

Controversies in Clinical Trials Globalization

As new information and important issues arise, CISCRP wants to help clinical trials professionals keep up to date. Here are some recent articles you'll want to take a look at:

Ethical and Scientific Implications of Globalization of Clinical Research

From *The New England Journal of Medicine*, Feb. 19, 2009
Seth W. Glickman, M.D., M.B.A., John G. McHutchison, M.D., Eric D. Peterson, M.D., M.P.H., Charles B. Cairns, M.D., Robert A. Harrington, M.D., Robert M. Califf, M.D.

Clinical trials are becoming increasingly globalized; yet trials done outside the established trial regions raise ethical and scientific concerns, according to the study authors.

While globalization of clinical trials may lower costs, says Glickman, downsides include:

- Ethical concerns about the lack of trial oversight, different standards and approaches to conducting clinical trials, and the monetary lure for subjects in low-income countries;
- Drugs may react differently on 'drug naïve' people in developing countries (i.e., people who have had little or no prior medication) than they do in residents of Western countries, thus, results can not be generalized;
- Genetics, cultural, and social factors influence drug metabolism, so these factors could make trial results less relevant to a US population.

<http://content.nejm.org/cgi/content/full/360/8/816>

Responding to Emerging Queries on the Legitimacy and Validity of Globalization of Clinical Trials

From *Clinical Trial Magnifier* Vol 2:3 March 2009
Johan PE Karlberg, MD, PhD, BSc

Karlberg responded to the New England Journal of Medicine article (at left) and to an article from the European Medicine Agency, entitled *Reflections Paper on the Extrapolation of Results from Clinical Studies Conducted Outside Europe to the EU population*.

Karlberg noted some valid points in Glickman's article, stating that the high illiteracy rate and lack of public health

care in emerging countries could lead toward unethical behavior in administering clinical trials.

However, he noted that many emerging countries have developed excellent infrastructure and practices for clinical trials.

Glickman's assumed cost saving of conducting clinical trials in emerging locations is incorrect, says Karlberg, as are claims that easier regulatory environments will lead to greater access to expanding markets; or expectation the accelerated recruitment will occur.

Karlberg also disputed the second paper, whose premise was that in global clinical trials, different medical practices, disease definition and study populations may make the foreign data non-applicable to an EU setting.

<http://www.clinicaltrialmagnifier.com/download.aspx?id=0c311436-7ee3-4bf3-8429-1375a64187fc>

Elusive Sponsor-Site Relationship Global clinical trial landscape changes pose new challenges for all sites – even AMCs.

From *Applied Clinical Trials*, Feb. 1, 2009
Kenneth A. Getz

Getz discussed important trends and challenges in globalization, privatization, and changes in size and scope of clinical trials sites. He calls for creative solutions and an investment of personnel and resources to establish successful sponsor site collaborations.

He pointed out the steady growth in the proportion of investigators in emerging regions, also noting that there has been a decline in the number of active FDA-regulated investigators conducting phase II and III trials in North America, while the opposite has occurred in Phase I studies.

Competition for clinical trials will intensify in the near future, according to Getz. The number of investigators per active IND has nearly doubled in the past decade, yet the average number of patients per NDA has declined by half. Sponsors are engaging more investigators to recruit fewer patients per IND.

<http://appliedclinicaltrials.findpharma.com/appliedclinicaltrials/Project+Management/The-Elusive-Sponsor-Site-Relationship/ArticleStandard/Article/detail/579328?contextCategoryId=43300&searchString=elusive%20sponsor>