

# Welcome to the 6<sup>th</sup> Annual Meeting of ISMPP

## Delivering Value and Driving Advocacy in Medical Publications

*April 19-21, 2010*

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# Transparency: *Promoting meaningful disclosure*

David Verbraska

Pfizer

IFPMA: Member of Regulatory  
Policy Committee



# Topics

“Meaningful Transparency” - What we do and why it is important

1. What, When: Information Disclosure
2. How: User Friendly
3. More Transparency to Come....

# Disclaimer

The following presentation and opinions expressed by the presenter do not necessarily reflect the views of Pfizer Inc. or IFPMA

# Evolving Expectations on “Transparency”

## *Ready, fire, aim?*

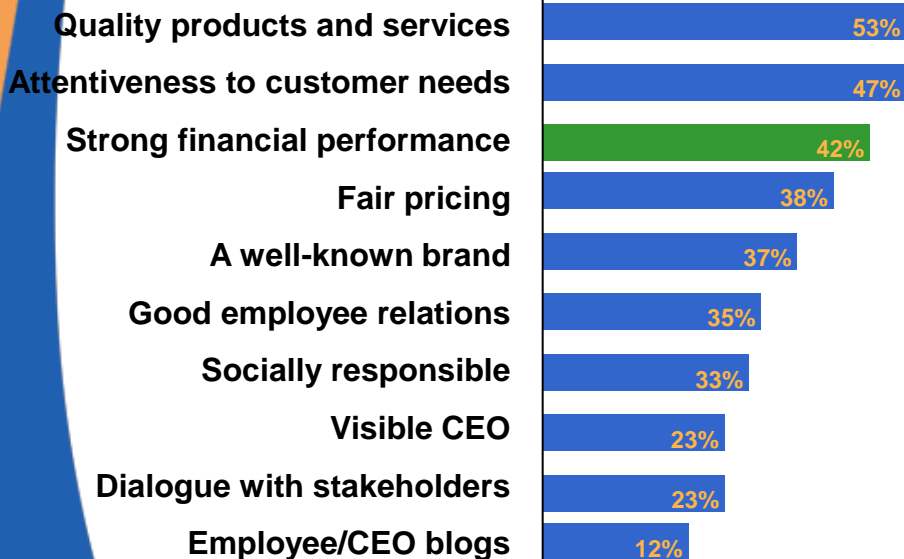


# Corporate Reputation

## *“Transparency & honesty” matter most*

What shapes your trust in a company?

U.S. 2006



How important are these factors to corporate reputation?

U.S. 2010



# Goal of Transparency

## *Key Focus on Impact*

To provide meaningful information and insight that enables patients to have informed conversations with their physicians about health care treatment options.

- Benefits:
  - Empowered decision-making
  - Confidence in the system and medicines
- Meaningful disclosure is an ethical obligation.

# “Meaningful” Transparency

1. Useful information to decision-making
  2. User Friendly
- Information, yes.
  - But information needs context
    - Not communicating just to communicate
  - Meaningful Information requires:
    - Public and available
    - Aggregated, organized, searchable
    - Consistency of data
    - Audience understanding
  - **Is more always better?**



# Know your Audience

**Who are you publishing to  
and how will they use your information**

## Audiences

- Patients
- Healthcare providers
- Academic researchers
- Journal editors
- Third party payers
- Lawyers
- Industry competitors

## Uses

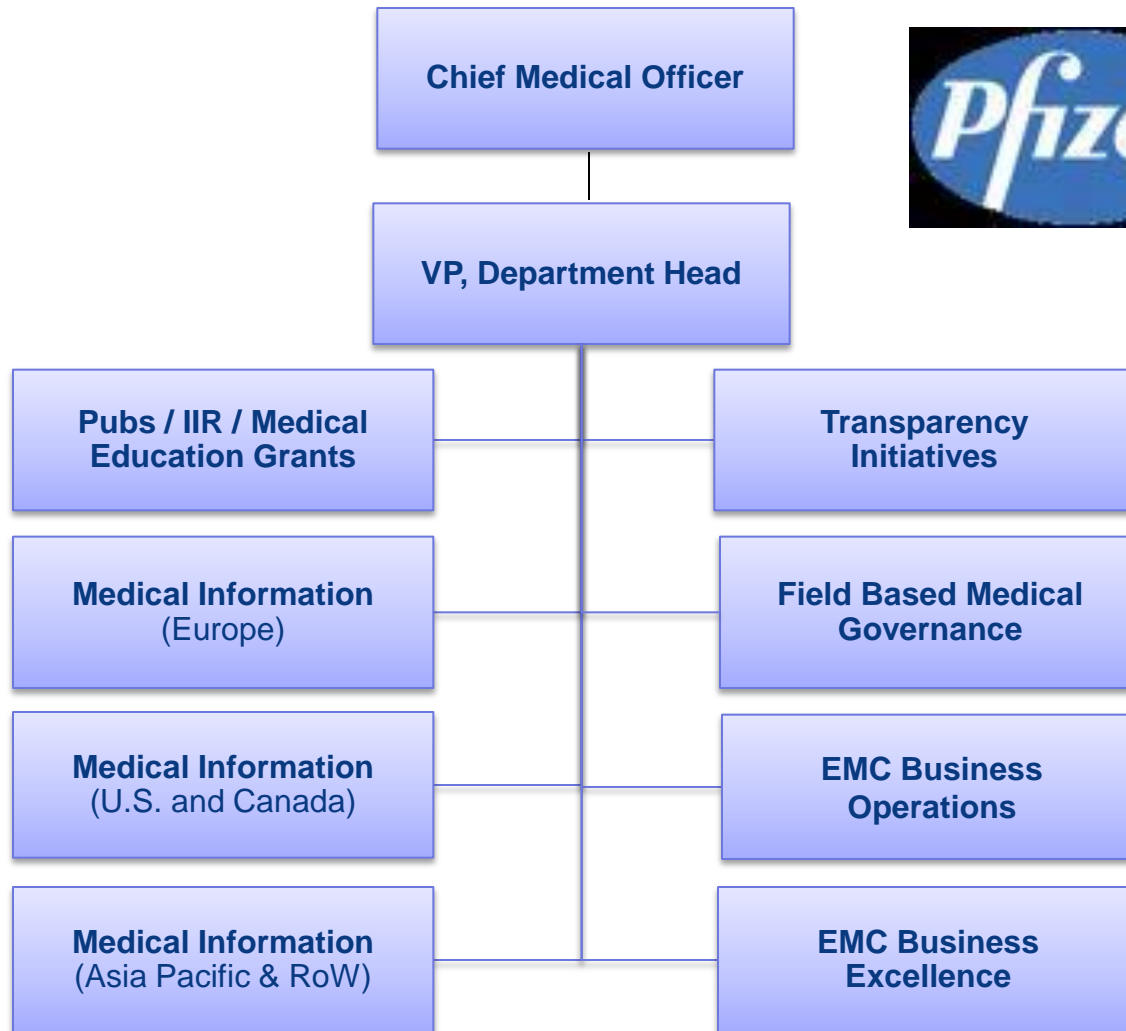
- Guide/inform treatment decisions at physician and patient levels
- By editors when reviewing manuscripts
- By industry to inform clinical programs
- Re-analyze individual study data
- To conduct meta-analyses and reviews

