

# Clinical Trial Data Disclosure Policies for the Future

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Pfizer Global Research and Development

Ann Arbor, Michigan

# The Healthcare Debate

## *Running for President?*

Marietta Yoder, RN  
Kalona, IA



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### **Does Bush's Budget Proposal Set Right Priorities on Health Care?**

Feb 9, 2005 - Wall Street Journal

President Bush unveiled his 2006 budget proposal on Monday, kicking off the annual tussle in Congress over which programs to fund more, less or not at all.

On health care, a political hot potato and a top concern of Americans, the president's plan includes cuts in discretionary spending at the Department of Health and Human Services. Medicare spending, meanwhile, is budgeted for \$340 billion, a 17% increase due largely to new prescription-drug coverage.

### **Kansas -- GOP leaders block governor's health care plan**

Feb 10, 2005 - Journal-World

By Scott Rothschild

TOPEKA — Republican budget writers today blocked a major part of Gov. Kathleen Sebelius' health care reform plan.

"We don't feel there is enough detail," Rep. Brenda Landwehr, R-Wichita, and vice chair of the House Appropriations Committee, said.

# Rising Costs of Health Care

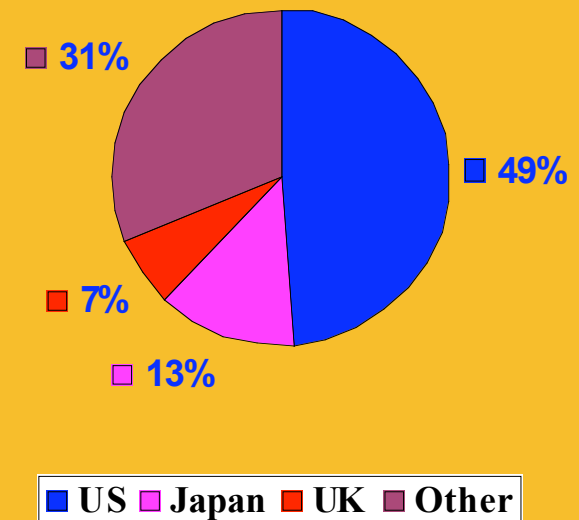
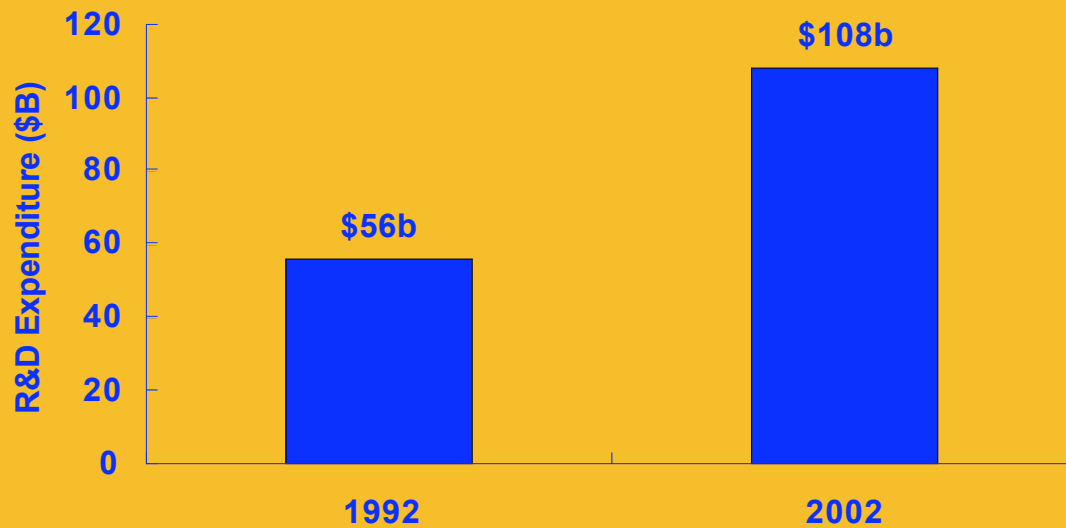
## Annual Healthcare Cost Per Person

1980	\$2,207
1990	\$3,541 (+60%)
2000	\$4,461 (+26%)

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Total increase from 1980 to 2000 = 102%

