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When Clinical Trials Suffer From ‘Complicated’ Interactions

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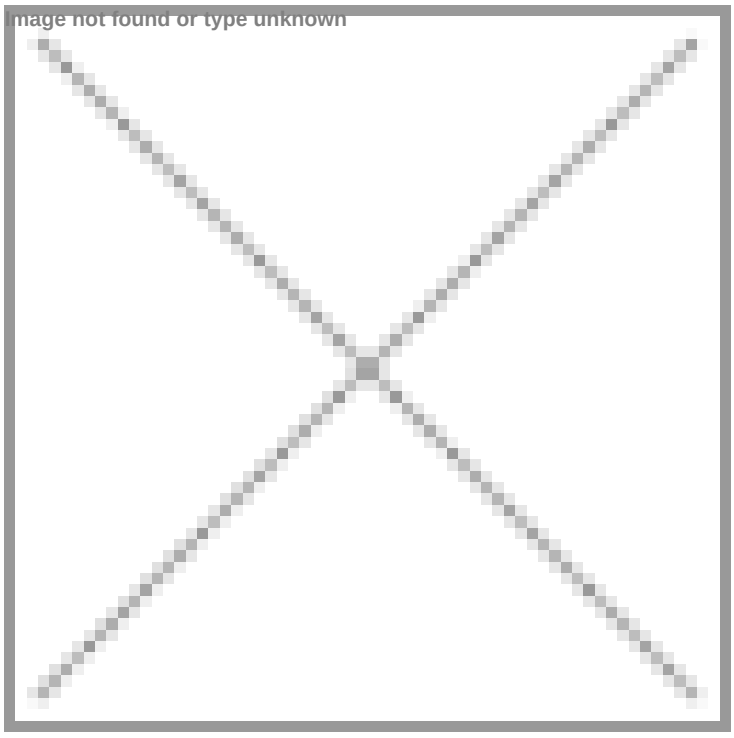
Diversity in culture, language, and data gathering methods will further increase the difficulty of clinical trials as they become more international, particularly with the growing number of sites being employed across China, Japan, South Korea, and India. Clinical trial management involves several scientific, commercial, and practical requirements that the industry will continue to struggle to satisfy without more cooperation across research sites, sponsors, and stakeholders. The need for better site-sponsored-CRO coordination will only increase as clinical trials continue to become more complicated.



When almost half of clinical trial stakeholders describe their working relationships as "complicated," it’s a sign that something needs to change.

That sentiment was one of several findings that came to light with Advarra’s recent industry survey of more than 200 stakeholders across the clinical research ecosystem. The results, which included responses from clinical research sites, sponsors, and clinical research organisations (CROs), highlight significant barriers to collaboration while offering concrete steps to overcome them.

The feedback provides a picture of an industry grappling with communication gaps, staffing shortages, and technology overload. However, the findings also point to practical solutions that could transform these strained relationships and accelerate the development of new treatments.

While nearly two-thirds of sponsors say their relationship with sites is "collaborative," just about half of sites say the same about sponsors, and only 31 per cent characterise their relationship with CROs as such. The survey also found efficiency gaps – sites reporting they must copy or transcribe data between systems about 60 per cent of the time, and the same

percentage saying they frequently enter identical data into multiple systems. These duplications can lead to data errors and trial delays.

Overcoming these barriers will be critical in 2025, as clinical trials continue to become more complex as new regulatory requirements kick in and stakeholders change or add new technology systems to generate and capture data. As clinical trials become more global – especially with the increasing number of sites being used across China, Japan, South Korea, and India – differences in culture, language and data collection systems will only add to the complexity.

Without greater collaboration between research sites, sponsors, and stakeholders, the industry will continue to struggle to meet the many scientific, business, and practical demands related to running clinical trials.

Communication Gaps Persist Despite Frequent Contact

Perhaps surprisingly, the survey found that frequent communication doesn't necessarily mean effective communication. Despite regular contact (approximately weekly), 60 per cent of site respondents and 43 per cent of sponsor/CRO respondents identified improved communications as a critical need.

