WHITE PAPER

How improved collaboration is increasing clinical trial productivity and performance

A KEY QUESTION

How can sponsors, CROs and sites collaborate to accelerate clinical trial success?

KEYWORDS Clinical Trials, Clinical Sites, Site Connections, Productivity, Collaboration, Communication

What sponsors need from clinical trials is changing

Drug development is a complex race. The complexity comes from the need for good science to bring credible safety and efficacy data for regulatory approval. The race is to achieve this as quickly as possible without compromising those fundamentals. There are many strategies that sponsors, CROs and sites employ to win this race, but anything that can positively impact the recruitment and retention of participants, regularly cited[1] as the most impactful cause of delay, will help.

One of the many ways sponsors seek to make this happen is through the enrollment of different patient populations from a variety of sites, spreading the risk of delay and leveraging sites of differing start-up speed track record and capacity. In so doing, they seek to bring their innovations to market faster without compromising safety.

To achieve this, trial sponsors need a strong, diverse and integrated ecosystem of trial sites, an ecosystem that enables sites to thrive in large, complex, multi-country and multi-site trials. This takes collaboration, clear and open communication between sponsors, clinical research organizations (CROs) and sites. Technology helps, but a lack of integration across different platforms means that, for now at least, keeping humans in the loop is critical.

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In this short guide, we reflect on strategies to improve trial site productivity and performance such as:

- **Fostering a collaborative environment is essential.** The different stakeholders in a clinical trial have different experiences, different pressures and different perspectives. The best results are achieved when there is alignment on the goals and a collaborative environment where everyone is focused on trial execution and solving problems
- **Effective collaboration requires clear, open communication.** This means that site leaders are comfortable speaking openly with their CRO about any issues, so those issues can be understood and resolved

Barriers to trial productivity and achievement of goals

While every trial and every site are different, there are common obstacles that can negatively impact trial productivity, which can affect the achievement of the key trial goals as well as the timeline and budget. Challenges can include:

- **Site-specific issues.** These issues include staffing, lack of experience or expertise in the therapeutic space and technology issues. Individually and collectively, these challenges can impact a site's enrollment and productivity. A multi-site trial is only as efficient as its least productive site
- **Inefficient or ineffective workflows.** Workflow issues can hurt productivity by creating delays, cost increases and potential quality issues. Even minor workflow issues, if multiplied across multiple sites, can have a significant impact, such as delaying regulatory filings and market entry
- **Over-reliance on "experienced" trial sites.** At times, drug sponsors and CROs can lean too heavily on well-known, experienced trial site locations. However, there can be value in considering so-called "research-naïve" sites, which will likely have individuals and teams with trial experience. By considering such sites, sponsors and CROs may be able to broaden the geographic reach and variety of patients enrolled in a trial, reduce the travel burden on patients, reach patients in trusted community healthcare settings and build the next generation of sites and capabilities
- **Over-reliance on technology.** While technology has tremendous value to offer sponsors, CROs, sites and—crucially—patients, it is not a silver bullet. Technology must be used when appropriate, for specific use cases, while retaining a human in the loop. It is important not to forget that trials are conducted by people, and the participants are people. For example, it is no good for a platform to be made available in English when the likely trial participants only speak Romanian

Actionable strategies to help trial sites thrive

1. **Prioritize variety along multiple dimensions in site-selection decisions.** There are numerous benefits to creating a heterogenous mix of sites in a trial, including access to different types of sites, different patient populations and a new group of researchers
2. **Foster a collaborative environment between key stakeholders.** Open communication is an attitude, built on team spiritedness and a common desire to work together to solve challenges in bringing trials to patients and new treatment options to market. Collaboration fosters an environment where all stakeholders can be comfortable and transparent with all aspects of the trial, from major, big-picture issues to small details. The open communication that is the bedrock of collaboration builds trust, which allows a trial to thrive and makes it possible to address challenges when issues arise
3. **Bespoke productivity-related initiatives and interventions.** The most effective CROs do not pressure a site to be ready to take on trial responsibilities, nor do they arrive onsite with a pre-determined list of improvements to make. The best approach is to take the time to understand what is happening at each site, to help stakeholders understand the key challenges and then to prioritize tangible opportunities for improvement
4. **Streamline the number of steps and touchpoints for all internal workflows.** Reducing redundant or unnecessary processes leads to opportunities to improve productivity and speed, helping trials stay on schedule and under budget. A critical assessment of daily workflows can identify steps or processes that need to be revisited

5. **Utilize enabling technologies.** While technology is not a silver bullet, when deployed appropriately, it can reduce or eliminate mundane tasks that improve efficiency and decrease investigator and staff burnout. For example, the use of devices such as tablets at the point of care to scan documents or enter information can improve speed and reduce errors
6. **Streamline and prioritize payments to trial sites to reduce delays.** Among the many important elements of a clinical trial is ensuring smooth cash flow. This single issue repeatedly ranks highly in survey of site challenges [ref SCRS[2]]. Streamlining payment is essential to reduce delays and foster goodwill and is another way to build trust. Creating an environment where there is a clear understanding of payment will enable the sponsor, CRO and site to operate with confidence that payment terms and schedules will be adhered to, fostering an even greater spirit of collaboration that promotes smoothly, reducing delays in patient recruitment and removes an important source of frustration

7. **Invest in clinical research associate (CRA) capabilities.** Improving the effectiveness of CRAs has downstream benefits, such as the availability to invest in CRO-site relationships and listening to opportunities to improve

8. **Invest in appropriate patient training.** Different patients have different training needs and preferences, which can vary by age, language, learning styles, neurological capabilities and more. All of these factors impact patients' ability to learn, so it's important to recognize these differences so that training can be tailored to the patient and cohort. This tailoring is an area where technology can play a role in improving and increasing patient participation and retention

9. **Conduct "dry runs."** Despite careful consideration of protocols, issues that sponsors and sites would never have thought about don't become apparent until there is real-world experience. These might be issues related to running a complex study, conducting a study with a large cohort of people or running multiple tests at the same time. Have enough kits been ordered? Where should they be stored? Are patients expected to provide too many samples in a single day?

   A proven solution is for the site team and the CRO to work together on a "dry run," where mock patients go through every step in the trial process. This will surface any issues, provide valuable insights, enable the site to resolve problems and lead to more successful trial execution

These strategies can help trial sponsors and CROs work with sites to improve each site's capabilities, productivity and performance. The ultimate result is improving the speed and effectiveness of the trial, while developing capabilities that can be leveraged in future trials.[3]

Collaborate forward: a major initiative to improve trial collaboration

Fortrea, a leading global CRO, has collaborated with the Society for Clinical Research Sites (SCRS) on **Collaborate Forward**, a working group comprised of 16 leading organizations that will develop best practices to reduce administrative burdens across the clinical research ecosystem.

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References

1. Chaudhari N, Ravi R, Gogtay NJ, Thatte UM. Recruitment and retention of the participants in clinical trials: Challenges and solutions. *Perspect Clin Res*. 2020 Apr-Jun;11(2):64-69. doi: 10.4103/picr.PICR_206_19. Epub 2020 May 6. PMID: 32670830; PMCID: PMC7342338.
2. https://myscrs.org/wp-content/uploads/2024/08/Site-Payments-and-Patient-Reimbursements-Global-Perspective.pdf
3. Fortrea, "Increasing trial productivity: Addressing site-specific challenges to improve site engagement," AR_PRO_0005_Site Engagement_0625_chapt5.

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