# Healthcare R&D is Big Business



# Consumerism is on the Rise

**ANNUAL MEETING 2005**

GOVERNORS OF THE WORLD ECONOMIC FORUM  
FOR HEALTHCARE

DAVOS - THURSDAY 27 JANUARY

**CAN ENLIGHTENED CONSUMERS CONTRIBUTE TO RATIONALIZING  
HEALTH SPENDING AND IMPROVING QUALITY OF CARE?**

**The patient of the future**

Produced by: Phyllis Yale, Partner, Bain & Company, USA;  
Franz-Robert Klingan, Manager, Bain & Company, USA;  
and Brian Martin, Consultant, Bain & Company, USA

Thursday 27 January  
Hotel Derby, Fluelia 1  
18.00 - 19.30

Exhibit 2: While starting at different points, both Europe and the US are moving along the consumerism spectrum



Pressure is building

- Consumers sense a need for change
  - 81% believe healthcare quality to stagnate or decline in next 10 years
  - 61% believe change is urgent and necessary
- EU amending legislation to provide consumers with more information and choice
  - G10 principles recommend greater system transparency and allow competition among drugs not reimbursed by EU states
  - Recent EU legislation passed to allow DTC advertising for AIDS, asthma and diabetes drugs

At an inflection point

- High employer interest
  - 16% of employers are very likely or somewhat likely to offer a CDHP option to employees by 2006
- Payers prepared to respond
  - Nearly 70% of payers offer a consumer-driven health plan or are considering one
  - UnitedHealth acquired the largest CDHP insurer to jumpstart its market entry
- Huge forecasted growth in enrollment in CDHPs
  - 58M projected enrollment by 2010, up from 2.4M today

Sources: *Risk and Insurance*, May 2004, quoting Eastbridge Consulting Group's Report, "Health Savings Accounts, A First Look"  
Mercer's National Survey of Employer Sponsored Health Plans (2003)  
Stockholm Network, *Impatient for Change*, 2004

# More Questions

**"Will professionalism be a casualty of MODERN MEDICINE?"**

A day-long sesquicentennial symposium on professional values in medicine accomplishes its goal, stimulating thoughtful exchanges and beginning a dialogue that many say was overdue.



**Deb Stern**, wife of moderator and symposium organizer David Stern, and **Thomas Stern, M.D.**, father of David and a practicing cardiologist in Memphis, Tennessee, with **James Woolliscroft**, executive associate dean of the Medical School.

By **Jeffrey Mortimer**

The bold question chosen for the title of a day-long symposium on the medical camp to be about 135 deeply, a no day, especi

Invited sp including t of Californ uly membri ciation of J media, fro by Warner Aetna and Also partic Berland, M herself and Cross-Cov on the nig

The unexp drug deve Lambert in expressed "Challeng most vibra Peter Cor involved in

Pande, who had served on the Michigan faculty before joining Parke-Davis, noted the advantages and disadvantages of academic-commercial collaborations as he has experienced them. "The focus and means of the pharmaceutical industry, combined with academic medicine, have led to advances that would not otherwise be possible," he said.

But he also noted the "potential problems" in the relationships between individuals and the industry. In the case of the clinical practitioner, "the hazard arises from the inability of average practitioners to distinguish between the promotional and the educational," i.e., their reliance on drug company representatives for information about pharmaceuticals. In the case of researchers, he observed, "when you're on the faculty, easy access to funding from the pharmaceutical industry is alluring. The danger is if that's the only or prime consideration." And then there is the "academic physician delivering 50-100 talks a year on behalf of the pharmaceutical industry. This is an area where some caution may be advisable."

## Clinical Trial Registration

### A Statement From the International Committee of Medical Journal Editors

Catherine D. DeAngelis, MD, MPH

Jeffrey M. Drazen, MD

Frank A. Frizelle, MBChB, MMedSc, FRACS

Charlotte Haug, MD, PhD, MSc

Unfortunately, selective reporting of trials does occur, and it distorts the body of evidence available for clinical decision-making. Researchers (and journal editors) are generally most enthusiastic about the publication of trials that show either a large effect of a new treatment (positive trials) or equivalence of 2 approaches to treatment (noninferiority trials). Researchers (and journals) typically are less excited about trials that show that a new treatment is inferior to standard treatment (negative trials) and even less interested in trials

**A** volunteer for research because they trust that their participation will contribute to improved health for others and that researchers will minimize risks to participants. In return for the altruism and trust that make clinical research possible, the research enterprise has a

Irrespective of their scientific interest, trial results that place financial interests at risk are particularly likely to remain unpublished and hidden from public view. The interests of the sponsor or authors notwithstanding, anyone should be able to learn of any trial's existence and its important characteristics.

