

## **"Accelerating Global Drug Development: The Science and Practice of Ethnobridging"**

**Stan Jhee, Murray H. Rosenthal, Samira Moran, and Larry Ereshefsky, 2006, 157 pages, California Clinical Trials, \$99.95**

**Review by Norman M. Goldfarb**

"Accelerating Global Drug Development: The Science and Practice of Ethnobridging" is essential reading for any clinical scientist interested in racial and ethnic factors in clinical research. The relatively slender volume is packed with examples and citations for further investigation.

The book includes eight chapters:

- A global approach to accelerating drug development: ethnic considerations
- The impact of pharmacogenomics and pharmacogenetics on drug development
- Clinical evidence of ethnic and racial differences in drug pharmacodynamics and pharmacokinetics
- Ethnic and racial differences in the pharmacokinetics of drug metabolism
- Ethnic and racial differences in the pharmacokinetics of drugs: absorption, distribution, elimination
- Non-genetic basis for ethnic and racial differences in pharmacokinetic parameters
- Pharmacokinetic analysis of ethnic groups using population methods
- Recruitment and retention of study volunteers

This book has been selected for  
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Essential reading for clinical research professionals

The book makes a convincing case that race and ethnicity can be vitally important in the efficacy and safety of drugs. The key word in the previous sentence is "can"; a table lists criteria for determining when racial and ethnic factors are likely to be important. For example, drugs with nonlinear pharmacokinetics and narrow therapeutic dose ranges are more likely to be sensitive to racial and ethnic factors.

The book includes comprehensive surveys of racial and ethnic differences in drug metabolism and effect. For example, the AUC (area under the curve of drug concentration over time) of the cardiology drug nifedipine (Procardia) is two to three times higher in the average South Asian than the average Caucasian. Because the averages mask individual variation, the future of pharmacogenetics is bright.

National eccentricities can appear in unusual ways. For example, if you plan to conduct a Phase I trial in Korea, you should be aware that Korean hospitals often serve charcoal-barbequed meat, with significant impact on the metabolism of drugs such as antipyrine, phenacetin and theophylline. Mexicans are relatively unlikely to participate in trials that require autopsies because some individuals believe that the autopsy request may itself hasten death or that post-mortem autopsies are painful to the dead.

The book raises red flags about the relevance of carefully controlled clinical trials to populations with widespread use of tobacco, alcohol, nutritional supplements, or herbal medicines. For example, in countries with a high incidence of tobacco smoking such as

Russia (48%) or Bangladesh (50%), clinical trials that exclude smokers seem charmingly naive. In the United States, 18% of adults use vitamins or herbal products concurrently with prescribed medications, so clinical trials that do not recognize these chemicals as concomitant medications may miss an important source of variability.

The authors have conducted bridging studies in California for marketing applications in Japan, but only because they limit their study populations to recent immigrants from Japan whose diet, lifestyle and other ethnic considerations remain representative of like persons in Japan.

The book is available at <http://www.cctrials.com/>

### **Reviewer**

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or [ngoldfarb@firstclinical.com](mailto:ngoldfarb@firstclinical.com).