JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 7, No. 6, June 2011 "Can You Handle the Truth?"

"CMR International 2010 Pharmaceutical R&D Factbook"

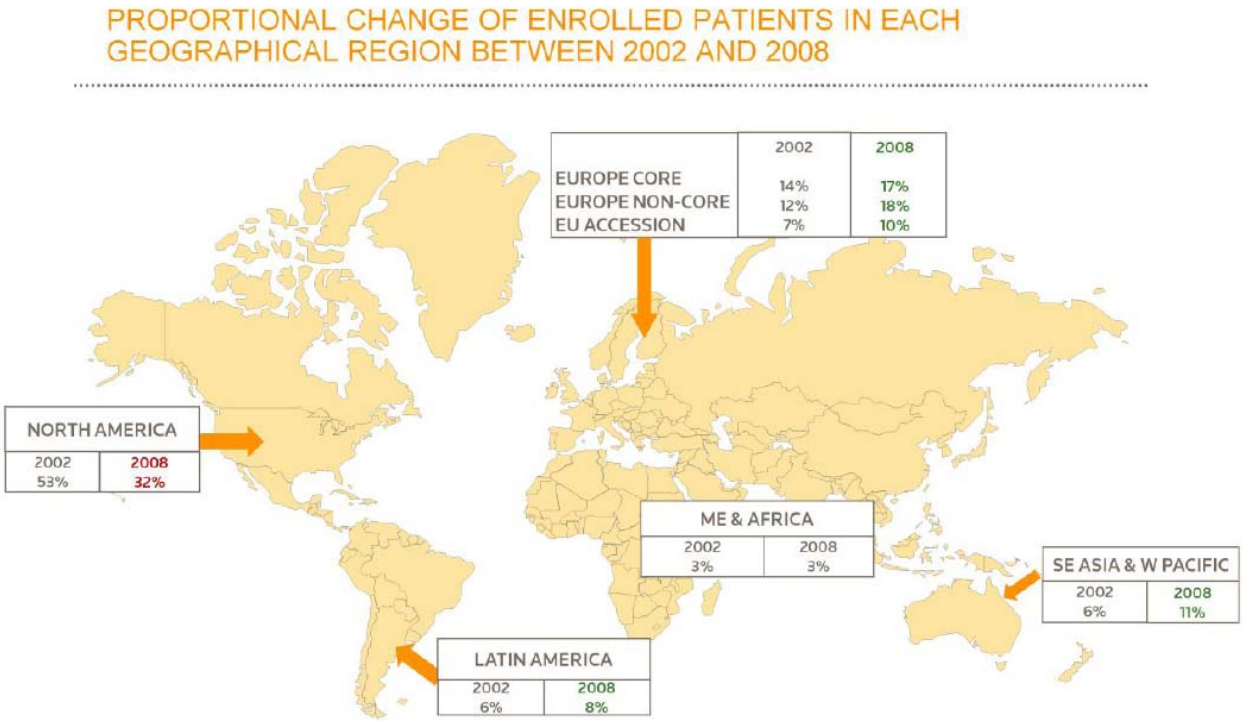
Thomson Reuters, 2010, 97 pages, $9,990

Review by Norman M. Goldfarb

"CMR International 2010 Pharmaceutical R&D Factbook" presents the most important results from CMR performance benchmarking programs in 75 charts and figures in 11 chapters:

- Overview
- R&D resources
- R&D pipeline volume
- Success rates
- Cycle times
- Regional comparisons
- Therapeutic area focus
- Biopharmaceutical focus
- Clinical function
- Patents
- Global generics market

The following chart describes the globalization of clinical research:



The implications of each chart and figure are summarized. For a delightful change from most data in the industry, descriptions of methodology, definitions and data sources provide assurance that the charts mean what they claim to mean.

A few of the many fascinating findings include:

- The count of 30 new active substances (NAS) first launched onto the world market in 2009 bounced back nicely from the low of 23 in 2008. ("New active substances" include 26 new molecular entities (NME) (including biologics) plus radiopharmaceuticals.)
- In 2009, clinical research consumed 38.2% of R&D expenditures, up from 37% in 2008.*
- The number of active substances entering Phase III trials increased by 138% from 2005 to 2007, but dropped back down to the 2005 level by 2009. Phase I and Phase II both experienced declines of one-third from 2008 to 2009.*
- From 2005 to 2009, the number of line extension products submitted to the FDA for marketing approval increased from eight to 25.*
- From 2004-2006 to 2007-2009, the number of project terminations in Phase III increased from 18 to 38.*
- The average Phase III study in 2008 took 797 days to complete, including 129 days for start-up (protocol approval to first subject enrollment) and 358 days for enrollment.*
- In 2008, the FDA's median approval time for new active substances (329 days) continued to be faster than that of other major regulatory agencies.

* Based on a survey of 18 pharmaceutical companies

The report is available at http://cmr.thomsonreuters.com/shop.

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.