

"Emerging Markets Clinical Development Series"

Cutting Edge Information, 2010, 961 pages, \$7,695 each

Review by Norman M. Goldfarb

"Emerging Markets Clinical Development Series" includes five reports:

- Africa: Understand the Risks but Do Not Overlook Africa's Potential
- Asia: Harnessing the Best of the East and West
- BRIC (Brazil, Russia, India and China): Promise Outweighs the Concerns
- Central and Eastern Europe: Leading Clinical Operations in Emerging Markets
- Latin America: Looking South of the Border to Improve Clinical Outcomes

The combined reports include hundreds of charts and figures. This review will focus on the report on Latin America.

Latin America is one of the friendliest regions for clinical operations because of its large, treatment-naive populations concentrated in metropolitan areas, reverence for physicians, cultural receptivity to technological advances, relatively advanced healthcare infrastructure, proximity to the United States, and ease of communication, with only two primary languages (Spanish and Portuguese) and many physicians who are fluent in English. Relatively few clinical trials (4,000) are currently conducted in Latin America.

Although survey respondents rate Latin American patient access high (8.0 out of 10), the regulatory environment rates only 4.9 and intellectual property protections rate 6.3. Latin America consists of numerous independent countries, of course, and each country has its own unique mix of characteristics. For example, Peru and Chile have relatively swift regulatory processes. Some countries require study sponsors to continue treatment for study subjects after a study concludes, even if the company discontinues development of the study treatment. Costa Rica is well organized for clinical research, but recently halted new studies pending new legislation. Guidance from Latin American contract research organizations (CROs) is therefore well advised.

The report focuses on Brazil, Mexico and Argentina. These three countries — Brazil (199 million), Mexico (111 million), and Argentina (41 million) — comprise 60% of the region's total population of 581 million. The smaller countries have smaller populations but are also less utilized for clinical research.

Brazil's pharmaceutical market is growing at the rate of 18% per year, comprising a 38% share of the Latin American pharmaceutical market in 2009. Mexico's share is 21% and Argentina's 9%. Venezuela's share is 16%, but political and economic instability is an issue, as in some other Latin American countries.

The report highlights Columbia as an excellent country for clinical research. Drug trafficking and guerilla warfare sound like showstoppers but are geographically limited and not problems for clinical research. The country has a population of 46 million, experienced investigators, quality research sites, fast regulatory processes, and clear and useful regulations.

The report is available at <http://www.cuttingedgeinfo.com>.

Reviewer

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