# Words of caution?

- *“It’s about knowledge but what we have is bureaucracy.”*
  - Senior European Regulator
- *“Transparency is a means to an end, not an end to itself.”*
  - Executive at global health care company

# External Medical Communications Team

*“Timely, accurate, fair balanced”*



# Meaningful Disclosure

## *Providing Information*

Industry has done a lot;  
but there is more to do

# Where Are We Now

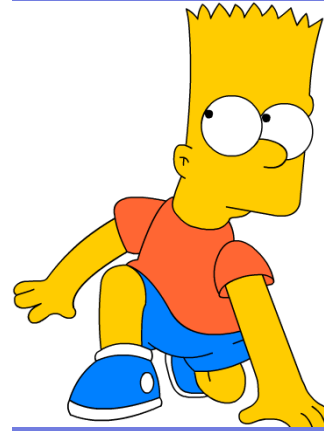
## *Misaligned Expectations?*

**“You cannot escape the responsibility tomorrow by avoiding it today”**



Abraham  
Lincoln

**“I didn’t do it. No one saw me do it. No one can prove anything”**



Bart  
Simpson



# My Brother-in-Law – the doctor

- Medical institution heavily involved with pharmaceutical industry
- Reasonably skeptical
- Should be among the most informed and confident



# Clinical Trials – What to Disclose

## *Industry Joint Position (revised Nov 2009)*



- **Minimum: All clinical trials in patients**
- Maintain protections for privacy, intellectual property and contract rights

### Registry

- No later than 21 days after initiation of patient enrollment
- Unique identifier – transparency and avoid multiple postings
- Include Minimum Trial Registration Data Set (WHO May 2006)

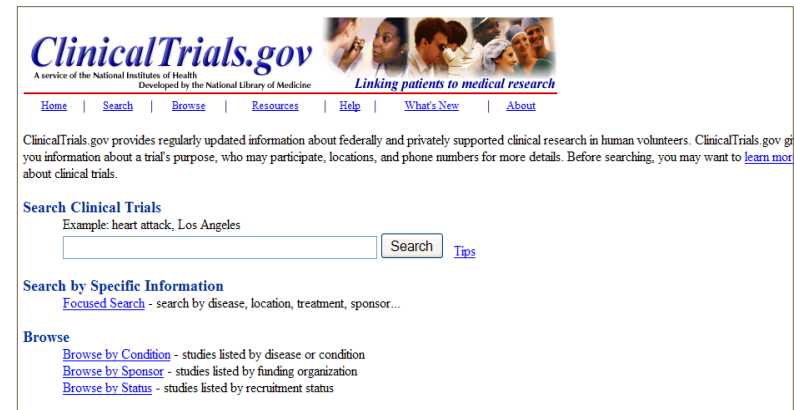
### Results

- Plus failed development studies if significant medical importance
- No less than one year after approval
- Cite the article if published; if not published use ICH E-3 summary format

# Protocol registration

- ❑ Early work by ICMJE, WHO and others
- ❑ Enables studies to be tracked to publication
- ❑ Enables review of submitted manuscripts against the protocol summary
- ❑ Helps reduce duplication
- ❑ Provides opportunities for participation

Is this clinical trial fully registered? A statement from the International Committee of Medical Journal Editors



The screenshot shows the ClinicalTrials.gov website. At the top, the logo reads "ClinicalTrials.gov" with the tagline "Linking patients to medical research". Below the logo is a navigation menu with links for Home, Search, Browse, Resources, Help, What's New, and About. A search bar is present with the example text "Example: heart attack, Los Angeles" and a "Search" button. Below the search bar, there are sections for "Search by Specific Information" (with a link to "Focused Search") and "Browse" (with links for "Browse by Condition", "Browse by Sponsor", and "Browse by Status").

Credit:  
Andrew Freeman  
GSK



# Results registration

- ❑ Pioneered by industry
- ❑ Results in the public domain irrespective of outcome and whether or not studies are accepted for publication

## GSK Clinical Study Register Launched October 2004



The screenshot shows the GSK Clinical Study Register website. At the top left is the GSK logo (GlaxoSmithKline). To the right is a search bar with the text "Search this site:" and a "Search" button. Below the logo is a navigation menu with links for "Home", "Protocol Summaries", "Result Summaries", "GSK Prescription Medicines", and "Contact GSK". The main content area features a "Clinical Study Register" heading and a paragraph explaining that the register provides an easily accessible repository of data from GSK-sponsored clinical studies. It also includes a circular image of a doctor and a patient. On the left side of the main content area, there are links for "Protocol Summaries", "Result Summaries", "GSK Prescription Medicines", "Contact GSK", "Glossary of Terms", and "Terms and Conditions". At the bottom left of the main content area, there is a "Useful Links" section.

The screenshot shows the Lilly Clinical Trials website. At the top left is the Lilly logo. To the right is a navigation menu with links for "Home", "Search", and "Contact". Below the logo is a navigation menu with links for "Trial Results", "Initiated Trials", "Recruiting Trials", "Terminology", and "Education". The main content area features a "Trial Results by Product" heading and a paragraph explaining that the clinical trial results section includes result summaries of completed Phase 1 through Phase 4 Lilly-sponsored clinical studies conducted on Lilly marketed products since July 1, 2004. It also includes a circular image of a doctor and a patient. At the bottom left of the main content area, there is an Adobe Reader logo and a link to download the PDF format.

## Lilly Clinical Trials Launched December 2004



Credit:  
Andrew Freeman  
GSK



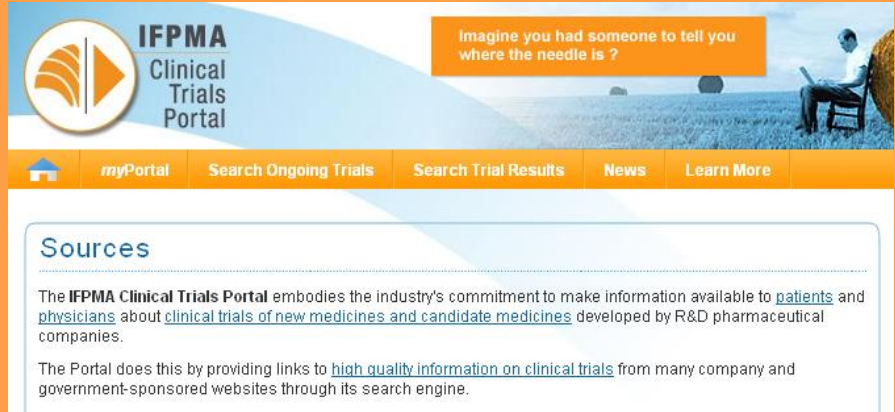
# Clinical Trials – Where to Disclose “Central sources and Portals”

US central sources:

  
ClinicalStudyResults.org

**ClinicalTrials.gov**  
A service of the U.S. National Institutes of Health

International Portals:



The screenshot shows the IFPMA Clinical Trials Portal website. The header features the IFPMA logo and the text "IFPMA Clinical Trials Portal". A navigation bar includes links for "myPortal", "Search Ongoing Trials", "Search Trial Results", "News", and "Learn More". The main content area is titled "Sources" and contains two paragraphs of text. The first paragraph states: "The IFPMA Clinical Trials Portal embodies the industry's commitment to make information available to [patients](#) and [physicians](#) about [clinical trials of new medicines and candidate medicines](#) developed by R&D pharmaceutical companies." The second paragraph states: "The Portal does this by providing links to [high quality information on clinical trials](#) from many company and government-sponsored websites through its search engine."

