ブログ等）について既に導入済み（NCI）や検討されている（IFPMA）ところもあった．

日本でも問題になっているインターネットを利用しない高齢者については，アメリカでも同じように問題を抱えているのが現状である．NCI では，医師を通じた情報提供か，情報を郵便等で送付することで対応していることがわかった．

臨床研究・治験登録件数を WHO の ICTRP と Clinicaltrial.gov と比べた時，ICTRP の方が約 25%多い．例えば，日本で行われている臨床試験・治験の登録データ数について，JPRN の臨床研究・治験データ約 11,000 件に対し，WHO の ICTRP は約 15,000 件である．Clinicaltrial.gov や他の primary register に登録している約 4,000 件の英語データは今後どうするか検討が必要になると思われる．WHO の臨床試験・治験データベースを利用・協力した NHS choices のような情報提供の可能性も考えられる．日本で行われている臨床試験・治験約 2,900 件の英語データが登録されている Clinicaltrial.gov ウェブサイトから xml 形式のファイル（zip）をダウンロードし，臨床試験・治験データを取得して，データフォーマットを行うことも可能かもしれない．アメリカの法令により，治験依頼者は（ClinicalTrials.gov へ）臨床研究・治験に関する結果の提出が義務付けられている．日本はまだ法令化されていないので，今後検討されることも考えられる．

IFPMA は，企業をベースにした組織なので EMA や WHO との連携は特にないが，今後データベースの増加，ユーザビリティの向上，多言語化（増やす），チュートリアルの作成などの機能のアップデートを出版物が多いため，日本製薬工業協会（製薬協: JPMA）へ翻訳を依頼しており，製薬企業の連携が強かった．

NCI は，ユーザビリティテストやフィードバック，調査等を積極的に取り組んでおり，今後さらに clinical trial の検索結果について，患者向けへわかりやすい trial のタイトルの説明等を入れることなど考えている．NCI は海外にも情報を発信しており，例えば，TRI（臨床研究情報センター）は，がん情報サイト PDQ 日本語版（臨床試験検索）ページについて，NCI とライセンス契約し，がんに関する最新かつ包括的な情報サイトを運営し，情報提供を行っている．NCI は海外情報発信している運営組織でもあるので参考になる点が多くあると思われる．

E.結論

ウェブサイト運営に関しては，米国の組織，製薬企業を除き，人的資源，資金面ともに少ないため，十分なユーザビリティ，フィードバック，調査を行うことができず，ウェブサイトの改善や機能の追加が非常に難しいことがわかった．

一般の情報から臨床試験・治験へアクセスが可能な NHS choices のような情報提供サイト，患者向けと研究者向けがあり，IFPMA のような複数の臨床試験・治験データベースから串刺し検索が可能なサイト，患者，医療専門家等のそれぞれのニーズに合わせた情報提供サイトであり，特に患者向けのウェブサイトは，画像，動画，ソーシャルメディアを使用した NCI のようなウェブサイトなど，患者さんの視点で作られていて，臨床試験・治験へスムーズに情報が得られる有用なウェブサイトがあり，検索機能やシステム，サイト構成やコンテンツ等参考になる点が多くあった．

F.研究発表

1. 論文発表
   なし

2. 学会発表
   なし

G.知的財産権の出願・登録状況（予定を含む）

1. 特許取得
   なし

2. 実用新案登録
   なし

3. その他
   なし

International Federation
of Pharmaceutical
Manufacturers & Associations

IFPMA

Representing the research-based pharmaceutical industry

IFPMA Leadership

IFPMA

President	Vice President	Vice President	Director General
			
John Lechleiter, Ph.D. Chairman, President and CEO Eli Lilly and Company	Masafumi Nogimori Chairman Astellas Pharma Inc.	Stefan Oschmann Merck Executive Board Member and CEO of Merck Serono	Eduardo Pisani

IFPMA Mission

IFPMA

- IFPMA is a non-profit NGO with over 40 years of advocacy experience in the international arena
- IFPMA advocates policies that encourage discovery of and access to life-saving and life-enhancing medicines and vaccines to improve the health of people around the world.

"Our objective is to improve health around the world by contributing expertise, building trust, and establishing solutions for global health"

IFPMA Objectives

IFPMA

- encourage a global policy environment that is conducive to medicines innovation, both therapeutic and preventative, for the benefit of patients around the world;
- promote and support principles of ethical conduct and practices voluntarily agreed upon as exemplified by the IFPMA Code of Practice;
- promote and support the adoption of high standards of manufacturing practices and quality assurance for pharmaceutical products;
- contribute industry expertise and foster collaborative relationships and partnerships with international organizations, national institutions, governments and non-governmental organizations dedicated to the improvement of public health, especially in developing and emerging countries;
- assure regular contact and experience-sharing and coordinate the efforts of its members towards the realisation of the above objectives.

