



Five Best Practices for Taming the Global Clinical Trial Beast

All clinical trials come with inherent challenges. Sponsors must navigate an intricate web of regulatory issues, approval time frames, operational complexities, and perhaps the greatest hurdle – patient recruitment and retention. These predictable challenges are compounded exponentially in global clinical trials due to their scope.

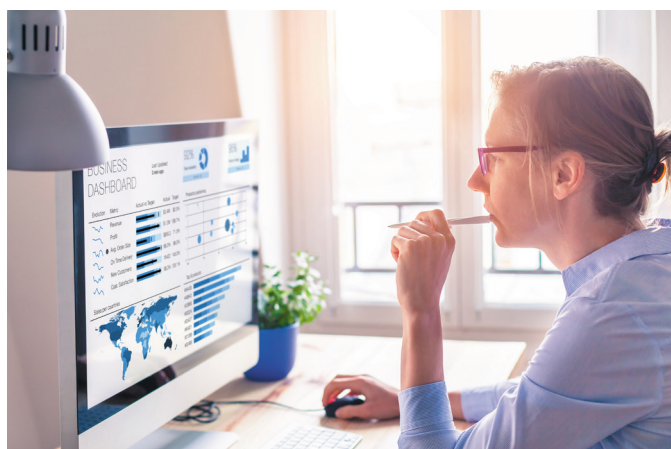
Global studies may encompass thousands of patients at hundreds of sites that cross international boundaries, as well as huge amounts of data. If not thoughtfully planned and strategically managed, global clinical trials can quickly spiral out of control. That leaves sponsors exposed, both financially and in terms of their reputation, and the industry lacking the potential advantages of a new therapy. Before designing the next breakthrough global study, sponsors should consider these five best practices:

Best Practice #1: Conduct a Proper Feasibility Study

Proper planning seems to be a given when designing a global study, but surprisingly, it is an area that is often overlooked. Many studies fail to comprehensively address all the key areas of a clinical programme – regulatory, operational and patient recruitment. A full feasibility study should provide a complete picture of time frames and costs across all these categories, as well as the probability of overall clinical trial success.

Simulation modelling is a good place to start to help predict outcomes and determine whether the time frame for a specific clinical trial is practical or whether it makes sense to consider alternative time frame proposals. A variety of approaches exist that help sponsors improve the quality, efficiency and cost-effectiveness of decision-making.

In addition, feasibility studies should consider how various geographic locations might affect the speed and efficacy of a clinical



trial. Key questions about a locale that can better inform decision-making include:

- What other types of clinical trials have been completed in the country?
- What is the regulatory framework for approvals? For instance, working with some review boards will add a significant number of months to the process.
- Is the country stable from a security/political standpoint?
- What data exists to support positive patient recruitment and retention?
- What cultural roadblocks exist? For example, the patient populations in some countries frown upon use of placebos in clinical trials.

Having regulatory and politically mindful “boots on the ground” in any given locale, as well as access to an epidemiologist, can go a long way toward better geographic decision-making.

Best Practice #2: Listen to the Data

First-to-market is a critical success factor in a competitive marketplace. Pharmaceutical manufacturers must run efficient clinical trials to ensure opportunities are not missed.

That said, many global clinical trials cave to time-to-market pressures and essentially back into a strategy and timeline based on commercial optimisation. Be careful, because this approach can be a recipe for disaster. It's important that sponsors not only run full feasibility studies but also heed what the data tells them. If a time frame is not practical, backing into the equation will only exacerbate challenges and create additional costs.

Best Practice #3: Include Investigators and Patients in Trial Design

Investigators and patients are the foundation of clinical trial success, yet the industry often leaves these stakeholders out of the protocol design process. Getting input from the clinicians who work face-to-face with patients enables study teams to better determine which approaches will work best and identify potential pitfalls to study design.