 World Health Organization

INTERNATIONAL CLINICAL TRIALS REGISTRY PLATFORM  
SEARCH PORTAL

# Clinical Trials – Where to Disclose

## *National Registries (Mar.10)*

**Mandatory** transparency requirements are in place (or soon will be) for the following countries. Most have (or will have) their own registry:

- ✓ Argentina
- ✓ Brazil
- ✓ Croatia
- ✓ Czech Republic
- ✓ Europe
- ✓ France\*
- ✓ India
- ✓ Iran
- ✓ Israel
- ✓ Italy
- ✓ Malaysia
- ✓ Netherlands
- ✓ Norway
- ✓ Peru
- ✓ South Africa
- ✓ Spain
- ✓ Chinese Taipei
- ✓ United States
- ✓ Turkey

\* Includes mandatory results posting

**Voluntary** registration is in place or pending in additional countries

- ✓ Africa
  - Pan African Registry
- ✓ Australia
- ✓ Canada
- ✓ Chile
- ✓ China
- ✓ Cuba
- ✓ Germany
- ✓ Hong Kong
- ✓ Japan
- ✓ Latin America
- ✓ New Zealand
- ✓ Sri Lanka
- ✓ Chinese Taipei PMS
- ✓ UK

Credit:  
Jacqueline Sayers,  
Roche

# Pfizer Publication Policy

- Supports ICMJE guidelines on authorship
- Requires
  - Recognition of medical writers in the publication
    - author (if meet criteria)
    - acknowledgement
  - Medical writers work under the direction of the authors
  - Disclosure of funding source(s)
    - study, writing support, other support
  - Disclosure of potential conflicts of interest

Pfizer marketing colleagues are not involved in preparation, planning or content development of publications

# Pfizer Medical Education Grants

## **Pfizer Changes Its Funding of Continuing Medical Education in the U.S.**

*Support to Focus on Academic Medical Centers, Hospitals,  
Associations and Medical Societies*

*Eliminated Direct Support for Commercial CME Providers*

- In 2008, eliminated direct funding support for CME programs by for profit (commercial) providers, including medical education and communication companies (MECCs)
- In 2009 implemented a quarterly competitive grant review process to encourage more innovative, high-quality grant applications and align with resource availability throughout the year by way of a periodic rather than continuous review
- Require all major grant applicants to meet criteria equivalent to ACCME's highest level of accreditation
- In addition, Pfizer will continue to publicly report all CME grants provided in the U.S. at [www.pfizer.com](http://www.pfizer.com) along with grants and charitable contributions made by Pfizer to US patient, scientific and medical organizations and healthcare related support to civic organizations



# Pfizer Physician Disclosure

## Disclose payments to:

- All practicing healthcare professionals who can prescribe medicines (includes physicians, NPs, PAs)
- Major institutions for ongoing clinical trials (before July 1, 2009)
- All principal investigators and other entities for Phase I-IV clinical trials sponsored by Pfizer beginning after July 1, 2009

## Disclose payments for:

- Clinical development and commercial consulting
- Promotional speaking
- Phase I-IV clinical trials
- Investigator-initiated research
- Educational items
- Meals and business-related travel

# Pfizer Physician Disclosure

## 2009 Data (Starting July 1<sup>st</sup>) Posted March 2010

- Annual report if the recipient receives **≥\$500** in aggregate
- Include **meals or business-related travel expenses ≥\$25**

## 2010 Data (full year) Posted March 2011

- **No threshold** of \$500 or de minimus of \$25

## 2011 Data will be posted quarterly starting June

## The New York Times

April 1, 2010

**Senator Charles Grassley:** *“It’s a real milestone for the transparency campaign to have one of the biggest drug makers in the world respond with an initiative like this.”*

## The New York Times

April 12, 2010

### Data on Fees to Doctors Is Called Hard to Parse

By DUFF WILSON

Pfizer recently became the latest big drug maker to start disclosing payments to doctors who act as consultants or speakers. But many followers of the pharmaceutical industry are still finding it far too difficult to follow the money.



# Meaningful Disclosure

## *User Friendly*

Need to ensure that information is accessible and understandable to the specifics of audiences

# My Mother – the patient

- Relatively well informed but seeks more information on medication, treatments
- Lots of sources – more is not necessarily better for her
- Should be better empowered with aggregated sources and perspective



# Pfizer Pipeline Transparency

The screenshot shows a Microsoft Internet Explorer browser window displaying the Pfizer Pipeline website. The address bar shows the URL: <http://www.pfizer.com/research/pipeline/pipeline.jsp>. The page features the Pfizer logo and a banner for "Research & Development". A navigation menu includes links for HOME, ABOUT PFIZER, PRODUCTS, RESEARCH & DEVELOPMENT (highlighted), and RESPONSIBILITY. Below the menu, the breadcrumb trail reads: Home > Research & Development > Pipeline. The main content area is titled "Pfizer Pipeline – Our Medicines in Development" and contains the following text: "Our pipeline of new medicines in development is the largest in the pharmaceutical industry, focusing on a broad range of unmet medical needs spanning 10 Therapeutic Areas. Pfizer invests more than \$7 billion annually in the research and development of new products across more therapeutic areas than any other company in our industry. Relying on the strength of our pipeline and scientific talent, Pfizer has generated a steady stream of breakthroughs over the years. Our research continues to work around the clock and around the globe to ensure the..."

This graphic provides a detailed view of the Pfizer Pipeline information. At the top, it features the Pfizer logo and the text "Pfizer Pipeline as of February 28, 2008". Below this, there is a vertical stack of images showing laboratory equipment, including test tubes and a pipette. To the right of these images, there is a "Looking for" section with two "Select" buttons. At the bottom, there is a "Pfizer" logo and some small, illegible text.

# Product Labels / Med Guides

All Products | Wyeth.com - Microsoft Internet Explorer provided by Pfizer Inc

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Print Mail Word Excel PowerPoint

Address http://www.wyeth.com/products Go Links

Wyeth.com Health Care Professionals Worldwide Search Wyeth.com All Wyeth Sites

**Wyeth** Our Products Patient Health Research & Clinical Trials About Wyeth Careers News Investor Relations

Printer-friendly Page E-mail This Page

**All Products**  
 OTC Products  
 Prescription Drugs  
 Animal Health Products

**Health Care Professionals Log In**  
 E-mail Address:   
 Password:   
 Submit

[Forgot your password](#)  
[Register](#)

**Wyeth Family of Products**  
 Wyeth is a world leader in the research and development of innovative, high-quality health care products. Our product portfolio spans the range of top-selling pharmaceutical and biotechnology products, consumer health care products, and animal health care products.  
 224482-01

**View Products by Therapy Areas**  Search

**View Products Alphabetically**  
 All | A-C | D-F | G-K | L-N | O-Q | R-T | U-Z

Results 1-20 of 76 < Previous | 1 | 2 | 3 | 4 | Next >

Product	Therapy Areas	Links
<b>Advil® Brands</b>	Aches and Pains	<a href="http://www.advil.com">www.advil.com</a>
<b>Alavert®</b>	Allergies	<a href="http://www.alavert.com">www.alavert.com</a>
<b>Anbesol®</b>	Oral Health	<a href="http://www.anbesol.com">www.anbesol.com</a>
<b>Antivenin (Micrurus Fulvius) (Equine Origin) North American Coral Snake</b>	Infectious Disease	<a href="#">Prescribing Information</a>
<b><u>BeneFIX® Coagulation Factor IX (Recombinant)</u></b>	Hematology	<a href="#">Product Overview</a>

