolling at the same time. We see sites declining studies at this stage based on another opportunity when the trial you would be submitting for may not start until after it is completed.

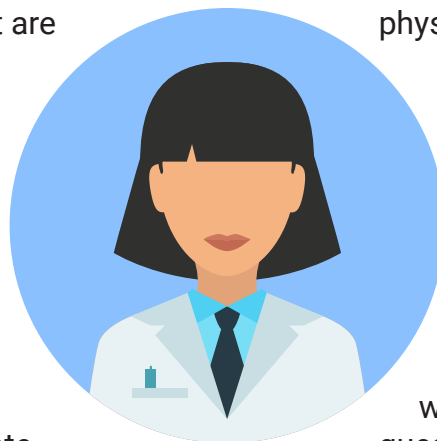
What experience is needed?

Experience is a large part of what Sponsors look for – but not necessarily the only thing. If it's a large study with 100+ sites – you can be more aggressive with your pitch, especially if you've conducted trials in a similar area or similar patient population. Just be sure to expand upon this in your feasibility.

How many patients are sites expected to screen/randomize per month?

This information is crucial to measure the effectiveness of your site. Be sure your site can deliver at least the expected number of patients. Don't over sell your site if you won't be able to meet enrollment goals. It is also

important to consider all of your resources so you do not undersell yourself – when thinking about your patient access keep in mind your database, community potential, referring physicians, etc.



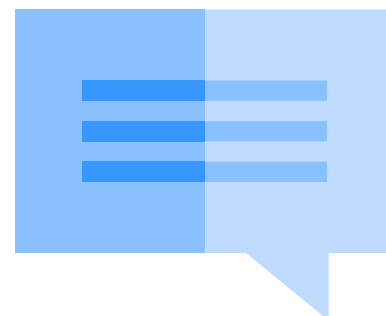
What type of site would be ideal for this trial?

This is a great question to gauge what type of sites the sponsor or CRO is looking for. Should the site be more of a hospital or a typical research site? These open-ended questions will help you fill out a solid feasibility questionnaire.

Is there any special equipment required for successful completion of this protocol?

Oftentimes sponsors will cover the cost of any added equipment, or at least part of it, which may make the trial worth doing. If the sponsor/CRO is not playing on funding the equipment make sure you understand the potential cost of purchasing it yourself – the cost of the equipment may outweigh the financial benefit of the study!

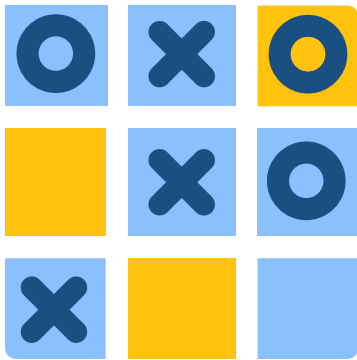
It's also imperative that you communicate the need for a deadline extension early. Many times sponsors understand that you're busy, but how you communicate that is key. If an extension is permitted be sure you're able to deliver in that timeline. A solid timeline standard is 3 business days for a completion of a feasibility.



Remember you're building a relationship with the sponsor, so a solid communication foundation is great place to start.

III. Make an Impression - Don't Just Be Another Site!

It may sound cliché – but in the midst of qualified sites all vying for the same study, it can be difficult to stand out from the crowd. Try to provide as much data as possible when filling out your feasibility. It's all in the details – metrics and past successes are a great way to beef up your feasibility, they also provide memorable tidbits and insight into your site, making you stand out from the rest.



Don't be afraid to include experience for which you didn't quite reach enrollment goals. Showing why your site didn't enroll gives the sponsor insight on how you address challenges,

and shows that you're ready to make changes in order to enroll. We all learn from our mistakes - so if you have solid reasoning be sure to explain it in your feasibility. Maybe the inclusion criteria was extremely challenging. Maybe you were added to the study a few months before enrollment ended. Sponsors will understand and appreciate your honesty.

In contrast, if you just provide metrics with no follow up details or explanations, you may be passed over. Explain how you will use recruitment metrics from the past to better prepare for this particular study. Also it's important to provide aggressive but realistic timelines for your site. Even if the expected number of patients you'll enroll is less than what the Sponsor is asking for – provide evidence for why you think a lower number is better.

Its also Imperative to fill out all of your questions – don't leave anything blank. If you take every question into consideration with a solid answer, it will showcase your attention

to detail and respect for the Sponsor's time. Sponsors can tell when feasibilities are rushed, making it easy for them to place you in the "No" pile.

Think of ways to help your site stand out in the crowd of the rest of the sites. Research is becoming more and more competitive. That's why making a first impression is vital when you want to be awarded more studies.

IV Feasibility Scenarios

Site A

Question 1:

What percentage of patients would come from the site's database, referrals and other (specify)?

Answer:

40% Database

20% Referrals

40% Advertising

__% Other

(Please specify): _____

Question 2: If you have a high rate of potential referrals please explain in detail how you recruit through referrals.

We have a strong referral network

Question 3 If you have a high rate of patients coming from advertising, please explain in detail how you recruit through referrals.

Advertising has always been effective for our site

As you can see, Site A included very little detail. Instead of the site just saying "We're the best" the site should have included more detailed reasons why. The sponsor wants to know that their investment in your site will produce results, and they base their decision on evidence from the feasibility questionnaire.

SITE B:

Question 1:

What percentage of patients would come from the site's database, referrals and other (specify)?

Answer:

70% Database

20% Referrals

10% Advertising

__% Other

(Please specify): _____

Question 2: If you have a high rate of potential referrals please explain in detail how you recruit through referrals.

We have three orthopedic physician practices within our area that have referred patients to our site for the past seven years. They refer so many patients that our physician referrals alone sent our site 11 of the 34 patients that we enrolled.

Question 3 If you have a high rate of patients coming from advertising, please explain in detail how you recruit through referrals.

Each time we are able to receive an average of \$10,000 for advertising we enrolled 8 and 6 patients each of the past two radio campaigns for OA of the Knee. We also have enrolled several patients utilizing our partner organization's online advertising campaign for \$2,000 for two months.

Even though Site B has less direct clinical trial experience, their feasibility questionnaire showcased their strengths and provided great detail. In this case we have seen that sponsors are more likely to go with Site B with less experience, rather than site A with more experience due to their more detailed feasibility questionnaire.



IV. Feasibility is Complete, Now What?

Once your feasibility is complete, its important to follow up and keep that line of communication open. Follow up with the sponsor contact after you've submitted and be sure to reconfirm patient population and your prior experience. Be sure the way you present your site is professional and cohesive; this includes emails, your website, and any branded materials you send over to the sponsor. Consider a Site Sell Sheet – a one sheet outlining all of your capabilities, inclusive of your PI/ staff experience. A well-designed site one sheet not only provides a great first impression of your site – it shows the sponsor that your attention to detail goes beyond your practice. See an example [here](#). **What are we linking this to?**

Overall, as the feasibility questionnaire is the most important document outlining your site, it's important to have a well presented submission in order to gain more awarded studies. Be aggressive, but don't promise more than you can handle, and be sure to add detail to each question of the assessment.

For further questions or interest in a dedicated business development specialist, please contact the BTC Network today.