WHITE PAPER

Building trusted study-ready site connections

A KEY QUESTION

How can active collaboration between the CRO and site network help hone protocols and minimize delays in study startup and patient recruitment?

KEYWORDS Collaborative Partnerships, Study-ready Site Connections, Patient Recruitment, Technology Integration, Biotech

Sites represent both the front line and the last mile of a clinical trial, underlining the essential role they play in making clinical trials a reality for the patients in their care. It stands to reason, therefore, that by focusing on removing the roadblocks and challenges faced by sites and patients, more cutting-edge treatments will reach more patients sooner.

Building on our 30+ years of experience as a CRO and our agility as a newly independent entity, we have established Fortrea Site Connections to coordinate our site-focused efforts. Learn how we're proactively engaging sites, actively listening to their needs and responding with innovative new approaches that seek to truly enable sites to do what sites do best: deliver trials to the patients in their care.

Applying new thinking through a deep understanding of the role of sites

Sites are integral to optimizing clinical research performance and productivity, and the Fortrea Site Connections program is designed to recognize the pressures they face and respond by supporting specific objectives, such as:

- **Evaluating protocol design and performing pre-study run-throughs:** Involving partner sites pre-award helps us work with sponsors to design protocols that can be practically performed, identify avoidable barriers and anticipate the likely reaction of target patient populations. Where possible, this includes pre-study start test runs to identify areas where improvements can be made
- **Recruiting, enrolling and retaining patients:** Sites are tasked with engaging and screening the potential participants as well as supporting retention. Based on our experience, we have found that Fortrea Site Connections partner sites demonstrate a recruitment rate 1.8 times higher than non-partner sites and experience startup timelines 17% faster than non-partner sites, reflecting the shared commitment to timelines and protocols

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- **Meeting goals for including diverse patient populations:** Sites are an integral part of ensuring accessibility to trials by reaching the diverse communities they support and aiding sponsors' diversity goals in clinical trials. Fortrea Site Connections supports this through its Diversity Dashboard, helping sponsors and sites maintain a live picture of recruitment metrics and make adjustments accordingly
- **Ensuring compliance with the protocol and regulations:** Our clinical research associates (CRAs) work with sites to ensure protocols are followed to meet regulations. With new innovations in the pipeline, Fortrea seeks to increasingly remove human errors to maintain our very high standard of data quality delivery
- **Enabling clinical intervention:** Ongoing site-level monitoring is critical for high-speed clinical intervention to guide patient care. Through technology innovations, Fortrea is working to enhance sites' abilities to monitor patient compliance
- **Collecting data:** Sites are expected to collect high-quality data per protocols, increasingly using a variety of hybrid on-site and remote digital methods. Fortrea Site Connections helps sites understand and integrate on-site, digital and home-visit data collection methods

Site Advisory Board: Listening to the voice of the site to identify issues and innovate to remove barriers

Fortrea Site Connections incorporates a dedicated Site Advisory Board. This multidisciplinary group of experts, who represent sponsors and sites of all sizes and geographical locations, provides a unique opportunity for Fortrea, sponsors and sites to speak openly about their day-to-day challenges and review new concepts and potential innovations, helping us further help sites do what sites do best.

Based on our combined experiences and listening sessions with site clinicians and investigators through the Site Advisory Board, we have analyzed trends and learned about the primary challenges sites face.

The Site Advisory Board currently represents more than 440 sites across 25 therapeutic areas and 9 countries.

We have learned that we can help remove barriers by:

- **Streamlining requirements for site education:** We're finding ways to minimize certification needs for Fortrea-run studies by acknowledging previously attained certificates that can be transferred to new studies. We also recognize the burden of training at sites and are taking steps to enhance the experience by making more user-friendly, accessible training materials and reducing the time spent training
- **Reducing the need for multiple logins:** Recognizing the burden of technology, we're managing (or even eliminating) the need for multiple logins across multiple digital environments
- **Supporting ancillary trial management:** We're working to make it easier for sites to keep up with administrative tasks related to paperwork, invoicing and payments
- **Designing site- and patient-centric protocols:** We're collaborating with sites to gather critical feedback about sponsors' protocols, for example, if an invasive screening procedure might discourage participants from enrolling or if a study requirement places an unnecessary burden on the site and/or patients
- **Examining the clinical trial workflow:** We are continually inviting sites to share their end-to-end process, from recruiting to study close out, to help illuminate key pain points and inform problem-solving
- **Elevating the voice of the patient:** By listening to the sites and their experiences with patients, we are working to better understand patients' expectations and determine how we can best meet their needs throughout a trial
- **Evaluating site- and patient-facing technology:** We understand that sites appreciate technology platforms and digital solutions that reduce—and don't add to—the complexity of their work. We also know that patients must benefit from technology in a trial and aim to ensure that the levels and types of technology in a trial are appropriate for patient groups

Transforming the value of site technology

As sponsors are increasingly incorporating digital health technology into their studies and conducting trials with hybrid approaches of on-site and remote participation, we know that the use of technology in clinical trials must make sense for every user and every touchpoint. While individual solutions may offer unique features that streamline some aspects of the clinical trial, sites often have to bear the brunt of working with multiple, disparate technologies for each trial. And, as the primary contact for patients on trials, sites also find themselves acting as "tech support" for the patients in their care.

Managing multiple technology systems and accompanying logins while educating patients on how to use devices or home data collection technologies places additional responsibilities on sites and takes them away from their primary role. The rapid development of multiple technology "solutions" risks hindering rather than helping sites and patients on trials.

To better leverage technology advances in a trial and provide value for both sites and patients, Fortrea Site Connections is actively developing a suite of integrated solutions to:

- **Minimize complexity:** We want to limit the number of different technology solutions required for each study through a cloud-based, simplified sign-on experience
- **Unify disparate systems:** We're developing a more streamlined, clinical workflow through a vendor-agnostic, unified environment with a single repository for study documents and records
- **Support patient monitoring:** We are enhancing sites' abilities to monitor patient compliance through a central dashboard
- **Promote user-centered design:** Accessible user interfaces are foundational to our work to improve the site and patient experience

By leveraging our vantage point in the industry—and the invaluable input of our Site Advisory Board—we are focusing on cutting-edge thinking to reduce the complexity of incorporating technology into a trial and help sites maintain their focus on patient care.

Looking ahead to continually elevate our site partnerships

Our future at Fortrea is shaped by our ability to be extremely agile when it comes to listening and responding to the needs of sponsors, sites and their patients. The Fortrea Site Advisory Board is actively expanding as it adds new chapters to include diverse types of sites and incorporate sites' unique perspectives from specific geographic regions, such as the EU and China.

By giving a voice to site investigators, clinicians and healthcare workers, we seek to continually improve our understanding of how current practices are helping or hindering sites and apply our experience to take action and drive change. Together, we can not only meet sites' needs but also make trial participation easier for patients, deliver high-quality trials to sponsors and advance life-changing treatments.

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