Official Relationship with the United Nations

IFPMA

Based in Geneva, IFPMA has a formal consultative status with the United Nations and its specialist bodies, including:

- World Health Organization (WHO)
- World Intellectual Property Organization (WIPO)
- United Nations Children's Fund (UNICEF)
- United Nations Conference on Trade and Development (UNCTAD)
- United Nations Economic and Social Council (UN ECOSOC)
- United Nations Industrial Development Organization (UNIDO)

IFPMA has also formal relationships with the World Bank and the World Trade Organization (WTO)

IFPMA Global Health Network

"Improving global health through collaborations and dialogue"

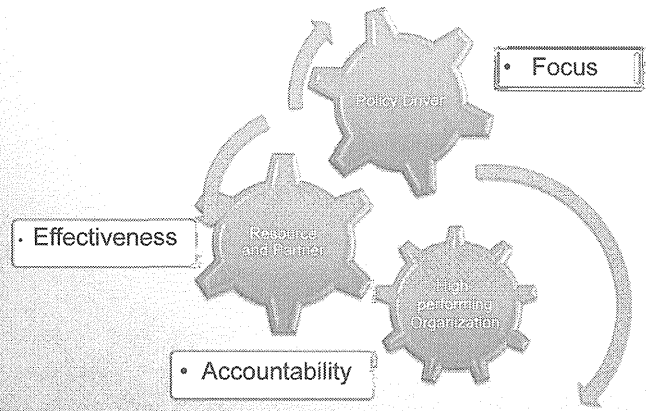
IFPMA

International Alliance of Patients' Organizations
The Global Fund To Fight AIDS, Tuberculosis and Malaria
GAVI ALLIANCE
Convention on Biological Diversity
UICC global cancer control
WMA
The NCD Alliance
Member States' Permanent Missions to the UN in Geneva
UNAIDS
International Hospital Federation
fip International Pharmaceutical Federation

...and many more

IFPMA Guiding Principles

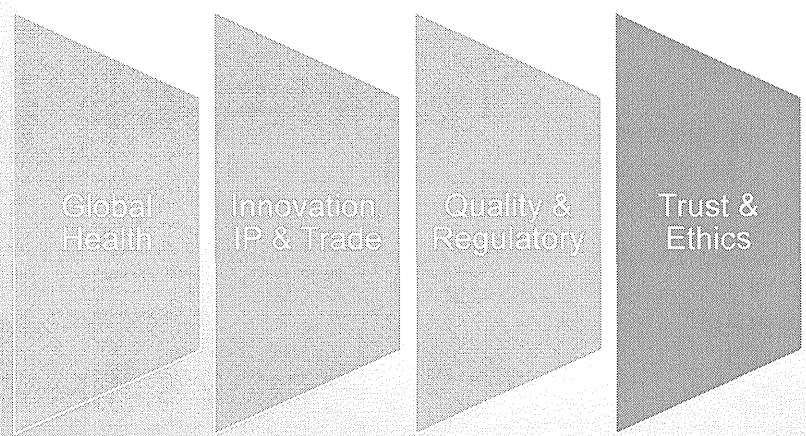
IFPMA



Policy Areas

"IFPMA works to address a wide range of complex global health issues including sustainable access to medicines and vaccines, biopharmaceutical innovation, quality and regulations, and trust and ethics".

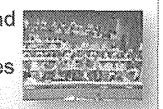
IFPMA



IFPMA Services for Members

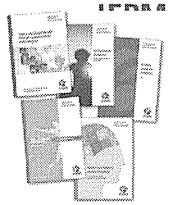
- **POLICY BRIEFINGS**
  - Advocacy kits
  - Position papers

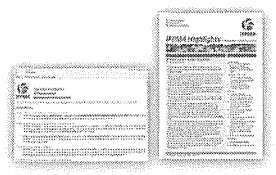
- **SOCIAL & ECONOMIC RESEARCH NETWORK (SERN)**
  - Global network of national associations for the exchange of socio-economic data
- **PUBLIC AFFAIRS**
  - Accreditation of members to access WHO, WIPO, WTO meetings
  - Advising on national impact of international regulations
  - Support for national advocacy efforts on strategic issues impacting our industry
  - Facilitation and policy coordination of industry associations and members
  - Policy and technical workstreams and sharing of best practices



IFPMA Services for Members

- **PUBLICATIONS**
- **MEDIA**
  - News releases
  - Articles
  - Interactions with UN correspondents
- **EVENTS**
  - Biennial Assembly
  - Geneva Pharma Forums
  - World Health Assembly Reception
- **ELECTRONIC UPDATES**
  - Daily press review
  - Monthly internal newsletter
- **ONLINE TOOLS**
  - IFPMA website, a comprehensive information resource
  - Online Developing World Health Partnerships Directory
  - Clinical Trials Portal
  - Online Code of Practice Training





How to get information about trials

A user journey through the IFPMA Clinical Trials Portal

R&D Industry Commitment to Transparency

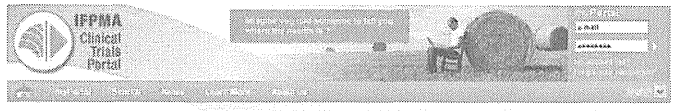
Commitment #1	Commitment #2
Industry will make information about all ongoing trials in patients publicly available	Industry will also post summary results of all completed trials in patient after drug approval

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.

