SUMMARY

In 2005, biotechnology and pharmaceutical companies spent approximately $51 billion on research and development efforts, with $21 billion spent on clinical trials. In comparison, government contributions to clinical trials were considerably smaller. The National Institutes of Health (NIH) spent $2.9 billion on clinical trials in 2005 and budgeted $3.0 billion for 2006. The Department of Defense has stated an increase in its funding of clinical trials, but the actual numbers are difficult to determine since much of the military budget is classified.

The mapping of the human genome has accelerated preclinical development activity. Companies currently are implementing new technologies in their research and development programs at all stages of drug development. Many clinical trials are beginning to include pharmacogenomics as a facet of research protocols. New technologies and the outsourcing of clinical trials to lower cost countries will slow the recent annual increases in expenditures to an average annual compounded growth rate. The current spending levels are high; the slower growth rate still translates into tremendous investment in research and development efforts by this industry.

The Food and Drug Administration (FDA) and other sectors have been concerned that recent investment in research and development programs has not produced a greater number of successful new drug applications (NDAs). For this reason, the FDA initiated the Critical Path Initiative (CPI) to increase collaboration between academia, government, and industry to increase the success rate of bringing new and novel therapies to market.

Funding for clinical trials comes from NIH, other federal agencies, private organizations, and the biopharmaceutical industry. The biopharmaceutical industry is the largest contributor to the funding of clinical trial processes. More than of U.S. biotechnology and pharmaceutical companies' R&D budgets is devoted to clinical trial funding.

The majority of clinical trial funding is spent on Phases II and III, depending on the drug class. These are the pivotal phases of any clinically based research effort.

Cancer and endocrine disorders receive the majority of research funding from industry. Central nervous system (CNS) disorders receive the second largest amount, with heart disease a close third in 2005.

In this report, clinical trials are counted by product, device or some novel combination. Clinical trials are not counted by number of sites or permutations on the same product.

TABLE 11

U.S. CLINICAL TRIALS BY ORGANIZATION TYPE AND PHASE, 2005
(NUMBER OF CLINICAL TRIALS RECRUITING SUBJECTS)

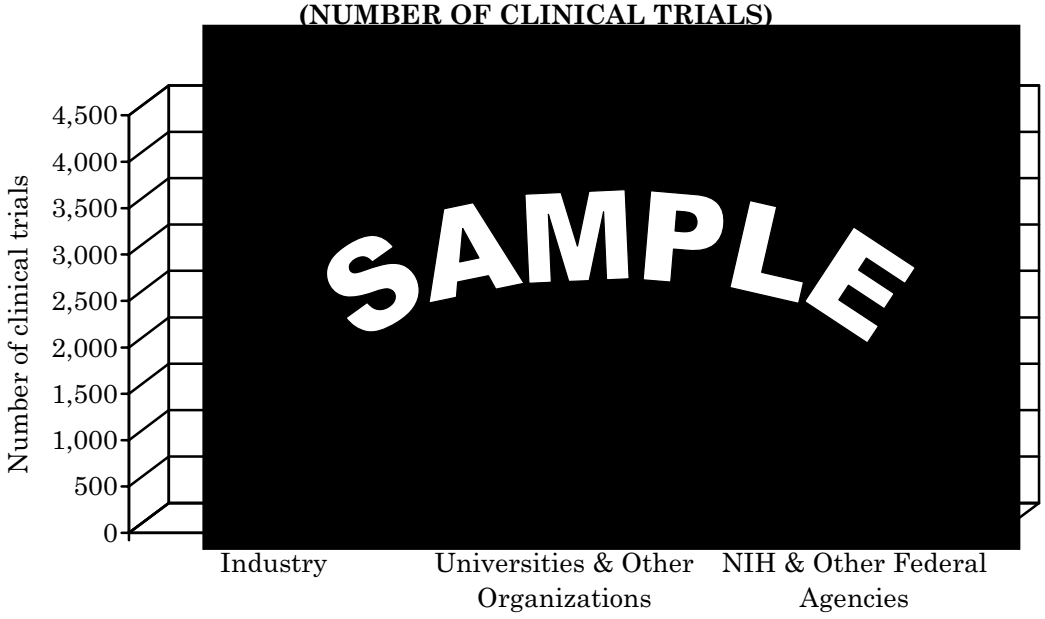
Phase	Industry	University or Other Organization†	National Institutes of Health‡	Other Federal Agency†	Total*
Phase I					
Phase II					
Phase III					
Phase IV					
Total					

*Horizontal columns do not add up since many of the trials have more than one sponsor, in more than one category.
† Many of these clinical trials are for treatment, prevention, or other purposes.

