EMEA Participant Engagement: A Sponsor's Guide to Taking Trials Global

Best Practices for Participant Recruitment and Retention in Europe, the Middle East, and Africa.

The globalization of clinical trials is a trend decades in the making.

Whereas the early 2000s saw studies mainly in the Americas, broader site representation has steadily increased. For instance, in 2022, Europe conducted approximately 1,000 more clinical trials than the Americas. This made Europe the leading World Health Organization (WHO) region for clinical trial activity and marked the 16th consecutive year that Europe's trial output surpassed that of the Americas.

Several factors have pushed sponsors to activate international sites, including diversity initiatives that target underrepresented groups across race and ethnicity. But no matter why a sponsor takes its study abroad, the how is what sets it up for success — particularly how recruitment and retention are approached.

All regions see regulatory complexity, participant identification challenges, and cultural differences differently. And they all require a specialized engagement playbook that accounts for those nuances. This is the playbook for EMEA (Europe, Middle East and Africa).

Sharing the expertise of Michal Kouril, director of strategic solutions and partnership, EMEA at WCG, this resource explores what sponsors should know as they expand to EMEA. From data privacy protections and provider touch point opportunities to cultural considerations, we'll discuss how study plans can address geographical nuances to create the best possible recruitment and retention program.

SECTION 1

Regulatory Considerations

As with study start-up elsewhere in the world, activating sites in Europe, the Middle East, and Africa involves many regulatory considerations that affect a sponsor's engagement strategy.

And although sponsors should never approach EMEA through a one-size-fits-all lens — after all it spans a transcontinental region across multiple countries — a universal takeaway does hold true: **What sponsors do or did in the U.S. for recruitment and retention of the trial may not always apply internationally.**

One reason is that EMEA countries may be subject to multiple layers of regulatory involvement, Kouril said.

"In the U.S., you have one main authority, which is the FDA — but in the EMEA, you may have to deal with many different rules from different agencies," he said. "For example, the European Medicines Agency (EMA) oversees drug approval in the European Union (EU), but each European country still has its own rules for recruitment and retention. Just because the EMA approves a treatment, it doesn't mean it will be approved in a specific country."

That regulatory complexity can extend timelines as sponsors confront the need to submit to the EMA while addressing whatever country-specific rules may apply to their clinical trial plan, Kouril added. That's especially relevant now as the EU transitions from its incumbent submission system (EudraCT) to the new Clinical Trials Information System — a change that could also create a time-intensive learning curve for new submitters.

Similarly, a range of data-security regulations in EMEA can add to the regulatory challenges when globalizing trials — such as South Africa's Protection of Personal Information Act or Israel's Protection of Privacy Law. But it's not just country-specific regulations to be aware of; regional rules may factor in, too. In the EU, for example, there's the General Data Protection Regulation (GDPR), enacted in 2018, which has set strict standards and high penalties for organizations in any sector.

GDPR does not mean there are no country-

specific protections in the EU, however. In addition to GDPR, European countries may also be subject to their own national data-protection rules, such as the Commission Nationale de l'Informatique et des Libertés in France.

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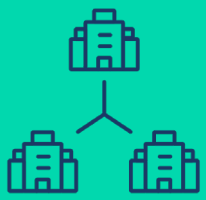
"For the sponsor coming to Europe who assumes that GDPR is the only data protection regulation, it's important to know that this is not the case," Kouril said. "Every country will have their own data-protection rules, and that creates even more nuance for sponsors to learn."

What does all this regulatory complexity mean for sponsors eyeing an expansion across the Atlantic? Kouril recommended that they first take a planful approach: Become familiar with the rules and regulatory agencies involved, learn the various requirements, and account for the additional time necessary to navigate submissions.

"But also, leverage local knowledge by working with companies who have that native expertise," he said. "This doesn't mean working with small companies on a country-by-country level. For example, here at WCG, we have individual country managers who were in most cases born in those countries. With that local expertise, you have someone who speaks the language and understands the nuances of that country, which really helps."



SECTION 2

Site & Participant Identification Through Referral Provider Networking

One of the most important mechanisms sponsors have for meeting enrollment goals in EMEA is through referral provider networking. In this model, which tends to be different from that in the U.S., local clinic physicians might refer protocol-eligible patients to a study site conducting the trial, such as a large academic center.

"A lot of times, the referral provider doesn't have anything to do with the study," Kouril said. "But it's an additional touch point opportunity — if you tap that referral provider, then they may have an additional pool of patients who might be suitable for the study."

