



## Conducting Feasibility for a New Clinical Trial

*Meagan Vaughn, Ph.D.,  
Research Scientist*



### **What does the word “feasibility” mean to you?**

It may seem like a simple question, but I have found that “feasibility” has many interpretations within the clinical research industry. When we work with a sponsor to conduct feasibility for clinical trial planning, our first task is to figure out what their definition of feasibility is, and more specifically, what questions they are trying to answer.

Most often, the question is “How many sites will we need to meet our enrollment target and timelines for this study?” Of course, this is an important question, but asking this question can be putting the cart before the horse. The foundation of a successful study is a protocol that is both scientifically sound and viable from an operational perspective. Assuming the former has been sufficiently vetted, the first goal of conducting feasibility should be to test the

assumptions of the latter. This is the time to think through the logistics for the site and the subject, and consider the protocol requirements that might affect factors like enrollment, retention, and data quality. Use this exercise to formulate questions that will stimulate a dialogue around these issues with potential investigators. For this type of early stage feasibility, you also need to think about the right tool to gather the information needed, and a web-based survey probably isn’t going to cut it if you are looking for thoughtful feedback. This is the time to leverage relationships with investigators and coordinators to have some focused conversations using your questions as a guide for the discussion. More often than not, they will be able to quickly identify potential show stoppers in your inclusion/exclusion criteria, as well as assessments or design elements likely to result in frequent protocol deviations.

Once the feasibility of the protocol has been thoroughly evaluated, the next step is to examine the feasibility of the trial given the constraints of timelines and resources. To this end, a web-based survey can be a quick way to gather data to inform enrollment projections and come up with a list of candidate sites. Below are a few points to consider when crafting a feasibility questionnaire:

- Asking the right questions is just as important as not asking unnecessary questions. Stay focused on the key pieces of information needed. If you aren't going to analyze it, don't ask the question.
- A poorly written question will result in unreliable data. Consider your audience and have several people review and test the survey before deploying. For example, consider the question "How long does study startup typically take at your site?" Without defining the starting point (receipt of the protocol, site selected, or receipt of the regulatory packet), the answers may vary widely.
- Judicious use of skip logic and display logic in an electronic questionnaire can reduce the burden on respondents and provide cleaner data to the person on the receiving end. For example, you can use skip or display logic to drill down into specific topics that may only be relevant for some sites (such as regulatory history for sites that have had an inspection).
- Engage sites in the feasibility process by asking questions requiring their input (e.g., any question that starts with "In your experience...").

➤ Use the right tool to collect information. At Rho, we use Qualtrics as a survey platform. This platform provides many advantages for conducting feasibility, including:

- Responsive surveys (skip logic, display logic, survey branching),
- Piped text (automatically fills in certain fields for sites that have responded to previous surveys), and
- Real-time reports that can be published to the web for sponsor review

One strategy that we have found to be successful in helping sponsors meet timelines for study startup is to start feasibility and site identification activities under a consulting agreement during the RFP/bid-defense/contracting process. Once a CRO partner has been selected, the team can hit the ground running with site startup activities. This type of early feasibility effort can also facilitate protocol development by gathering site feedback on key operational parameters.

The take home message for feasibility? Spend a little time thinking critically about the key pieces of information that you need that are unique to your project and goals. This will help to hone your feasibility strategy so that you can ask the right questions using the most effective approach.

#### **ABOUT THE AUTHOR**

*Meagan Vaughn, Ph.D., Research Scientist, designs and implements clinical trial feasibility assessments. She has over 10 years of experience in scientific writing and editing, has authored and contributed to numerous peer-reviewed publications, and serves as a reviewer for several medical and public health journals.*

