

WHAT DEFINES A TRULY GLOBAL PATIENT RECRUITMENT ORGANIZATION?

Global recruitment for clinical trials is far from a “one-size-fits-all” proposition. Enormous language, cultural, political, and socioeconomic differences exist in many of the countries that are becoming primary outsourcing locations for clinical research. Regional variations and cultural understanding of clinical research need to be taken into account when recruiting patients in these emerging markets.¹

Hallmarks of a Global Leader

To be considered truly global, a Patient Recruitment Organization (PRO) must meet some key requirements. First and foremost, the **ability to capture data and track activity** throughout the enrollment continuum and across all countries is essential for a performance-based PRO to price on patient consent milestones. Sponsors need to see metrics such as which markets are providing the most patients, which tactics are generating the best response, and which sites are not scheduling appointments. This can only be achieved through tightly integrated technology.

In addition, regardless of where it is headquartered, the organization must have a robust **infrastructure of worldwide resources** in the areas of:

- Privacy – retaining intimate knowledge of data privacy regulations and consent requirements in individual countries, backed by investments in technology to provide complete protection of confidential patient data.
- Finance – having the financial solvency and cash position to allow for investments in building, maintaining and adapting the necessary infrastructure to meet constantly changing global needs.
- Compliance – recognizing that different countries have very different regulatory and auditing requirements.

There is also no substitute for a stable workforce of dedicated **regional employees**, e.g.:

- Multilingual regulatory staff working closely with an in-country network of regulatory experts.
- Legal professionals with US, EMEA, APAC and LA experience who know local laws around consent, marketing, clinical trials, etc.
- Field-based Site Strategy Consultants who visit the trial sites on a regular basis, and in-house dedicated Site Services specialists who facilitate ongoing communications among the sponsor, Contract Research Organization and sites, to anticipate and proactively resolve potential logistical and quality issues.

¹ Denise Myshko, “Global Patient Recruitment,” *PharmaVOICE*, March 2009.

As for external communications, offering **worldwide marketing capabilities** does not simply equate to translating patient materials into different languages. It is critical to understand the market and the form of delivery that is likely to be most successful in a specific region.



Global marketing considerations

- Adapt methods, messaging, and emotional appeal to each country.
- Emphasize the benefits to study subjects.
- Incorporate the norms, customs and culture of each country into recruitment ad design and copy. For example:²
 - Testimonial quotes are not as effective in Germany. It's a cultural bias; they prefer objective facts, figures, graphs, etc.
 - In South Africa, patient recruitment ads cannot say "drug," but rather, "medication." And even UK English may need some adaptation for South African audiences.

Frequently, multiple versions of the same documents must be provided by the sponsor. The quality and wording of translation for patient materials needs to be tailored to the local style of communication. Regional dialects or several dominant languages may have to be incorporated, especially in the translation of informed consent forms.³

Educating Key Audiences

In many countries, the general public is not familiar with the concept of clinical trials; they just know their local clinics. Specific activities of global PRO operations start with promoting cultural understanding and awareness of clinical research and recruitment methodology. This can include dialoguing with opinion leaders and developing relationships with advocacy groups. Centralized recruitment may be new to many trial sites, but on the whole, they are likely to be open to it when they can clearly see the benefit of adding patients and revenues, and understand exactly how much of their time will be required.

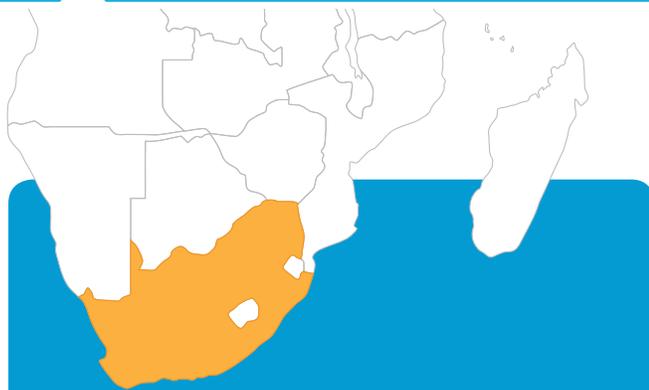
There remains a lot of misconception around what can and cannot be done in patient recruitment in most countries. The issue is not that certain tactics or approaches can't be used, but that people involved with the clinical trials *perceive* they can't be used. Increasing the research site footprints and/or extending study deadlines are not always viable solutions to address patient enrollment challenges, yet sponsors are reluctant to change based on a fear of breaking tradition. A true global PRO will be able to look outside of the traditional and push forward new and innovative approaches in each country.