The case against selective reporting is particularly compelling for research that tests interventions that could enter mainstream clinical practice. Rather than a single trial,

The case against selective reporting is particularly compelling for research that tests interventions that could enter mainstream clinical practice. Rather than a single trial, it is usually a body of evidence, consisting of many studies that changes medical practice. When research sponsors or investigators conceal the presence of selected trials, the studies cannot influence the thinking of patients, clinicians, other researchers, and experts who write practice guidelines or decide on insurance-coverage policy. If all trials are registered in a public repository at their inception, every trial's existence is part of the public record, and the marketplace stakeholders in clinical research can explore the full range of clinical evidence. We are far from this ideal at present.

# Recent History

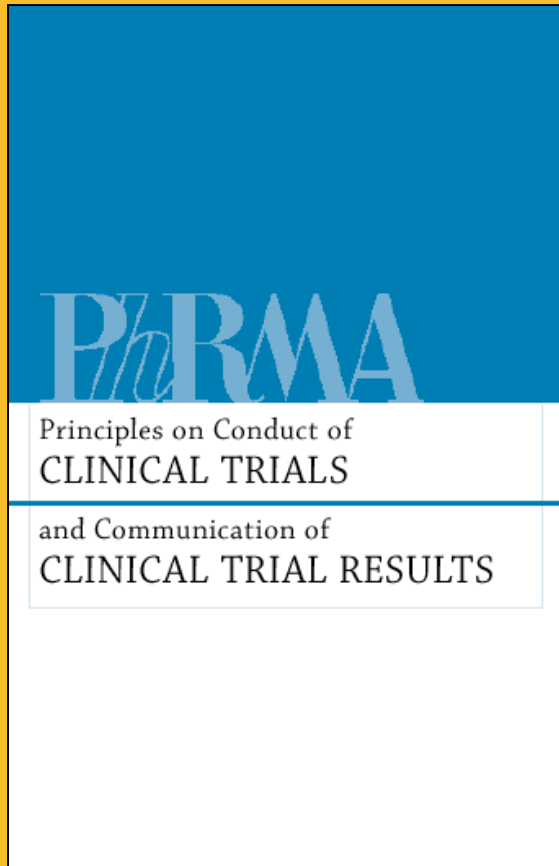
- 1997 FDA Modernization Act (FDAMA)
- 2000 NIH/NLM Clinical Trials Databank
- 2002 PhRMA publishes *Principles on the Conduct of Clinical Trials and Communication of Clinical Trial Results*
- 2002 PhRMA member companies commit to disclosing the results, positive or negative, of 'hypothesis testing' clinical trials
- 2004 PhRMA launch [ClinicalStudyResults.org](http://ClinicalStudyResults.org), a centralized repository for trial results in a standard format and presentation

“The innovative pharmaceutical industry is committed to increasing the transparency of the clinical trials our member companies sponsor.”

- *International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)*
- *European Federation of Pharmaceutical Industries and Associations (EFPIA)*
- *Japanese Pharmaceutical Manufacturers Association (JPMA)*
- *Pharmaceutical Research and Manufacturers of America (PhRMA)*

# Registration of Trials

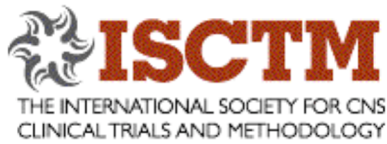
# Commitment to Voluntary Registration



- All company-sponsored hypothesis-testing (non-exploratory) clinical trials conducted on drugs and biologics *marketed in the US or intended for marketing in the US*
- New and ongoing hypothesis-testing studies, regardless of the disease or condition
- Will utilize [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- Will follow informational and timing provisions as outlined in Section 113 of FDAMA
- Trials given a unique identifier
- Compliance

# Clinical Trials Registry

- Requires companies to register *applicable* clinical trials within 21 days of enrollment initiation, for the purpose of *enhancing patient access to information* about clinical trials in which they might wish to participate.
- PhRMA member companies already have *a legal responsibility* to register trials that test treatments for serious or life-threatening diseases and conditions on *[www.clinicaltrials.gov](http://www.clinicaltrials.gov)*.