Start | Internet | 98% | 1:40 PM



# Pfizer US Post Marketing Commitments 2007

- **More timely US PMC information**
  - Pfizer site updates weekly
- **More complete US PMC information**
  - Additional PMCs unreported by FDA
  - Information on revised and renegotiated PMCs
- **Easier to use**
  - User-friendly design for lay public
  - Clarifies redundant, multiple records
- **Greater context for public**
  - Provides educational material such as study types, status definitions, study development process, glossary, FAQs

The top screenshot shows the Pfizer website's 'Post Marketing Commitments' page. It includes a search bar, navigation links, and a section titled 'In This Section' with links to 'What are Post Marketing Commitments?', 'Product-Specific Post Marketing Commitments', 'Active Post Marketing Commitments Summaries', 'FAQs', and 'Glossary'.

The bottom screenshot shows a detailed table of Product-Specific PMCs for Ziprasidone HCl. The table has the following columns: Generic Name, Brand Name, Application Number, Commitment Type, Status, US Approval Date, Due Date, and PMC Description.

Generic Name	Brand Name	Application Number	Commitment Type	Status	US Approval Date	Due Date	PMC Description
Ziprasidone HCl	Geodon	20-825	Pre-Clinical	Ongoing	02/05/2001	04/25/2001	response study for dTC effect. (PID-000005)
Ziprasidone HCl	Geodon	20-825	Clinical Trial	Submitted	02/05/2001	04/25/2001	unexpected death study of ziprasidone and other atypical antipsychotics. (PID-000005)
Ziprasidone HCl	Geodon	20-825	Clinical Trial	Ongoing	02/05/2001	06/30/2006	bipolar study (PID-000005)
Ziprasidone HCl	Geodon	20-825	Clinical Trial	Ongoing	02/05/2001	03/31/2006	03/30/2007 10:21 AM (GMT-4:00) added (PID-000005): submit the results of a clinical study or studies examining the short-term efficacy and safety of ziprasidone as add-on therapy in bipolar patients currently taking mood stabilizers (e.g., lithium, valproate) and long-term efficacy and safety of ziprasidone in bipolar disorder (PID-000005)
Ziprasidone HCl	Geodon	20-919	Clinical Trial	Submitted	06/12/2002	10/31/2004	03/30/2007 10:37 AM (GMT-4:00) added (PID-000005): Conduct an assessment of the reproductive toxicity of IM ziprasidone



European PMCs  
Feb 2010

# Policy Disclosure

## Advocating For and Disclosing Policies to Public

The screenshot shows a Microsoft Internet Explorer browser window with the address bar displaying <http://www.merck.com/corporate-responsibility/business-ethics-transparency/ethics-financial-support-third-parties/approach.html>. The page content includes the Merck logo and navigation menu at the top, followed by a sidebar on the left with categories like 'Corporate Responsibility' and 'Our Corporate Responsibility Approach'. The main content area features the title 'Disclosure of Company Grants to Organizations' and a sub-header 'Listening, responding and working toward a healthier future'. Below this, there are tabs for 'Overview', 'Approach', and 'Priorities and Goals'. The 'Approach' tab is active, showing three guiding principles: 1) Independence, 2) Transparency, and a 'Listings of Grants' section. The 'Listings of Grants' section states that starting October 2008, Merck reports grants over \$500 provided by the Company's Global Human Health division to U.S. organizations. A right-hand sidebar contains a 'MERCK LINKS' section with various links such as 'Implementing ethical business practices' and 'Corporate governance'. The browser's taskbar at the bottom shows several open applications including 'Inbox - Micros...', 'Microsoft Word', and 'Microsoft Pow...', along with system icons and the time 1:24 PM.

Disclosure of Company Grants to Organizations - Microsoft Internet Explorer provided by Pfizer Inc

File Edit View Favorites Tools Help

Address <http://www.merck.com/corporate-responsibility/business-ethics-transparency/ethics-financial-support-third-parties/approach.html>

Where patients come first **MERCK**

Patients & Caregivers | Healthcare Professionals | Worldwide

Quick Find Search

HOME | ABOUT MERCK | PRODUCTS | NEWSROOM | INVESTOR RELATIONS | CAREERS | RESEARCH | LICENSING | THE MERCK MANUALS

Corporate Responsibility

Our Corporate Responsibility Approach

Summary Data, Awards and Resources

Researching New Medicines and Vaccines to Address Unmet Needs

Improving Access to Medicines, Vaccines and Health Care

Ensuring Confidence in the Safety and Quality of Our Products

Conducting Ourselves Ethically and Transparently

Ethical Sales and Marketing Practices

Disclosure of Company Grants to Organizations

Fostering a Fair, Transparent and Open Environment

Managing Our Environmental Footprint

Advocacy and Outreach

Our Impact on Local Communities

Executing the Basics

Philanthropy at Merck

Disclosure of Company Grants to Organizations  
*Listening, responding and working toward a healthier future*

Overview Approach Priorities and Goals

The following three principles guide our approach to providing financial support to medical, scientific and patient organizations:

**1) Independence**

Merck respects the independence of medical, scientific and patient organizations and refrains from using our financial support to influence the policies of organizations or to promote specific medicines. To support independence, Merck will support only organizations that obtain funding from a variety of sources.

**2) Transparency**

Merck supports transparency of our interactions with medical, scientific and patient organizations including financial support that we provide them. We believe this is an important step in building public trust with both Merck and those with whom we provide support. Making public our support also enhances the visibility of Merck's commitment to help advance health and science.

**Listings of Grants**

Starting October 2008, Merck is reporting grants over \$500 provided by the Company's Global Human Health division to U.S. organizations in support of independent accredited educational programs for health care professionals. [Click here](#) for listings of grants ( PDF\* 169KB). Over the course of 2009 Merck will expand this disclosure to include other grants. Merck will update these lists on a quarterly basis.

**MERCK LINKS**

- » [Implementing ethical business practices](#)
- » [Corporate governance](#)
- » [Merck's Code of Conduct](#)
- » [Ethical sales & marketing practices](#)

INTERNET

Start | Inboxes - Micros... | FW: Upcomin... | Microsoft Word | Microsoft Pow... | Eli Lilly and Co... | Disclosure o... | 98% | 1:24 PM



# Pfizer Safety Portal

The screenshot shows the Pfizer Safety Portal website. The browser address bar displays [http://pfizer.com/responsibility/medicine\\_safety/](http://pfizer.com/responsibility/medicine_safety/). The page features a navigation menu with links for HOME, ABOUT PFIZER, PRODUCTS, RESEARCH & DEVELOPMENT, RESPONSIBILITY (highlighted), INVESTORS, and NEWS & MEDIA. Below the navigation is a breadcrumb trail: Home > Responsibility > Medicine Safety. A search bar and text size controls are also present.

The main content area is titled "Minimizing patient risk: Your role in medication safety". It includes a video player with a woman in a professional setting and a "Patient Resource Kit" section with links to "Medicine safety for kids", "Safety checklist", "Partner with your pharmacist", and "My health & medications".