Ethics Committees and Standards

Much as they would coordinate with the Federal Drug Administration in the US, sponsors and PROs must work with regional Ethics Committees (ECs) and adhere to the regulatory approval timelines of each country. They must submit the study protocol, questionnaire, ads and other marketing materials for approval by a national committee (the Central Ethics Committee or CEC) and, often, individual state committees where the site(s) will be located. Most CECs meet once a month.

² Anecdotal observations throughout this paper were provided by in-country professionals on the front lines of clinical research. It is essential to retain experts who know how to navigate the ethical standards for each country.

³ *PharmaVOICE*, March 2009.



In South Africa, government institutions are understaffed; as a result, it can be a time-consuming (6- to 8-month) process to get approvals for trials there.

For now, every European country has its own committees, but legislation change coming in 2018 may make it easier to get trials approved, with a two-level approach. Under the new regulations, approval of a trial by one EC will “green light” it in general across the European Union, but patient recruitment materials will continue to be approved at the country level.

Understanding the nature of existing doctor-patient relationships is also very important. In many countries that are becoming dominant in clinical research, the strong relationship between patients and their physicians greatly facilitates patient enrollment and retention, but quality of referrals can be an issue.⁴ In addition, there are often related country-specific ethics considerations between doctors and patients; e.g., some German physicians will not allow PROs to check their patients’ medical records.

Cultural/Socioeconomic Issues and Sensitivities

Addressing the differences in each country for a successful recruitment campaign involves many factors. Logistically speaking, global studies will always present more of a challenge to recruiters, who are ultimately responsible for ensuring that patient rights are fully protected.⁵

For example, in many emerging regions, illiteracy is a major obstacle, because it creates significant barriers to informed consent. Some countries are addressing this problem by using different means of communication or additional informed consent forms. Furthermore, because of poverty, many patients do not have access to medical treatment, which greatly influences their decision to participate in clinical trials.

Medical standards of care also differ among countries, making the use of one protocol with the same inclusion/exclusion criteria difficult to adhere to globally. Patients who would be eligible in one country may be automatically given a restricted concomitant medication as standard of care in another country and would not be eligible for the trial.⁶

As previously noted, confirming the confidentiality of patient data should always be a top priority. Many European nations forbid the use of individual patient IDs (birthdate, initials, etc.) as a safeguard. Sites must inform patients of this during pre-screening.

⁴ *PharmaVOICE*, March 2009.

⁵ Ed Miseta, “3 Common Myths Related to Global Patient Recruitment,” *Clinical Leader*, October 30, 2014.

⁶ *PharmaVOICE*, March 2009

Last but certainly not least, global PROs must show sensitivity to regional reimbursement/ compensation differences, e.g.:

- In Hungary, patient reimbursement (except for travel expenses) is not permitted except in Phase I trials.
- PROs cannot specifically mention reimbursement in South Africa.
- In Poland, reimbursement in *fixed* amounts is viewed as payment to the patient, which is prohibited. Therefore, reimbursement must be based on actual receipts.

The new EU clinical trial regulations address reimbursement and mention set amounts for patients' time, as well as travel reimbursement, but this is still to be finalized.

Finding a Multifaceted Partner

The global landscape for clinical trials can be viewed as a giant puzzle with multiple solutions. Every country requires an individualized approach, and sponsors should engage a PRO that is broadly experienced and attuned to these nuances, with the resources and capabilities to be truly effective worldwide.

About Acurian

Acurian, a subsidiary of PPD, is a leading full-service provider of clinical trial patient enrollment and retention solutions for the life sciences industry. The company increases the enrollment performance of investigator sites worldwide by identifying, contacting, prescreening and referring people who live in the local community but are unknown to a research site. As a result, trial sponsors complete enrollment without incurring the unexpected expense of adding sites or time.