# NIH/NLM Registry

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

**ClinicalTrials.gov**

A service of the National Institutes of Health  
Developed by the National Library of Medicine



*Linking patients to medical research*

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ClinicalTrials.gov provides regularly updated information about federally and privately supported clinical research in human volunteers. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. Before searching, you may want to [learn more](#) about clinical trials.

## Search Clinical Trials

Example: heart attack, Los Angeles

Search

[Tips](#)

## Search by Specific Information

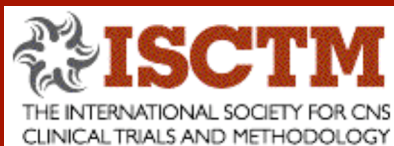
[Focused Search](#) - search by disease, location, treatment, sponsor...

## Browse

[Browse by Condition](#) - studies listed by disease or condition

[Browse by Sponsor](#) - studies listed by funding organization

[Browse by Status](#) - studies listed by recruitment status



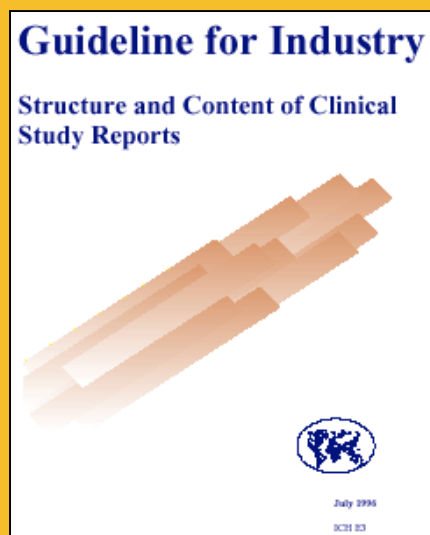
# Clinical Trial Registry Requirements

- Accessible at no charge and open to all prospective registrants; managed by a not-for-profit organization
- A mechanism to ensure the validity of the registration data, and electronically searchable
- Must include the following information:
  - a unique identifying number
  - a statement of the intervention (or interventions) and comparison (or comparisons) studied
  - a statement of the study hypothesis
  - definitions of the primary and secondary outcome measures
  - eligibility criteria
  - key trial dates
  - target number of subjects
  - funding source
  - contact information for the principal investigator.

# Clinical Trial Results

# Commitment to Disclosure of Results

- If trial results are published in a peer-reviewed medical journal, the database should include
  - a citation to or link to the journal article and/or
  - a summary of the results in a standard, non-promotional format, such as the ICH E-3 summary format,
  - a description of the trial design and methodology
  - results of the primary and secondary outcome measures
  - safety results
- Unpublished trials results posted in ICH E-3 summary format
- Results should include unique identifier used to register the trial at inception



# Study Results Databases

**ClinicalStudyResults.org**

About Us | How Can My Company Participate? | Useful Links

**About ClinicalStudyResults.org**

The ClinicalStudyResults.org site is a central, widely accessible, web-based repository for clinical study results in a reader-friendly, standardized format. This database will serve the valuable function of making clinical trial results for U.S.-marketed pharmaceuticals more transparent. More importantly, it is designed as a key tool to provide information to practicing physicians and their patients.

**Clinical Study Results Primer**

- PhRMA Clinical Study Results Database
- Clinical Study FAQs
- Clinical Studies by Numbers
- Clinical Studies: Testing New Medicine
- Differences between Clinical Study Results Database and the Clinical Study Registry
- FDA's Role in Assuring Safe and Effective Drugs
- Glossary of Terms

**GlaxoSmithKline clinical trial register**

Home | Trial Register | Information for Healthcare Professionals | Contact GSK | GSK Home

## Welcome to the GlaxoSmithKline Clinical Trial Register

The GlaxoSmithKline (GSK) [Clinical Trial Register](#) provides an easily accessible repository of data from GSK-sponsored clinical trials, supplementing communications in journals, at scientific meetings, in letters to healthcare professionals and in approved prescribing information. Access to the Register is unrestricted, following acceptance of terms and conditions.