The sidebar on the left contains a "Values and Commitments" menu with links to Global Health, Community Programs, U.S. Patient Assistance Programs, Medicine Safety (highlighted), Environment Health and Safety, Diversity, and Education.

At the bottom of the page, there is a copyright notice: "Copyright © 2002-2008 Pfizer Inc. All rights reserved. This information is intended only for residents of the United States." and a "TRUSTe" site privacy statement logo.

Designed to provide broader public insight and information on medicine risk, benefit-risk balance

- Drug safety in R&D process
- Taking Medicines Responsibly
  - At your doctor's visit
  - After your prescription is filled
- Risk Perception
- Resources

# Trial Participant Education



## “Speaking Books”

Lower literacy audiences

Content includes:

- CT Objectives
- Patient Rights and Role

Partners include:

- WMA
- Steve Biko Centre
- South Africa



# User Friendly Case Study

## IFPMA's Trial Portal

# IFPMA in brief

- **IFPMA** – International Federation of Pharmaceutical Manufacturers & Associations
- **Non-profit**, non-governmental organization founded in 1968, representing **over 45 national and regional industry associations** and **25 R&D companies**

*Advocates policies that encourage discovery of and access to life saving and life enhancing new medicines to improve the health of patients everywhere*

# R&D Industry Commitment to Transparency

## Commitment #1

Industry will make information about all ongoing trials in patients publicly available

## Commitment #2

Industry will also post summary results of all completed trials in patient after drug approval

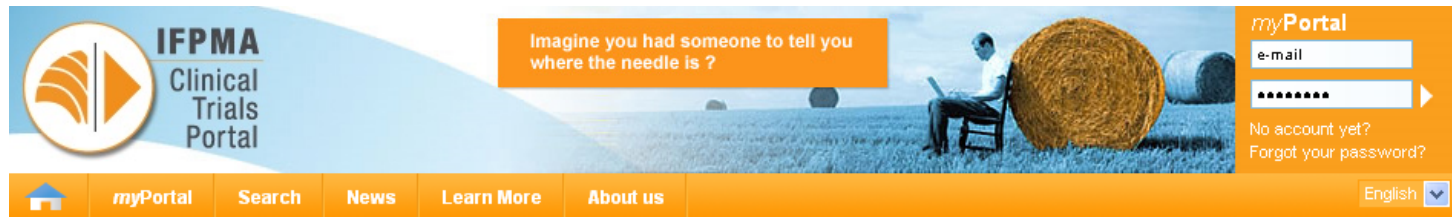


## A WORLD'S FIRST

September 2005

**Creation of the FIRST global clinical trials portal**  
To facilitate access to worldwide online CT information sponsored by R&D based pharmaceutical companies.

# Access Clinical Trials Information



**IFPMA**  
Clinical Trials Portal

Imagine you had someone to tell you where the needle is ?

myPortal  
e-mail  
No account yet?  
Forgot your password?

English

myPortal Search News Learn More About us

hundreds of diseases  
thousands of trials  
billions of people



Make sense of it!

Number of Clinical Trials made available by the IFPMA Portal - Data per region

IFPMA Clinical Trials Portal is brought to you by IFPMA on behalf of its Member Companies and Associations.

IFPMA Clinical Trials Portal ensures

- ▶ A **free** and **easy-to-use** interface for patients and health professionals alike to [ongoing clinical trials](#), [clinical trial results](#) and [complementary information](#) on related issues.
- ▶ **Non-promotional** and **reliable information**.
- ▶ Industry's commitment to the **transparency** of clinical trials.



[Mission Statement >>](#)

## Clinical Trial Quick Search



cancer

Search

### Advanced Search:

- ▶ [Clinical Trials](#)
- ▶ [Pediatric Clinical Trials](#)
- ▶ [Clinical Trial Results](#)
- ▶ [Pediatric Clinical Trial Results](#)

## myPortal



You are a patient?

Gain a **better understanding** of clinical trials through **personalized information**.



You are a physician?

**Advise** and **guide** your patients with **updated data** on clinical trials.



No need to visit 10 different websites to find non-promotional and reliable information on clinical trials.

# Sources

The Portal provides links to clinical trials conducted by R&D industry posted on company/industry association websites and government websites listed below.

## Government websites



## Company & Industry association websites



Bristol-Myers Squibb



Menarini








[ClinicalStudyResults.org](http://ClinicalStudyResults.org)

# IFPMA Portal in numbers

- The IFPMA Portal features **trials from 160+ countries** (Nov 09)

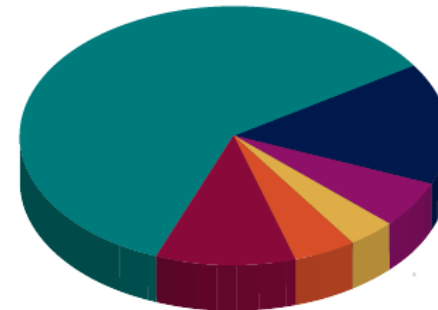
Number of Clinical Trials made available by the IFPMA Portal - Data per region









	Region of the Americas	64205
	European Region	56260
	South-East Asia and Western Pacific Region	10350
	African Region	1986
	Eastern Mediterranean Region	694

Number of results of completed clinical trials made available by the IFPMA Portal - Data per condition

Total: 8'750



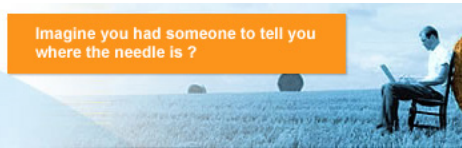
	Cancer	11%
	Cardiovascular diseases	5%
	HIV/AIDS	3%
	Diabetes	6%
	Neurological disorders and mental health	15%
	Other	60%

# Find information on ongoing / completed clinical trials



**IFPMA**  
Clinical  
Trials  
Portal

Imagine you had someone to tell you where the needle is ?



- Search by Medical Condition or Drug Name
- Search a particular country or city
- Search integrates synonyms, connected terms and translations

myPortal Search Ongoing Trials Search Trial Results News Learn More

## Search Ongoing Clinical Trials

Terms to search for:  
leukemia

Terms to exclude:

Trials conducted in:  
united states

use synonyms

**General Search Tips**  
If your search cannot find what you are looking you might want to consider these tips:

**Criteria languages:**  
You can phrase your search criteria in any of the site languages. A dictionary of common terms will include translation synonyms.

**Results language:**  
All results will, however, be shown in original language.

Search Clear

Synonyms, connected terms and translations included in the search *leucémie leukaemia leucemia leukemia 白血病*

Print  
Total results returned: 2752

### Title: Assessment and Determination of Chemotherapy Resistance in Newly-Diagnosed or First Relapse Leukemia Patients

**Infobox**  
**Status:** Recruiting  
**Sponsor:** University of C...  
**Location(s):** United States, Orange (California)

**Description:** The objective of this protocol is to collect leukemia specimens from adults (18 years of age) diagnosed with acute leukemia at time of initial diagnosis and, if applicable, at time of first relapse. Specimens, in conjunction with a de-identified data set, will be prospectively determined to determine potential chemotherapy resistance in this population. The specific aims of this study are as follows: To collect peripheral blood specimens from patients diagnosed with acute leukemia...

