Worldwide Clinical Trials

Checklist: Transnational Logistics for Successful Cross-Border Enrollment

Rare disease populations are small and often dispersed across a wide geography, which can challenge enrollment in global clinical trials and slow development of treatments. One solution to navigate patient dispersion is to utilize cross-border enrollment, where patients travel to enroll in sites located in a different country (site country) from where they reside (home country).

While this is an effective and proven strategy, cross-border enrollment is complex and must be carefully orchestrated to comply with regulations and to protect patient data and privacy. Due to the complexity, cross-border enrollment is not the solution for all trial challenges. We advise the approach be scaled with the value proposition of the trial being launched. Here are a few guidelines to address some of the most common concerns and to help your program properly plan to enroll and retain patients across borders:

- [ ] Pre-qualify prospective patients before they embark on any study-related travel by establishing clear gating criteria, with sensitive information held by a contracted third party.
- [ ] Translate all patient-facing materials into the patient's native language once approved for use, including consent forms. In addition, ensure the clinical research site has the ability to provide the needed translation services, or be prepared to provide the services for the site.
- [ ] Acknowledge country-specific insurance requirements and determine if patients will be covered under an existing policy or if study-provided insurance is needed.
- [ ] Incorporate a dedicated patient liaison who will engage with the patient directly and early to coordinate travel and accommodations, including visa, passport, and related documentation for the patient, family, and caregiver. Depending on the recruitment pathways, a cultural liaison can also improve the participant experience while in the host country.
- [ ] Cross-border enrollment planning benefits from high-touch engagement with sites, including discussion of their willingness and ability to receive patients who are foreign nationals.
- [ ] Confirm adequate transportation and delivery method of the investigational product when needed.
- [ ] Recognize that cross-border enrollment of pediatric patients often involves their entire family and plan accordingly for travel, accommodations, and medical visas when needed.
- [ ] Consider a pathway for medical oversight when in home country, including AE reporting.
- [ ] Recruitment pathways of the cross-border plan can be global or regional and broad or narrowly defined. Factors in that series of decisions include the host country regulatory statutes, host country immigration policies, protocol-specific assessment timelines, and more.

Worldwide has successfully utilized cross-border enrollment in rare disease studies around the globe and can help you leverage this strategy in your next program. To learn more about how we can tailor a cross-border enrollment plan for your study, contact us.

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