

"PAREXEL's Bio/Pharmaceutical R&D Statistical Sourcebook 2015/2016"

Mark P. Mathieu, editor, 2015, 438 pages, PAREXEL International, \$425.00

Review by Norman M. Goldfarb

"PAREXEL's Bio/Pharmaceutical R&D Statistical Sourcebook 2015/2016" is the industry's most complete compendium of statistics and other facts about drug development. The book includes hundreds of charts, tables, figures and analyses in six sections:

This book has been selected for
[The First Clinical Research Bookshelf](#)
Essential reading for clinical research professionals

- R&D Spending
- Products in Development
- Market Access/Reimbursement/Drug Pricing (new)
- Drug Development Costs/Complexity, Development Time, and Success Rates
- Regulatory/FDA Statistics
- International Statistics

A few of the fascinating findings in the book include the following:

- Spending in the U.S. in 2014 of \$374 billion on prescription and OTC drugs is about equal to the combined spending on alcohol (\$174B), coffee (\$48B), tobacco (\$108B), and lottery tickets (\$70B).
- Fifty-four percent of FDA-regulated commercial clinical trial starts in 2011-2014 were in four therapeutic areas: oncology, excluding blood cancers (27.0%); hematology, including blood cancers (10.1%); neurology (9.2%); and pulmonary, allergy and rheumatology (7.9%).
- The cost of gaining a quality-adjusted life year (QALY) is \$910K for Elaprase (Hunter syndrome), \$839K for Solari (hemoglobinemia), \$233K for Avastin (oncology), \$82K for Herceptin (oncology), \$72K for Tysabri (multiple sclerosis), \$41K for Sovaldi (hepatitis C), and \$2 for "novel antibiotics."
- Study participant drop-out rates are the highest for bipolar disorder (35%), prostate cancer (35%), Crohn's disease (32%), and schizophrenia (30%). They are the lowest for hypercholesterolemia (5%), pain (6%), hypertension (8%), type 2 diabetes (12%), and rheumatoid arthritis (13%).
- The median number of sites in a study is 72 for endocrine and metabolic disease, 42 for central nervous system, 26 for musculoskeletal system and connective tissue, 25 for infectious disease, and 12 for oncology.
- The average time to activate a Phase III site and the average enrollment rate per site are 8 / 9 in Western Europe, 5 / 10 in North America, and 16 / 21 in emerging regions. In other words, North American sites initiate the fastest, while emerging regions enroll the fastest, once they are initiated.

The book is available at www.barnettinternational.com.

Reviewer

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