As sponsors evaluate opportunities to connect with these trial-referral providers, Kouril recommended a regional approach based on where the predesignated study sites are. "I would go and look for the referral physicians in the close vicinity of the study site," he said. "You might create a radius search of, say, 20 miles, and look for potential referral providers who are not doing the study but may have the right patients."

The advantage of this approach is not just to find eligible participants in the immediate term but also to vet potential sites for the long term, Kouril added. If those referral providers become a trustworthy and reliable source of participants for multiple studies over time, they may prove their ability to execute the trial for future protocols.

"Very often, we may see that sponsors don't think of referral providers as a study site, at least not initially," he said. "But if they create a relationship with them and work with them on a regular basis as a referral provider over time, they might come to rely on them as a viable site in the future."

SECTION 3

Societal, Cultural, and Language Nuances

Understanding the societal, cultural, and language implications of an international trial strategy is critical — and for EMEA countries, that starts with considering how universal, single-payer healthcare affects the behaviors and motivations of trial participants.

Whereas financial barriers can limit clinical trial participation in the U.S. when people struggle to access broader care, other countries' socialized medical systems may mean financial concerns are less of a problem abroad. This may open the doors to more participation opportunities for those patients. It's an obvious advantage to EMEA expansion, but there's a catch, Kouril said.

"There's also generally less education about clinical trials in the EMEA region than there

is in the United States," he said. "Education and awareness about what it means to participate should be done more because it's still seen as risky and experimental for patients. When patients have free healthcare access, they may not see attending the clinical trial as a priority."

Additionally, sponsors should not assume participants are proficient in English, Kouril added. Although the EMA encourages translation for patient-facing materials such as posters or flyers, he says some forms of communication can get overlooked.

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"E-diaries and manuals are often in English, and when a payment card is provided, the card activation process is usually done in English, and so is the customer support," he said. "It is sometimes expected that, somehow, everybody in Europe (or other parts of the world) speaks English. But if you're talking to patients 50 or older, I'd say there's an 80% chance they won't speak English at all."

Sponsors should also be intentional about how their inclusion and exclusion criteria may read to international physicians and participants who operate from different vocabularies, measurement systems and standards.

For example, take the descriptor "obese."

"If you're looking for an obese patient, define what that means, because an obese person in the U.S. may be considered a morbidly obese person in another country," Kouril said. "Similarly, for glucose levels, they're measured differently in other countries than in the U.S. Or even if you say you're looking for a patient who is 6-foot-2, almost no one in Europe would know what that means unless you convert it."

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SECTION 4

Finding the Best Support for the Biggest Impact

Expanding a clinical trial to EMEA countries comes with certain opportunities, but there are also considerable challenges in regulatory involvement, data-security rules, cultural differences and other factors. That's why engaging with the right local, on-the-ground support through a partner like WCG can play a significant role in recruitment and retention, Kouril noted.

Such support should absolutely account for strategic outreach to target sites, including referral provider networking that aligns with study referral practices seen in Europe and beyond. Support should also accommodate what many sites need on-site: local, experienced clinical research coordinators (CRCs) to expand the impact of global research.

As with the U.S., much of the world is reckoning with severe healthcare staffing shortages. While these numbers are gradually improving, shortage disparities in some areas, such as the African and Eastern Mediterranean regions, are stirring up particular healthcare equity concerns. These shortages stretch the bandwidth of existing site staff and compromise their ability to perform recruitment and engagement.

"CRCs are great tools to build relationships with sites because once the clinical research coordinator is involved, the sponsors start getting the additional information on what's happening at the site," Kouril said. "The CRC will become an extension of the study team, helping inform outstanding challenges while also educating patients. With these opportunities, sponsors can bridge the gaps between themselves, participants and sites."

If you're looking to expand your trial to EMEA sites, learn how WCG experts provide sponsors like you with targeted site outreach and CRC services, as well as other support opportunities as appropriate.

Learn more

WCG is a global leader of solutions that measurably improve and accelerate clinical research Biopharmaceutical and medical device companies, contract research organizations (CROs), research institutions, and sites partner with us for our unmatched expertise, data intelligence, and purpose-built technology to make informed decisions and optimize study outcomes, while maintaining the highest standards of human participant protection. WCG raises the bar by pioneering new concepts, reimagining processes, fostering compliance and safety, and empowering those who perform clinical trials to accelerate the delivery of medical therapies and devices that improve lives.

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