The disconnect, then, lies not in the quantity but in the quality and consistency of interactions. Sites particularly emphasised the need for clearer messaging between sponsors and CROs, noting that misalignment between these parties often creates confusion at the site level.

Staff Training Challenges

Concerns regarding staffing have decreased recently, though respondents emphasised the need for better training and education, especially for new clinical research associates (CRAs). Sites specifically called for more comprehensive education around protocol requirements and study procedures. This is a critical area to focus on, since protocol deviations are the top cause of FDA warning letters, due to failure to follow investigation plans.

A well-respected organisation is working on providing tools and resources to help with these needs. The Association of Clinical Research Professionals (ACRP), a non-profit organisation, has launched a consortium that includes sponsors, CROs, investigator sites, academic institutions and regulatory agencies with a goal of building a diverse, research-ready clinical workforce. The group offers competency standards, recruitment help, industry education and awareness campaigns.

Technology: Promise vs Reality

While technology should theoretically streamline collaboration, the survey revealed significant friction points. Though 46 per cent of sites and 53 per cent of sponsors/CROs agreed that improved systems would enhance their relationships, only 29 per cent of sites felt that current sponsor/CRO technology solutions deliver on promises of integration and efficiency.

The challenge isn't necessarily the number of systems, but their lack of integration. Sites often must manage different platforms for training, investigational product accountability, electronic regulatory documents and data capture – with these systems varying across trials even from the same sponsor.

5 Actions to Transform Collaboration

Based on the survey findings, Advarra has identified five key actions that organisations can take to improve site-sponsor-CRO collaboration and accelerate clinical trials:

1. **Build Integrated Technology Systems:** Rather than adding more standalone solutions, organisations should focus on connecting the ecosystem and integrating existing systems. This could include implementing single sign-on capabilities and ensuring data flows seamlessly between platforms to reduce human error, automate repetitive tasks, streamline workflows and ultimately save clinical research professionals' time. The survey found that 85 per cent of respondents considered a centralised trial communications platform valuable or extremely valuable.

2. **Enhance Communications Channels:** Organisations should establish consistent points of contact and standardised communication protocols to manage turnover and ensure business continuity. Nearly all respondents (92 per cent of sponsors/CROs and 98 per cent of sites) rated having a single point of contact as valuable to extremely valuable.

3. **Optimise Real-time Reporting and Visibility:** Real-time access to trial data and performance metrics provides all stakeholders visibility to the same data, enabling teams to identify, align, and address issues quickly. This transparency enables faster decision-making and reduces the need for constant status updates.

4. **Empower Protocol Adherence:** Clear, step-by-step guidance for site staff can reduce protocol deviations and improve compliance. This is a process along the clinical trial pathway and should not be relegated only to the monitoring stage. The initial step is certainly a well-written protocol that is clear and conveys the same instructions in prose as in all tables and reference materials. The second step returns us to training: A well-trained sponsor or CRO representative is key to well-trained site staff. A strong CRA makes a big difference in site training, providing clarifications, responsiveness to site questions, and problem escalation, as needed. Protocol writing plus CRA and site staff training are preventative actions, while regular monitoring provides an opportunity for corrective actions.

5. **Improve Staff Training:** With the clinical research workforce facing significant shortages, investment in comprehensive training programmes is crucial for protocol success. This includes both initial onboarding and protocol training to reduce deviations and ongoing education to keep pace with evolving trial complexity.

Looking Ahead

Implementing these actions will require commitment from sites, sponsors, and CROs to ensure the changes are made systematically. Organisations that take concrete steps to address these challenges now will be better positioned to conduct successful trials in a competitive research environment. As clinical trials continue to grow in complexity, improved site-sponsored-CRO collaboration will become increasingly essential for bringing new treatments to patients more quickly and efficiently.

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