**ClinicalTrials.gov**  
A service of the U.S. National Institutes of Health

Home Search Study Topics Glossary

Full Text View **Tabular View** No Study Results Posted Related Studies

**Assessment and Determination of Chemotherapy Resistance in Newly-Diagnosed or First Relapse Leukemia Patients**

This study is currently recruiting participants.  
Verified by University of California, Irvine, January 2010

First Received: February 27, 2008 Last Updated: January 7, 2010 [History of Changes](#)

<b>Sponsor:</b>	University of California, Irvine
<b>Information provided by:</b>	University of California, Irvine
<b>ClinicalTrials.gov Identifier:</b>	NCT00631059

**Purpose**

The objective of this protocol is to collect leukemia cell specimens from adults (18 years of age) diagnosed with acute leukemia at time of initial diagnosis and, if applicable, at time of first relapse. These specimens, in conjunction with a de-identified data set, will be utilized prospectively to determine potential chemotherapy resistance in this patient population.

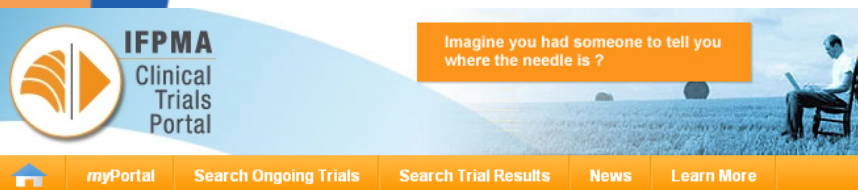
The specific aims of this study are as follows:

- To collect peripheral blood specimens from patients diagnosed with acute leukemia at time of initial diagnosis and, if applicable, at time of first relapse To evaluate the leukemia cells in the blood specimens for chemotherapy resistance utilizing the Hem(A)+ technology
- To develop a body of evidence from acute leukemia patients that demonstrates the applicability of the Hem(A)+ assay to determine the following:
  - Predict responders and non-responders to common chemotherapeutic agents
  - Track treatment results and comparison to prediction results from the assay
  - Identify optimal chemotherapy doses for each patient
  - Identify the most efficacious pharmaceutical agent combinations

Condition	Intervention
Leukemia	Other: Hem(A)+ Technology

Study Type: Interventional  
Study Design: Treatment Comparison, Single-Arm, Active Control, Single-Group, Assessment, Efficiency Study

# Find information on clinical trial results



- Search by Medical Condition or Drug Name

- Search integrates synonyms, connected terms and translations

### Search Clinical Trial Results

Terms to search for:

use synonyms

General Search Tips  
If your search cannot find what you are looking you tips:

Criteria lan  
You can phr any of the s common term synonyms.

Results lan  
All results w original langu

Terms to exclude:

Search Clear

Synonyms, connected terms and translations included in the search [ileocolitis crohn](#), [granulomatous crohn's disease](#), [ileitis](#), [terminal krankheit](#), [crohn crohn's enteritis](#), [crohn granulomatous](#), [回結腸炎](#), [morbus crohn](#), [ileocolite](#), [crohn's ileokolitis](#), [クローン病](#), [malaga crohn ileitis](#), [regional enteritis](#), [regional](#)

Print

Total results returned: 47

**Title: Protocol No. M02-404: A Multicenter, Randomized, Double-blind Placebo-controlled Study of the Human Anti-TNF Monoclonal Antibody Adalimumab for the Induction and Maintenance of Clinical Remission in Subjects with Crohn's Disease**

Infobox  
Sponsor: Abbott Laborato...  
Phase: Phase III  
Drug Name: Humira

Description: Protocol No. M02-404: A **Double-blind Placebo-controlled** Study of the Human Anti-TNF Monoclonal Antibody Adalimumab for the Induction and Maintenance of Clinical Remission in Subjects with Crohn's Disease. Rutgeerts P, et al. Adalimumab for Maintenance of Clinical Response and Remission in Patients with Crohn's Disease. Gastroenterology 2007; 132:52-65. Abbott La

more>>

ClinicalStudyResults.org

About Us How Can My Company Participate? Useful Links

These clinical study results are supplied for informational purposes only in the interests of scientific disclosure. They are not intended to substitute for the FDA-approved package insert or other approved labeling.

#### Drug Details

Company Name	Business Partner	Drug Name	Generic Name	Unique ID	Studied Indications or Disease	Phase	Approved Drug Label
Abbott Laboratories		Humira	Adalimumab	M02-404	Inflammatory Bowel Disease Crohns Disease	Phase III	<a href="http://www.nabbot.com/pdf/numira.pdf">http://www.nabbot.com/pdf/numira.pdf</a>

Clinical Study Summary  
Protocol No. M02-404: A Multicenter, Randomized, Double-blind Placebo-controlled Study of the Human Anti-TNF Monoclonal Antibody Adalimumab for the Induction and Maintenance of Clinical Remission in Subjects with Crohn's Disease  
Colombel JF, Sandborn WJ, Rutgeerts P, et al. Adalimumab for Maintenance of Clinical Response and Remission in Patients with Crohn's Disease: The CHARM Trial. Gastroenterology 2007; 132:52-65.  
Abbott Laboratories (Abbott) will use reasonable efforts to include accurate and up-to-date information, consistent with Abbott policies and procedures, on the ClinicalStudyResults.org web site. However, because, among other reasons, the status of studies often changes, Abbott can make no, and makes no, warranties or representations of any kind as to the currency or completeness of the information contained therein. Persons accessing and using information posted by Abbott on the ClinicalStudyResults.org web site do so at their own risk. Abbott disclaims all warranties, express or implied, including warranties of merchantability of fitness for a particular purpose. Abbott shall not be liable for any damages, including without limitation, direct, incidental, consequential, indirect or punitive damages, arising out of access to, use of, or inability to use information posted by Abbott on the ClinicalStudyResults.org web site, or any errors or omissions in the content thereof.

Company Study  
No document provided.

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# Access to the Portal in 6 languages

The screenshot shows the 'myPortal' website interface. At the top, there is a navigation bar with 'myPortal', '検索' (Search), 'メディアの方へ' (For Media), '検索方法' (Search Method), and '我々について' (About Us). A language dropdown menu is set to '日本語' (Japanese). The main content area is titled '臨床試験絞り込み検索' (Clinical Trial Refinement Search). It features a search box for keywords, an exclusion box, and a location selection box. A '頻言語の使用' (Use of Frequent Languages) section is highlighted with a checkmark, indicating that the search can be performed in the user's native language. A '参加者募集状況' (Participant Recruitment Status) section allows filtering by 'すべての臨床試験' (All Clinical Trials) or '適応外使用の臨床試験' (Off-label Use Clinical Trials). A '試験結果' (Trial Results) section allows filtering by '完了した臨床試験の結果' (Results of Completed Clinical Trials). A '検索' (Search) button and a '電子メールアラートを受け取る' (Receive Email Alerts) button are at the bottom. A right-hand sidebar contains a 'myPortal' logo, a 'あなたは患者さんですか?' (Are you a patient?) section with a link to '個人向けの情報を通して、臨床試験について理解を深めていただくことができます。' (You can deepen your understanding of clinical trials through information tailored for individuals.), a 'あなたは医師ですか?' (Are you a doctor?) section with a link to '臨床試験に関する最新データ提供と共に、ご担当の患者さんへのアドバイスや指示にご活用いただけます。' (Along with the latest data on clinical trials, you can use it for advice and instructions for your patients.), a '時間を節約できます。' (You can save time.) section with a link to '特定のご利用目的に合わせた無料のmyPortal電子メールアラートで、時間とリソースを節約できます。' (You can save time and resources with free myPortal email alerts tailored to your specific needs.), and a '今すぐ登録する (登録は無料)' (Register now (registration is free)) button.

