

2023 CLINICAL TRIALS DAY

VIEWS FROM BOTH SIDES OF THE ATLANTIC



UNITED STATES

Zena Smith
Sr. Vice President,
Clinical Trial Recruitment

What have been 1-2 key developments in your markets/experience with regard to clinical trial recruitment in the past few years?

At Spectrum Science, we consistently engage patients/caregivers & HCPs to understand their experiences, which will guide all recruitment efforts. The data has been precise; patients want to be heard, with the pandemic serving as a tipping point here in the U.S. Over the past 1-2 years, the industry has been moving in that direction with critical developments in incorporating Design Thinking for systemic patient engagement to truly understand the whole patient, beyond their clinical features and decentralized/hybrid trials design all to meet patients where they intend to dissolve barriers to enrollment with flexible and human-centered design.



UNITED KINGDOM

Jonny Holland
Associate Director,
Clinical Trial Recruitment

What have been 1-2 key developments in your markets/experience with regard to clinical trial recruitment in the past few years?

One of the key developments over the past few years from a UK perspective has been the 41% decline in the number of clinical trials initiated in the UK between 2017 and 2021, pushing the UK from 4th to 10th in the world for phase III trials. Many contributory factors have been named: pressures on the NHS and MHRA, shortage of research sites and staff, a convoluted approvals process, Brexit (including our departure from Horizon Europe), etc. etc. Whatever the factors, if the UK is to maintain its strong position in global clinical research, it needs a bold, actionable plan for the future. Advice from The review into clinical trials led by Lord O'Shaughnessy was due to be published this Spring is hoped to do just that. If these hurdles can indeed be overcome, then there is significant opportunity to make the most of the positive reputation that clinical trials have in the UK public mindset post-COVID. A 2021 YouGov survey showed that 78% believe research should be offered as part of routine NHS care, and 27% are more likely to take part in research following the COVID pandemic. At Spectrum, we ensure that the clinical trial experience is optimised for every stakeholder involved, from the potential participants just wanting to be understood, to the overburdened sites who just need the running of their studies to be made a little easier.

Where Commonalities Exist Across Both Countries

Different backgrounds. Different perspectives. Different identities. All of these are needed to improve representation in clinical trials. How have you seen diversity, equity, inclusion, and access in clinical research in your country or region?

Clinical trials need a diverse group of volunteers to participate in clinical trials to help make sure treatments are safe and work well for different communities. People may react differently to the same treatment based on age, gender, weight, race, ethnicity, and other factors. The inclusion of diverse patient populations in clinical trials is nothing new, but the topic rose to the surface because of the following:

- COVID
- FDA guidance was issued in November that addressed the multidimensional aspects of diversity and inclusion in clinical trials.
- Racial unrest in 2020 that grew following the tragic deaths of George Floyd, Breonna Taylor, and so many others illuminated the United States' long-existing health and social inequities.
- FDA draft guidance on Diversity Plans published in April 2022 marked an essential step in addressing decades of testing drugs primarily on White men. This is the first time there is a statutory requirement for diversity in clinical trials.

The industry is moving in the direction to align with PhRMA and FDA guidelines. We must ensure all potential patient populations are well represented in the research. It is a business strategy challenge, and we must consider it from the get-go. At Spectrum Science, we understand the importance of diversity in clinical trials to achieve better health outcomes. And we put this understanding into practice; in a recent trial, we supported our client in their target of recruiting 41% POC participants and exceeded the target for African American participants by 6%.

What trends are you seeing from a digital perspective (if any), in clinical trials recruitment in your country (or region)?

Digitalization is the key to moving forward in the U.S., and most sponsors are eager to use technology to streamline the clinical trial process and incorporate virtual components into trials to help reduce costs and improve efficiency. Technology advances can address some of the most common challenges that can tank studies and bias results, from poor study design and ineffective site selection to failure to recruit and participant dropout. Digital trends include decentralized trials, artificial intelligence (AI), machine learning, and wearable devices to improve clinical trial design, conduct, and analysis. These developments point to a future where clinical trials are more diverse, patient-centered, and technology-driven than ever before. Spectrum Science uses patient insights to help shape decentralized trial and digital strategies.

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