It is important to emphasize that approved prescribing information must continue to guide appropriate use of GSK medicines. This information may vary from country to country. **Before prescribing any product mentioned in this Register, Healthcare Professionals should consult prescribing information approved in their country ([view UK and US information for Healthcare Professionals](#)).** For prescribing information on individual products in countries outside the UK and US, please refer to the local GSK organisation in those countries ([view GSK Contact information](#)).

If further information is required on medicines in this Register, it should be noted that regulations sometimes restrict information which GSK can disclose directly to the public. The intention of this Register is to provide scientific information obtained from studies of GSK medicines. For healthcare advice, members of the public should consult Healthcare Professionals.

The Register provides scientific, non-promotional summaries of clinical trials in a consistent format, irrespective of whether the results may be viewed as positive or negative for GSK medicines.

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Trial Results | Initiated Trials | Recruiting Trials | Terminology | Education

**Eli Lilly and Company Clinical Trial Registry**

This site contains information about clinical trials sponsored by Eli Lilly and Company. This information is not intended to replace the advice of a health care professional. **Only a physician can determine if a specific medicine is the correct treatment for a particular patient. If you have questions regarding any information contained in this site, please consult a physician.**

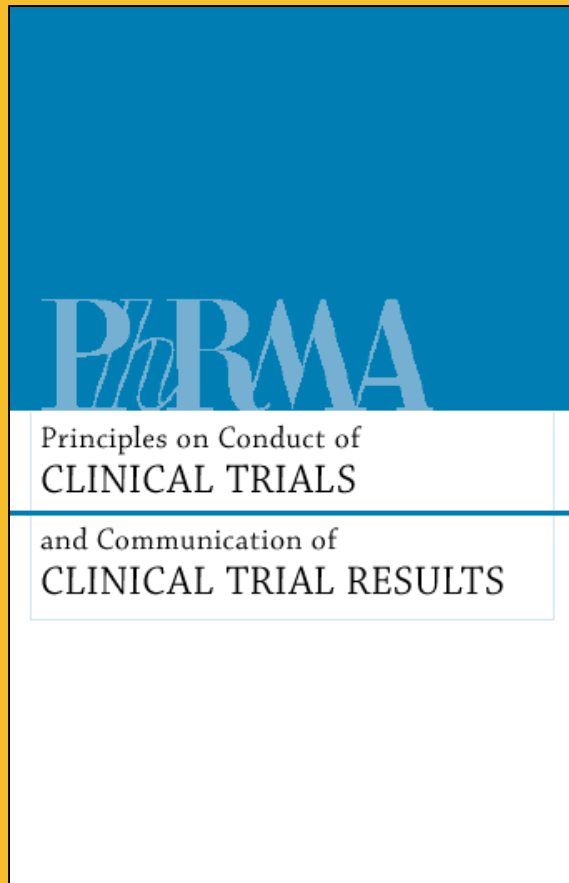
As part of the development process for medicines, Eli Lilly and Company conducts a series of clinical trials to help determine safety and efficacy of various test medications. This information may, or may not, relate to uses that have been studied and approved by various regulatory agencies around the world. The information contained in this site is not intended to promote or otherwise commercialize (directly or indirectly) any off-label or unapproved uses of Lilly medicines.

Eli Lilly and Company is committed to meeting patient needs through innovative medicine and clinical excellence. **When making prescribing decisions, physicians should always refer to the specific labeling information approved for the patient's country or region.**

Select any of the following links to get information related to clinical trials sponsored by Eli Lilly and Company:

- Trial Results by Therapeutic Area:** Provides summaries of completed clinical studies and/or references to publications or scientific presentations for marketed products by therapeutic area.
- Trial Results by Product:** Provides summaries of completed clinical studies and/or references to publications or scientific presentations for marketed products by product.
- Initiated Trials:** Provides a list of on-going clinical studies identified by their unique numerical code.

# Commitment to Disclosure of Results



- Regardless of trial outcome the results of all non-exploratory clinical trials on a marketed drug should be disclosed
- Results from exploratory trials should be disclosed if medically important and impact on a marketed drug
- Trial results for failed investigational products disclosed if medically important
- Disclosure must obey applicable local laws

# Conclusion

- Transparency is coming, BUT
- Mass confusion may occur, SO
- Physicians will need to educate patients, the public AND colleagues on
  - the nature of medical-scientific uncertainty and
  - its resolution through successive clinical studies and experience