Fortrea

Improving access in diverse communities for clinical trial participation.

Fortrea's toolkit of solutions to help improve the reach of clinical trials and enable you to recruit more representative patients

To bring safe and effective medicines and medical devices to the market, it is imperative that they have been trialed in a population representative of the disease demographic. When new treatments are only investigated in a homogeneous population, the full picture of their effectiveness cannot be truly understood. This can lead to further studies being required by regulatory agencies, incurring significant additional financial and time investment. To help ensure that more diverse and representative patients are enrolled in clinical trials, the **FDA recently launched guidance** to help sponsors achieve these goals.

Despite the importance of improving diversity in clinical trials, there are several barriers that deter patients from participating. Some of these issues are logistical, as the majority of clinical trials are run at large academic centers and research institutions located in large cities. While participation is feasible for those nearby, patients in more remote areas may struggle to access the site. In a **2018 study**, for example, the average distance traveled by participants for a cancer clinical trial study was **25.8 miles,** which increased to 41.2 miles for a Phase I study. These long distances not only burden the patient with high travel costs, but the time taken to make the journey can be incompatible with employment and caring responsibilities.

Beyond logistical concerns, patients may not be aware of suitable clinical trials, reflecting an additional barrier to trial access. As most trials are run by investigators at clinical trial sites, family doctors may not be aware of available trials and thus may be unable to recommend an appropriate trial for their patient.

Fortrea is committed to improving clinical trial access for all patients. Increasing and promoting patient access to trials improves representative patient diversity, helping to ensure the safety of medicines and medical devices for all. Additionally, improving access leads to more successful trial recruitment overall, minimizing timelines and maximizing trial efficiency. With our access to a privacy-law-compliant database of over 150 million patients, prospective participants can be directly contacted, including those in underrepresented demographics, while respecting their privacy.

Improving access to clinical trials is a multifaceted problem, and no single solution can solve the challenge. To improve clinical trial access, Fortrea has a suite of capabilities and tools collated into a single cohesive solution known as the Patient Recruitment Ecosystem. Additionally, as part of its **Diversity & Inclusion in Clinical Trials strategy**, Fortrea employs a three-pronged approach to help you **recruit a more representative demographic** for your clinical trial focused on:

1. Increasing community engagement
2. Building up a network of diverse investigators
3. Supporting sponsors with patient-centered strategies to build trust and reduce patient burden

Building up a network of diverse investigators

A major approach to improve recruitment of underrepresented demographics in clinical trials is to improve the diversity of the investigators running the trials. A lack of diversity among investigators can exacerbate recruitment issues caused by implicit bias: **a recent study** showed that 83% of Black patients living with metastatic breast cancer were somewhat or very likely to consider trial participation, but 40% were not informed of clinical trial enrollment (compared to 33% of non-Black respondents). Ensuring that studies include diverse investigators who not only better represent their community but speak local languages can **improve patient outcomes and strengthen trust**, leading to improved clinical trial diversity through their reach in underrepresented communities.

To support and build up a network of diverse investigators, Fortrea has set up partnerships with two integrated research organizations. The first partnership is with the Community Clinical Oncology Research Network, or CCORN, a company founded by oncologists. The partnership aims to determine causes of disparity and improve patient recruitment by **helping independent oncology practices, which often serve diverse communities, to get involved in clinical trials**. Improving the physical access to clinical trial sites overcomes barriers associated with traveling to large institutes, boosting recruitment rates.

The second partnership, with Circuit Clinical®, aims to **build a network of diverse investigators** who otherwise would not have the opportunity to participate in clinical trials. The partnership benefits from both Fortrea's access to a wide customer base, including healthcare providers and physician groups, and Circuit Clinical's expertise in creating high-performance clinical trial sites. Improving investigator diversity greatly increases participant recruitment and retention for more representative trials.

Patient-centered strategies

To overcome the logistical challenges patients face, Fortrea offers solutions to minimize the need for site visits through decentralized clinical trials (DCTs). DCT solutions enable remote, mobile, local, at-home and virtual elements for clinical trials. Two such capabilities include replacing face-to-face physician appointments with video calls and implementing digital applications patients can use to log their data.

The COVID-19 pandemic catalyzed sponsors' adoption of DCT capabilities to minimize disruption to trials. However, it is important to note that DCTs are not a one-size-fits-all solution. While they can significantly improve recruitment and retention of diverse participants, they are only beneficial if the trial design is sensitive to those anticipated to join, for example, patients in specific age groups. It is therefore critical that you **consider the patients' needs** when designing your study. Fortrea has generated a proprietary database of over 65,000 Voice of the Patient surveys enabling you to apply patient intelligence to your protocol design and build better trials from the outset.

Further improving access to clinical trials, Fortrea has recently launched mobile clinic screening events. Collaborating with its own medics, and powered by artificial intelligence algorithms, Fortrea can identify patient groups based on their known diagnostic profile and contact them about relevant screening events taking place nearby. Fortrea also educates patients about Clinical Research as a Care Option to inform them of **additional treatment pathways they can take**. The screening events can be run directly in hard-to-reach communities, as well as in collaboration with nominated local study site locations. Patients who take part in an event can later be alerted of the relevant clinical trial and be directly invited to learn more about the trial. Connecting with hard-to-reach communities in this way improves clinical trial access and promotes participation, thereby helping achieve recruitment goals quicker.

Conclusion

Ensuring diverse participation in clinical trials is crucial for the safety and efficacy of medicines and medical devices. Improving access to trials is, therefore, an essential consideration for sponsors. Expanding reach and building trust in diverse communities—in a longer-term, sustained manner—will encourage and retain a more representative demographic in your clinical trial.

Fortrea is committed to inclusive research, making clinical trials accessible for all. Together, Fortrea's strategy for Diversity & Inclusion in Clinical Trials along with the innovative solutions within the Patient Recruitment Ecosystem can enable you to recruit more diverse participants to meet your recruitment goals.

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