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# Best Practices in Site Feasibility Studies Can Set the Stage for a Healthy Trial

*By Conor Hale*

Well-performed, confident site feasibility studies, at times a tedious, thankless task, can become the single most important factor in reducing costs and time spent during a clinical trial, according to Wes Martz, associate director of WCG's clinical services division.

Leading causes of study delays and busted budgets — startup timelines, enrollment issues and attrition — can be mitigated through a comprehensive, centralized and transparent site evaluation process, said Martz, during a WCG webinar on best practices.

In addition, crowdsourced feedback from feasibility surveys can give sponsors, CROs, service providers and investigative sites the opportunity to re-calibrate their operations.

With wider adoption of benchmarking and other clinical trial management tools, sponsors know exactly how many sites they may need, which then turns feasibility processes into what is essentially a job interview, he said. That makes site pre-identification essential for efficient study startup.

Sponsors should evaluate potential sites' past recruitment and retention of the patient population, Martz said, including their track records in enrollment. A site's infrastructure, data quality and startup timelines, as well as any additional IRB or ethics committee requirements, should also be considered.

While the ability to recruit patients is at the top of the list, sponsors should also plan for the entire life of the study, including any possible future effects on accrual — such as whether or not the principal investigator is a specialist that patients may regularly see outside of a clinical trial, where they may feel more comfortable.

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—Wes Martz, associate director, WCG

In one example, a study of a respiratory syncytial virus vaccine had its site feasibility initiative focused solely on the ability to recruit — which made some sense, considering the trial required patients be enrolled within one to two days after birth, through NICUs and neonatologists, Martz said.

"The problem, of course, became clear very soon," he said. "The mothers didn't want to bring their babies back to the hospital on a regular basis. They had planned to bring them to their family physician or pediatrician."

"It's important to think about how the whole patient pathway works — not just up to enrollment, where you can grab them and provide the opportunity for the trial to the patient — but also to conduct that study ongoing," he said. Sponsors should keep an eye on whether patients are going to be more likely to regret participating later in the process, because they've committed to treatments they otherwise wouldn't have, and may feel like they're not getting any additional care.

Sponsors should tailor their communication and outreach strategies based on their product, study and scenario, as sites may receive dozens of feasibility surveys and questionnaires at a time. In return, sites can make themselves stick out from the pack by taking the opportunity to provide thoughtful responses and express enthusiasm for the scientific project.

Communicating with sites before they receive the invitation leads to higher response rates and faster turnaround times, Martz said. Even larger pharmaceutical and biotech firms that can bank on name recognition and established relationships with sites, can reduce the time needed to fill out questionnaires by more than half by communicating early, he said.

Smaller companies, or companies with a nascent intellectual property, may need to cast wider nets and market the product by sharing articles or even early study results. Educating the site personnel about why the product is exciting, possibly through doctor-to-doctor communications, can increase response rates significantly.

Now, the so-called "boring" studies — such as FDA-mandated postmarket trials, those with an unmotivated patient population or trials that simply do not pique the scientific interest of investigators — may require more of a site recruitment effort, Martz said.

Sponsors should broadcast any perks for sites that decide to participate: such as new technologies being utilized, cutting-edge

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trial management systems and the possibility for remuneration. Describing the study as "well-funded" can be a successful tactic, he said.

Feasibility questionnaires should be designed for the best experience by the sites and the end user, and the shorter the better. In some cases, this is a site's first indication of how your company does business, Martz said. Long, disjointed questionnaires with redundant questions seeking irrelevant information can be frustrating, making sites more reluctant to work with the sponsor in the future.

The format of the survey also can increase response rates. Questionnaire responses can be pre-populated into the form to minimize the chance for varied or incorrect interpretations of the questions, but sponsors should allow for qualifiers or explanations in critical sections.

Wherever possible, it's helpful to ask for hard, whole numbers — such as patient counts — instead of asking for percentages, which can give sites a license to make guesses, Martz said.

Sponsors should build a database of the responses they receive, to help pre-identify sites the next time around. It also lessens the burden on sites by eliminating the need to have them enter the same information repeatedly.

Meanwhile, a centralized reporting process can be scaled up to encompass a global feasibility initiative, and provide study leadership real-time views of site-level responses. It can also promote transparency and accountability for any decisions to proceed, Martz said, as well as foster a collaborative approach to the process.