Source: NIH, BCC Research

FIGURE 4

NUMBER OF CLINICAL TRIALS BY MAJOR SPONSORS, 2005
(NUMBER OF CLINICAL TRIALS)



Source: BCC Research

TABLE 21

NUMBER OF CLINICAL TRIALS USING NEW TECHNOLOGIES, THROUGH 2011

Technology	2004	2005	2006	2011	AAGR% 2006-2011
Antisense					
Apoptosis					
Biochips/microarrays					
Gene-therapy					
Genomics					
Novel drug delivery systems					
Stem cell therapy					
Total					

Source: NIH, BCC Research

Completion of the Human Genome Project has translated into an acceleration of activity in the biotechnology (and pharmaceutical) industry. This project has spawned the following new disciplines that are individually, and together, accelerating drug development:

- genomics
- bioinformatics
- pharmacogenomics
- proteomics

These new disciplines and other technologies have facilitated the identification of novel therapeutic compounds and will continue to do so. Biochips/microarrays, two-dimensional gels, X-ray crystallography and combinatorial chemistry are analytic techniques that support drug development and are evolving in parallel with these new disciplines. Cell therapies, novel drug delivery systems, protease inhibition, theranostics (a merger of diagnostics and medical treatment) and transgenics are biotechnological techniques that will require greater numbers of clinical trials in the near future.

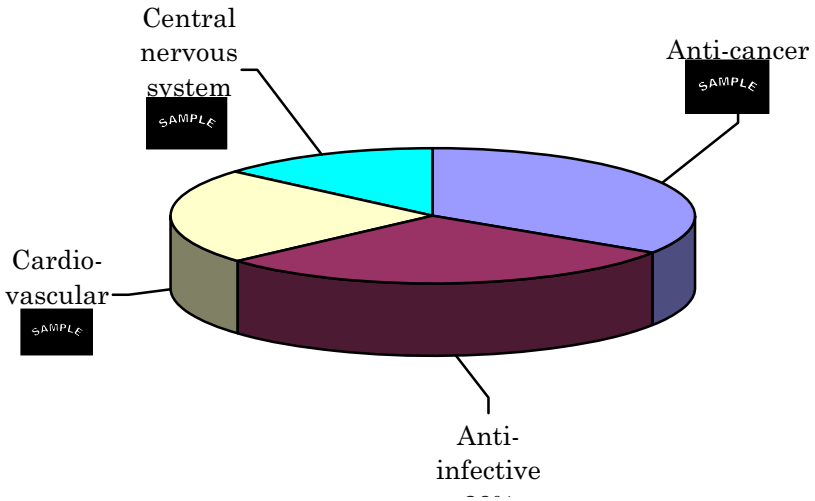
A more recent trend is an increase in natural biologically based products. The search for novel treatments has dichotomized into two trends: the heavy use of technology and the search into nature. The investigation into natural resources to find drugs is a returning trend, even though this form of investigation is considered more costly.

TRENDS IN SELECT THERAPEUTIC AREAS

A new publication series features recent patent targets for specific medical disease areas. This publication series began by analyzing patents produced in specific therapeutic areas. Titles in this publication series include the following: *Recent Patents on Anti-Cancer Drug Discovery*, *Recent Patents on Anti-Infective Drug Discovery*, *Recent Patents on Cardiovascular Drug Discovery*, and *Recent Patents on CNS Drug Discovery*.

FIGURE 12

NOTABLE PATENTS IN FOUR MAJOR THERAPEUTIC AREAS, 2005
(%)



LEGEND

Therapeutic Area	Number	Percent
Anti-cancer		
Anti-infective		
Cardiovascular		
Central nervous system		
Total		

Source: USPTO, BCC Research

CONCLUSIONS OF ANALYSIS

A tremendous amount of innovation is taking place in all therapeutic areas. The largest number of new patents is in the area of cancer therapeutics, which is also the largest area of funding.

The company has collaborations or licenses with the following entities: Active Biotech AB, Affymax, Alexion, Aphton, Applied Molecular Evolution (AME), Avecia, Aventis Pharma, Baxter, BioInvent, Biosite, Cambridge Antibody Technology, Celltech Therapeutics, Centocor, Chiron, Crucell, Diversa, Dompe, Dyax, duPont, Eli Lilly, Enzon, Genentech, Genzyme, ICOS, Invitrogen, Medical Research Council, Micromet, Millennium, MorphoSys, Onyx, Triton, Viventia Biotech, Zephyr, and ZymoGenetics.

PHARMACEUTICAL COMPANIES

TABLE 97

REVENUES AND R&D EXPENDITURES FOR SELECTED PHARMACEUTICAL COMPANIES, WITH PERCENT CHANGE, 2004 AND 2005
($BILLIONS)

	2004		2005		
Company	**Revenues**	**R&D Expenditures**	**Revenues**	**R&D Expenditures**	**% Change in R&D**
Pfizer					
Johnson & Johnson					
Roche					
GlaxoSmithKline					
Bayer					
Sanofi-Aventis					
Novartis					
AstraZeneca					
Abbott					
Merck					
Bristol Myers Squibb					
Wyeth					
Lilly					
Schering-Plough					
Novo Nordisk					

Source: BCC Research, Co

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