In complementary fashion, building stronger relationships with patients who might participate in the research not only ensures a stronger protocol but also improves retention rates. Sponsors should “pressure-test” the protocol by asking patients key questions about their lifestyles and how their families are affected by their disease. They should also gain insights into patients' limits. For instance, how many blood sticks is a patient willing to undergo? Or, are patients willing to fly to a particular location?

Outreach to patients optimally starts at a fairly early stage of protocol development, when a solid synopsis has been outlined.



While enough detail must exist to be able to request useful feedback from patients, the protocol should not have proceeded too far into the development phase to negate their input.

Protocols can then be developed to address the nuances identified, creating a study that is primarily written “for the patient, by the patient.” A study should engage patients on a level that makes them want to volunteer themselves and their time. Regardless of geography, they must feel confident that enough flexibility exists to support their current life situations.

Best Practice #4: Patient-centred Recruitment and Retention

Amid all the facets of a global clinical trial, patient recruitment and retention is the area where a study team should have the greatest control. Yet, recruitment and retention remains one of the greatest struggles in terms of identifying the right tactics.

Gone are the days when study volunteers were primarily identified through physician referrals and on-site chart reviews. Although these strategies are still part of recruitment, tactics must broaden to include direct outreach to patients. Patient-centric strategies are increasingly important to engaging trial candidates for the long term.

Today’s patients have more access to information than ever before, and many want to play a collaborative role in managing their diseases. Consequently, clinical trials should engage with patients in the same ways they are accustomed to communicating in other areas of their lives. That means using advanced technology and digital frameworks. Use of smartphones, tablets, wearables and handheld devices, for instance, should be mainstream in any recruitment and retention strategy. These tools can be used to share information, send appointment reminders, answer questions and maintain open lines of communication.

Other tactics that can support a patient-centric recruitment and retention strategy include: travel assistance, wearable devices or in-home nursing options when travel is difficult for patients; debit

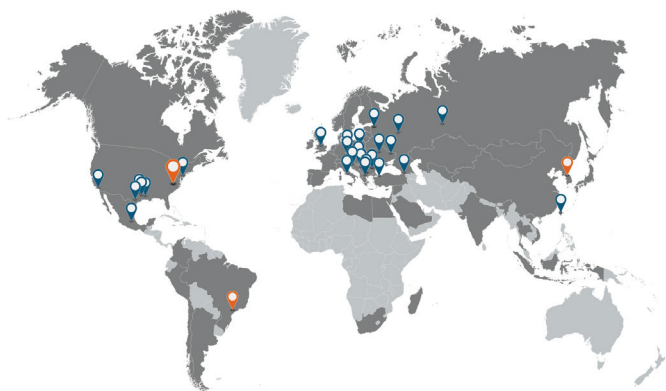
cards to cover the cost of meals and other needs; greater access to educational resources and clinical trial information; and access to online patient communities.

Best Practice #5: Choose Partners with Experience in Global Trial Development

Global clinical trials bring substantial insights and benefits to the medical community. In tandem with the opportunity, they are also characterised by sizeable complexities and resource requirements.

The business case for leveraging the expertise of a clinical research organisation (CRO) with specific experience in global trials cannot be understated. For a trial to run smoothly, those designing the operations and protocol must have a deep understanding of how to choose optimal partners and locations. They must have global reach, yet also the ability to be agile when needed. Use of advanced technology to support patient-centric recruitment and efficient operations also is an important consideration.

Global clinical trials are exceptional in terms of their opportunities and challenges. Sponsors engaging in an international study must do their due diligence to achieve success. Simply put, there are snares at every turn, so global clinical trial planning must minimise risk, provide maximum margin and remain flexible.



Jeffrey Zucker

Jeffrey Zucker, M.S., is senior vice president of Global Clinical Operations, Site Management and Trial Optimization at Worldwide Clinical Trials. He has been in the clinical research industry for over 20 years, most of which has been focused on Rater Training, Feasibility, Patient Recruitment, and Site Identification & Relations.



Email: jeffrey.zucker@worldwide.com