Enter your search Criteria in:

- English
- French
- German
- Japanese
- Spanish
- Swedish via

Fass.se website

More language soon



No dictionary needed: the same unique tool is available in your native language.

# Spelling suggestions



The screenshot shows the IFPMA Clinical Trials Portal. At the top left is the IFPMA logo and the text "IFPMA Clinical Trials Portal". To the right is a banner with the text "Imagine you had someone to tell you where the needle is ?" and an image of a person sitting in a field. Below the banner is a navigation bar with links: "myPortal", "Search Ongoing Trials", "Search Trial Results", "News", and "Learn More". The main content area is titled "Search Clinical Trial Results". It features a search input field with a magnifying glass icon, containing the text "cro". Below the input field is a dropdown menu with the following suggestions: "Croakers", "Crocidolite Asbestos", "Crocodile tears syndrome", "Crocodiles", "Crocus Autumn", "Crohn's ...", "Crohns ...", "Cronkhite-Canada syndrome", "Croomia", and "Cross ...". To the right of the search field is a checkbox labeled "use synonyms" which is checked. Below the search field are "Search" and "Clear" buttons. To the right of the search field is a box titled "General Search Tips" with a lightbulb icon. It contains the text: "If your search cannot find what you are looking you might want to consider these tips:". Below this are two sections: "Criteria languages:" with the text "You can phrase your search criteria in any of the site languages. A dictionary of common terms will include translations as synonyms." and "Results language:" with the text "All results will, however, be shown in their original language."



Not sure of the spelling? The Portal will suggest names for disease or medicines specified.

# Easy-to-understand explanations

**Search Ongoing Clinical Trials**

Terms to search for:

Terms to exclude:

Trials conducted in:

use synonyms

**General Search Tips**  
If your search cannot find what you are looking you might want to consider these tips:

**Criteria languages:**  
You can phrase your search criteria in any of the site languages. A dictionary of common terms will include translations as synonyms.

**Results language:**  
All results will, however, be shown in their original language.

**Synonyms, connected terms and translations included in the search** [ileocolitis crohn-enteritis colitis](#), [granulomatous crohn's disease](#) [ileitis, terminal krankheit, crohn crohn's enteritis crohn disease crohns enteritis, granulomatous 回結腸炎 morbus crohn ileocolite crohn's ileokolitis クローン病 maladie de crohn enfermedad de crohn ileitis, regional enteritis, regional](#)

[Print](#) [1](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#) ...

Total results returned: 373

**Title: A Phase 3, Multi-Center, Randomized, Placebo-Controlled Study to Evaluate the Clinical Efficacy and Safety of Induction and Maintenance Therapy With Abatacept in Subjects With Active Crohn's Disease (CD) Who Have Had No Prior Medical Therapy**

**Infobox**  
Status: Active, not recruiting  
Sponsor: Bristol Myers-S...  
Location(s): Australia  
[more>>](#)

**Description**  
abatacept...  
in patients who have not had an adequate response to other therapies. The **safety** of this treatment will also be studied.

**? "randomized": "Randomization"**  
The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

Provided by  
 IFPMA Clinical Trials Portal



Complicated trial postings are suddenly much easier to understand!

# Make Portal yours

myPortal



[You are a patient?](#)

Gain a **better understanding** of clinical trials through **personalized information**.



[You are a physician?](#)

**Advise** and **guide** your patients with **updated data** on clinical trials.



**Save Time**

Save time and resources **with free myPortal email alerts**, specifically defined to meet your needs.

- ▶ Save your search
- ▶ Repeat your search
- ▶ Receive an email when a new matching trial is posted

[Join now \(it's free!\)](#)



- Save your search and receive an email each time a clinical trial is posted in the medical category you are interested in.

- You let us do the work and spend less time searching for trials!

# Learn more about Clinical Trials

## Helping you understand the Drug Development Process

Understand the drug development process through an easy-to-use [interactive module](#) by [innovation.org](#).



Inside Innovation: The Drug Discovery Process

## FAQs

IFPMA provides access to on-going clinical trials and results of completed clinical trials. Use the navigation to get answers to questions you may have.

[Printer Friendly Format](#)

### 1. IFPMA CLINICAL TRIALS PORTAL

[Q: Why is the pharmaceutical industry developing a portal for searching information on clinical trials?](#)

[Q: What information can I find by use of the portal?](#)

[Q: How does the portal work?](#)

[Q: How can I print out my search results?](#)

### 2. CLINICAL TRIALS

[Q: What is a clinical trial?](#)

[Q: Why participate in a clinical trial?](#)

[Q: Where do the ideas for trials come from?](#)

[Q: Who sponsors clinical trials and where are they conducted?](#)

[Q: What is a protocol?](#)

[Q: What is a placebo?](#)

[Q: What is a control or control group?](#)

[Q: What are the different types of clinical trials?](#)

[Q: What are the phases of clinical trials?](#)



Understand the drug development process and find answers to frequently asked questions about trials in general or focusing on child-specific needs.

# Contact us

Please visit our website to find out more:

[www.ifpma.org/clinicaltrials](http://www.ifpma.org/clinicaltrials)

Contact person: Laetitia Bigger, IFPMA  
Email: [L.Bigger@ifpma.org](mailto:L.Bigger@ifpma.org)

