

## **"The Impact of Genomics on Clinical Trials and Medical Practice"**

**Gwen Acton, 2006, 239 pages, Cambridge Healthtech Associates, \$3,618.00**

**Review by Norman M. Goldfarb**

"The Impact of Genomics on Clinical Trials and Medical Practice" provides an excellent overview of a rapidly growing field. The report is ideal for pharmaceutical and biotech executives, especially those with responsibility for strategy, portfolio management, and business development. It presents technical topics in a form that is understandable to non-technical people.

Genomics is genetics on steroids. Whereas genetics focuses on single genes with low-throughput technologies, genomics works with numerous genes and high-throughput technologies.

The growing use of genomics to personalize medicine will make it ever more difficult to justify selling "shotgun" drugs to people who cannot possibly benefit and could be seriously harmed. Genomics helps identify populations that are most likely to benefit from a new drug, elucidate pharmacodynamics and pharmacokinetics, and reduce the cost of clinical trials by focusing on genetically homogenous populations that are most likely to respond. The challenge, of course, is that the economics of personalized medicine relies on relatively small populations, who may not be able to pay astronomical prices for treatment, even though that treatment has a high probability of success.

The report presents astonishing data that explain the promise and challenges of genomics:

- The function of about half of all identified human genes is unknown.
- The DNA sequence is 99.9% identical in all people, but two unrelated people will have about 1 million differences in their DNA sequences.
- Treatments are available for only about one-third of the 30,000 known diseases.
- Over 80% of drugs on the market cause serious side effects in some people, killing 100,000 per year, the fourth leading cause of death after heart disease, cancer and stroke.
- Over 42,000 terms are used to describe different cancers.
- More than 10 million Americans are asymptomatic carriers of a defective CFTR (cystic fibrosis) gene, but there are 1,000 known mutations in the gene.
- Many important diseases such as cancer, Alzheimer's, diabetes and schizophrenia have complex, multi-factorial causes.

The report has 49 tables and figures in seven chapters:

- Introduction
- Applications to clinical trials and medicine
- Genomic technologies for the clinic
- Advances in clinical genomic applications
- Business and strategic issues
- Interviews with experts
- Selected company profiles

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

**Reviewer**

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