Multicultural Issues in the Globalization of Clinical Trial Patient Recruitment

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As conducting global clinical trials becomes more prevalent in order to increase patient recruitment, multicultural issues surrounding cross-national trials are a critical challenge to address. A language service provider should provide accurate adaptations of information with a thorough understanding of local culture and knowledge in the target market~~s~~. Lack of well-translated material is one of the main causes of study delays and can ultimately cost bioscience companies millions if not managed effectively. As clinical research is the most expensive phase of development,[1] delays in developing a successful drug may result in losses of up to (US) $1 million per day. [2]

In order to accelerate the patient enrollment process, companies are conducting studies in emerging regions such as Eastern Europe, Latin America, Asia, and India. In these regions, patients may be willing to participate in order to gain access to modern diagnostic medicines and procedures, but informed consent is critical so that language differences do not interfere with trial methodology.

Differences in linguistic, cultural and population demographics within any cross-national trial must be addressed when initiating the trial, when planning implementation, and after the collection of the data.[3] Global trials present a number of cross-cultural challenges:

- Concern over accurate reporting of symptoms due to bio-psycho-socio-cultural perspectives
- Differences in governmental processes and regulatory requirements that affect submissions
- General language barriers and cultural differences affecting all forms of communication

In terms of international regulatory requirements, not all countries are part of the EU Clinical Trial Directive (25 out of 35).[4] One concern for global trials is the difficulty in drawing valid scientific conclusions with data from ethnically and culturally diverse populations.[5] In this case, multi-lingual translation can have a critical impact on the data.

Generally, without an experienced localization partner bioscience companies do not have the ~~variety~~ varied resources and highly-specialized linguistic capacity to manage the translation process necessary for a global clinical trial. When evaluating potential localization partners to assist with in-country multilingual and multicultural adaptations, it is essential to choose a company that has experience and capability within the bioscience sectors.

Upfront planning and logistics are critical success factors for global trials. Additionally, a system with multi-language capabilities is a necessity.[6] The ultimate time and cost savings, especially in large trials, make the upfront investment worth the extra effort.

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[1] Mathieu, M.P. (2001) Statistics on Drug Development (Section 3) in: Pharmaceutical R&D Statistical Sourcebook. PAREXEL International Corporation.

[2] Maloff, B. (1999) Partnering for success -Performance measurements for sponsors, contract research organizations and the site management organizations. Drug Information Journal 33, 655-661.

[3] Integrating Health-Related Quality of Life Into Cross-National Clinical Trials , Journal Quality of Life Research, Springer Netherlands, *Issue Volume 2, Number 6 / December, 1993,* 433-440

[4] *Ibid*.

[5] Rehnquist J. The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects. Office of Inspector General Department of Health and Human Services web site [online], (2001).

[6] Future Pharmaceuticals. An Analysts In Media Publication: Globalization and Patient Recruitment [online], (2008).