# What's Next

## *More Transparency to Come*



# It's an Evolutionary Journey



2002

**POLITICAL CONTRIBUTIONS**  
**TRIAL REGISTRATION on [clinicaltrials.gov](http://clinicaltrials.gov)**

2004

**TRIAL RESULTS on [clinicalstudyresults.org](http://clinicalstudyresults.org).**

2006

**PIPELINE**

2007

**U.S. POST MARKETING COMMITMENTS on [pfizer.com](http://pfizer.com)**

2008

**GRANTS AND CHARITABLE CONTRIBUTIONS**  
**MEDICINE SAFETY WEBSITE**  
**EXPANDED TRIAL RESULTS REGISTRATION**

2010

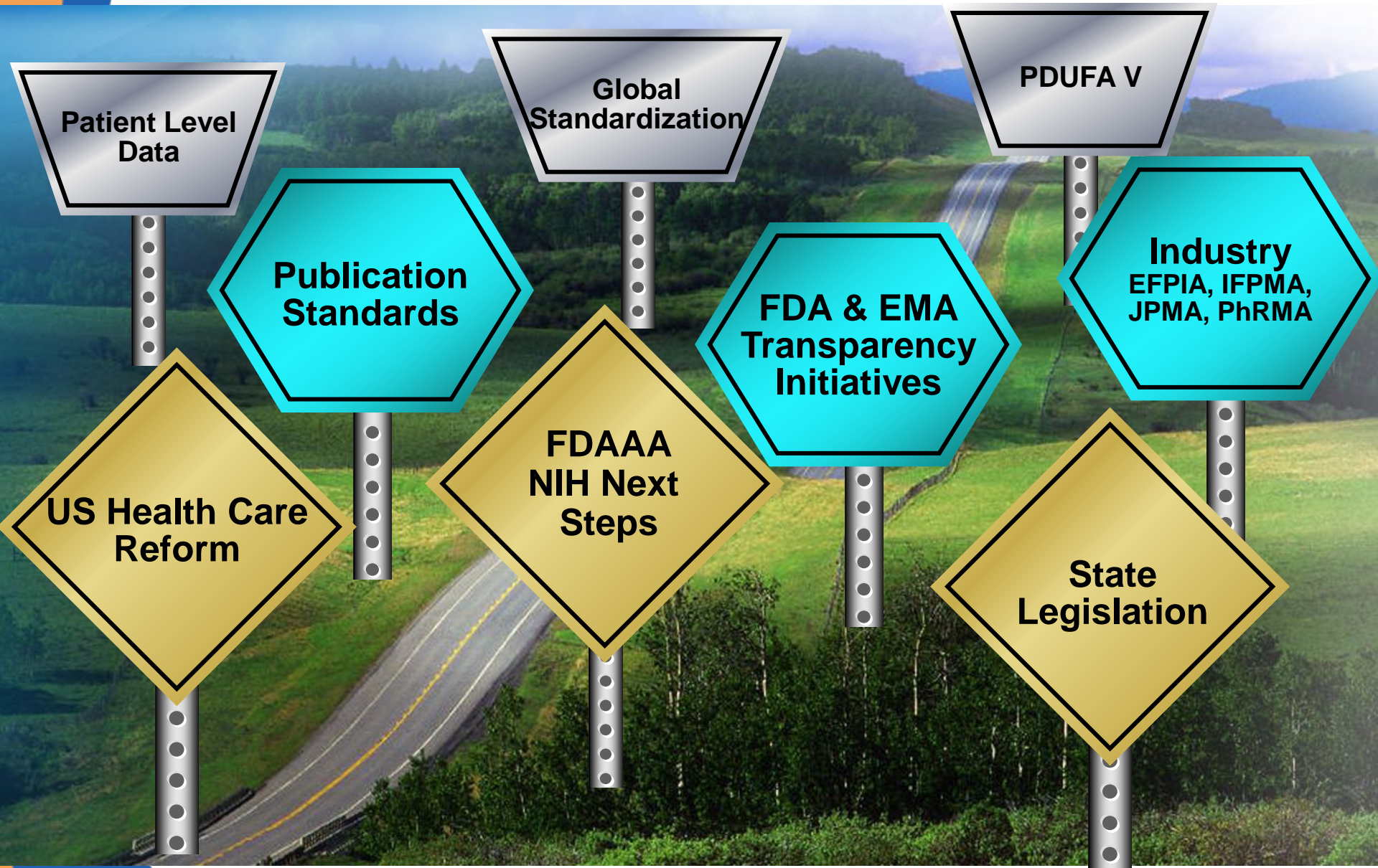
**EU Post Marketing Commitments**  
**HCP payment information on [Pfizer.com](http://Pfizer.com)**

*Pilots underway*

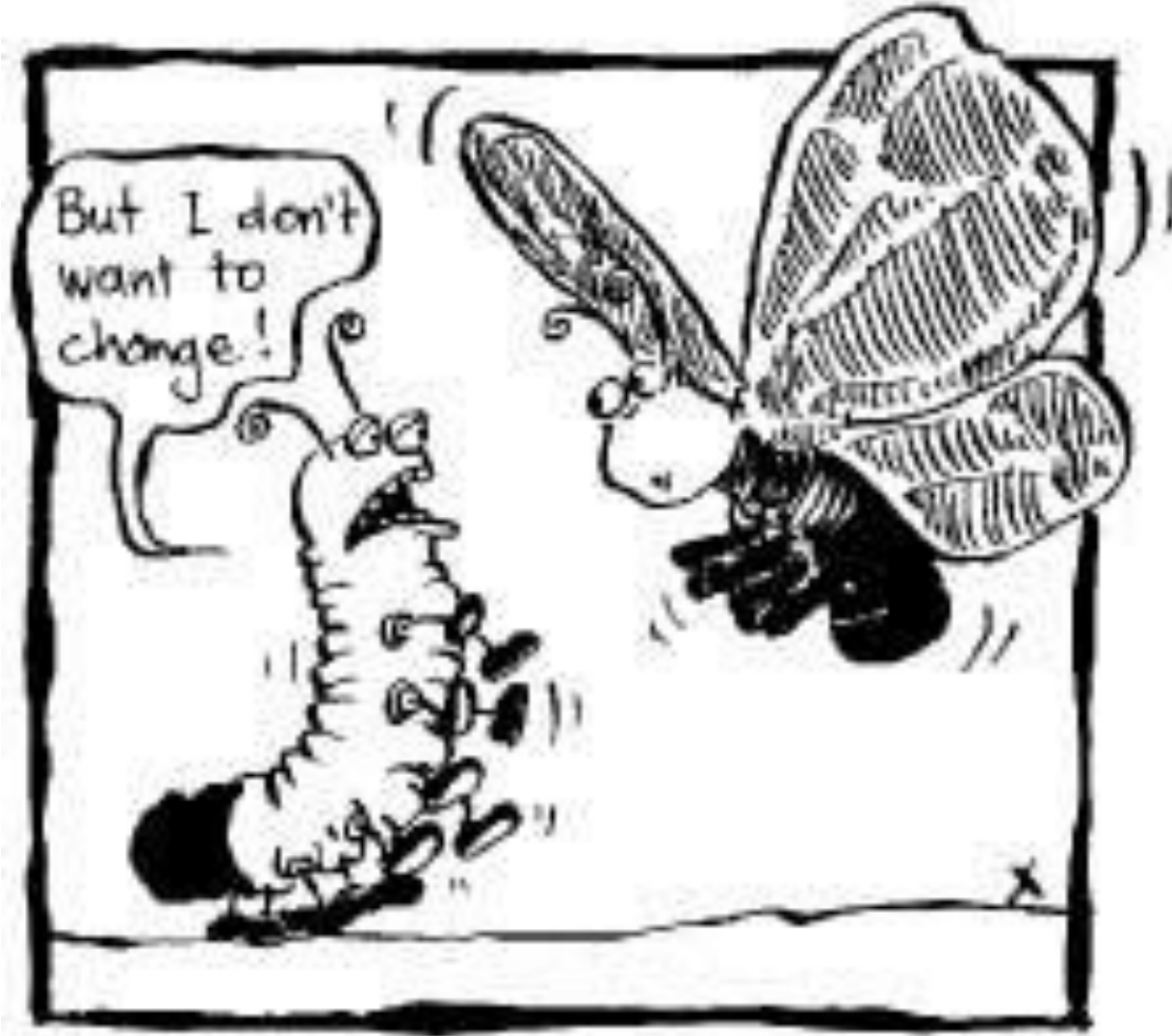
# Questions for the Future

- “Whose data is it?”
- “What additional categories of meaningful information should be disclosed?”
- “Where does public need to know end and intellectual property begin?”
- “When is the optimal time for disclosure?”

# Initiatives / Issues



**Change will continue,  
it's inevitable...and good...**







***“The patient is waiting”***



# Welcome to the 6<sup>th</sup> Annual Meeting of ISMPP

## Delivering Value and Driving Advocacy in Medical Publications

*April 19-21, 2010*