The Changing Face of Site Feasibility

Why a new clinical trial landscape demands greater collaboration and flexibility

Clinical research professionals have witnessed a shift in the industry's approach to clinical trials over the past decade. Large-scale, global trials that encompass hundreds of sites and many thousands of patients continue to give way to more narrowly defined studies focused on rare diseases, orphan indications, and the promise of genetic-level advances. This shift not only puts patient access at a premium but also forces us to reconsider our site selection values.

Today, sponsors and clinical research organisations (CROs) must assess the methodologies used to conduct feasibility studies for site selection. Traditional tactics treated the evaluation of clinical sites much like a competitive battle to see who came out on top. This will no longer suffice for trials in which the global patient pool consists of hundreds of candidates – or even fewer. Instead, we must ask ourselves, "How can we create a coalition that will get the research done?"

In a field that has long prioritised attributes such as investigator/staff experience and equipment and facility resources, sponsors and CROs must place patient access on top of the list of key selection criteria. The onus now is to be sure potential sites are not excluded due to lack of opportunity to participate in clinical trials. A deeper assessment can help foster mutually beneficial relationships between sponsors, potential sites, patients, and advocacy groups. It's a framework for success that requires a new level of creativity and critical thinking, as well as building strong relationships.

Traditional Feasibility Approaches, Proven Methodologies

Understanding how the industry needs to evolve begins with appreciating proven feasibility methodologies. There is value in assessing all aspects of feasibility that have traditionally set a study up for success; CROs simply need to consider how and where the application of these approaches fits into smaller-scale initiatives.

In the past, best practices dictated assessing the following categories for site suitability:

- Previous performance history
- Investigator and staff experience (inclusive of competitive trial activity)
- Access to patients
- Access to equipment/facilities/logistics
- Study start-up (inclusive of ethics, regulatory, import/export, etc.)

CROs conducting a feasibility assessment would likely have used a comprehensive questionnaire template that drilled down into hundreds of areas related to these categories. While access to patients has always been an important component, the matrix for establishing suitability would have placed high priority on the previous performance, investigator experience, and equipment/facilities/logistics categories.

Consider Fabry disease, a rare genetic condition that creates complications in key organs such as the kidneys, heart, and skin. Because the population of patients with Fabry disease is small and scattered across global geographies that lack clinical trial experience and resources, this approach would have automatically eliminated many sites that could provide essential patient access.

Depending on the depth of the potential candidate pool, the need to re-engineer the selection process may vary. That's why it's important to keep proven methodologies at the forefront and weigh each category to establish the right recipe for an effective site selection strategy.

Apply Flexibility to Feasibility Best Practices

Determining how to balance traditional methodologies with the need for flexibility starts during the proposal process. As CROs conduct epidemiological and other assessments, key information regarding the size of the patient pool, geographies where patients are treated, and the care pathway patients follow, will surface. This data should inform a strategic roadmap that covers tactics for collaborating with patient advocacy groups, partnering with clinical sites, and building strong patient relationships.

For example: On the country level, feasibility for a study related to Fabry disease should start with an understanding of the geographical footprint. A quick review would reveal that many of the countries where patients with Fabry disease are located lack clinical sites and investigators with clinical trial experience. As the feasibility assessment progresses, however, the CRO might notice that some of these countries have broader experience in gene

Region	Country	Experience (Fabry)	Experience (Gene Therapy)	Competition (Gene Therapy)	Patient Population	SU Days	Relative Costs
NAMER	United States						
NAMER	Canada						
APAC	Australia						
WE	United Kingdom						
CIS	Russia						

Example: Worldwide Opportunity Matrix

therapy trials. Although not directly associated with Fabry disease, such experience could prove advantageous as these studies allowed regulatory authorities to evaluate the complexity of increasingly complex risk/benefit profiles for patients. The CRO would then be able, and arguably obligated, to provide the proper training and support for these research-naïve sites.

The key is to develop a ranking matrix to evaluate the country or site opportunity. While "experience" may only rank as "medium" on the country opportunity matrix, high access to patients may ultimately offset the experience score. A CRO would then know where it needs to fill in the gaps. It might want to help inexperienced partners by providing additional education, best practice recommendations, and oversight, for example.

The approach to feasibility on the site level would be similar and would include a review of equipment and logistics. For some indications, ranking low in this area is a deal breaker. With a rare disease, however, CROs might have opportunities to adapt strategy. Take a study protocol that requires access to an MRI machine, for instance. If a site lacks an MRI machine, the CRO may be able to arrange for screenings at another organisation, along with patient transportation resources.

Ultimately, it's important that CROs and sponsors avoid constraining feasibility studies. Consider all data to make the best decisions. Although the methodology empowering traditional feasibility has value, there are very few factors that should be true deal breakers for all studies. We need to embrace flexibility and creativity over efficiency and familiarity as we rise to meet the challenge these new studies present.

Setting the Stage for Successful Partnerships

The feasibility process is becoming more intimate as the industry works to bring more target trials and rare disease studies to patient populations quicker. Old strategies such as blasting out e-mails to hundreds of sites hoping to identify the ideal sites through volume and then bombarding those sites with a bloated survey of 150 questions will not set the right tone for a long-term partnership.

Instead, CROs must invest in providing sites with improved customer service by providing single points of contact for the feasibility and site activation process. Additionally, sites might feel valued if they receive a short questionnaire with an embedded video that explains and showcases the mechanism of action and value proposition to potential patients who lack treatment options. Alternatively, in many situations, forgoing a questionnaire altogether and meeting face-to-face for a hybrid feasibility/pre-study site visit is ideal. Relationships are established through give and take, and strategies should be designed around the unique needs of the sites and the patient story. Investments in technology are needed to improve the experience for all stakeholders.

An open mind to innovation sits at the heart of future feasibility success. CROs and sponsors should carefully evaluate where their preconceived assumptions come from and whether they still apply in today's evolving landscape. Reaffirm effective methods, but throw out those based on older, broad-scope types of trials. With new thinking, the industry can raise the bar and increase the benefits for patients.

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