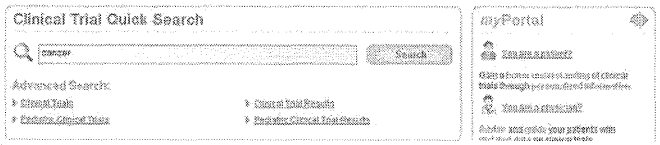
Access Clinical Trials Information



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

IFPMA Clinical Trials Portal ensures

- Access and easy-to-use interface for patients and health professionals alike to
- Non-promotional and reliable information
- Industry's commitment to the transparency of 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

ClinicalTrials.gov

Company & Industry association websites

AstraZeneca · Bayer · Bristol-Myers Squibb · Boehringer Ingelheim · GlaxoSmithKline · NOVARTIS · Roche · JNPIC · PhRMA

ClinicalStudyResults.org

IFPMA Portal in numbers

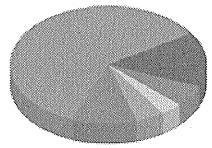
- Today, the IFPMA Portal features **trials from 160+ countries**

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 1050
- Eastern Mediterranean Region 894

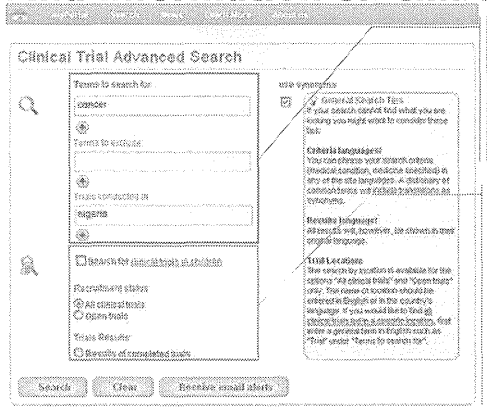
Number of results of completed clinical trials made available by the IFPMA Portal - Data per condition

Total: 8750



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

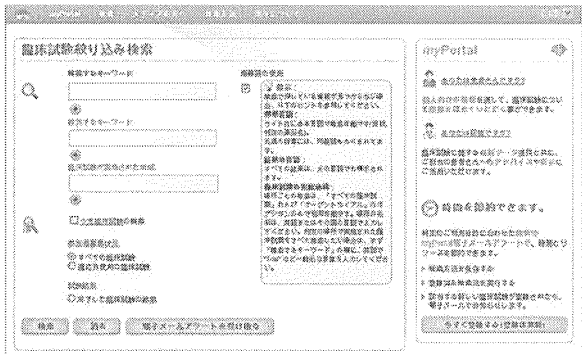
Find information on clinical trials



- Search by Medical Condition and Drug Name
- Search a particular country or city
- Learn more about trials in children
- Find information on ongoing and completed trials
- Find information on trial results

If you are interested in specific information on clinical trials, refine your search with the Portal filters.

Access to the Portal in 6 languages



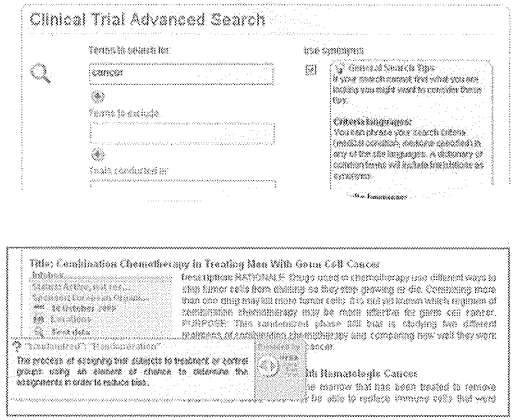
Enter your search Criteria in:

- English
- French
- German
- Japanese
- Spanish
- Swedish via Fass.se website

More language soon

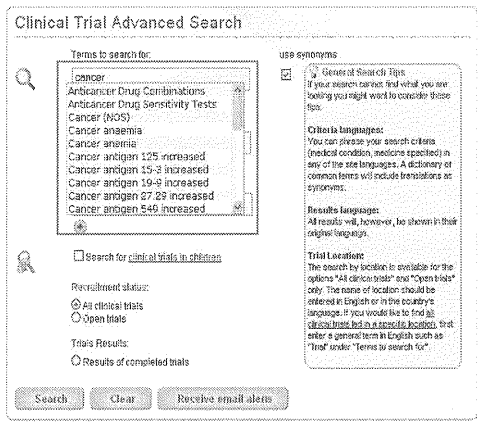
No dictionary needed: the same unique tool is available in your native language.

Easy-to-understand explanations



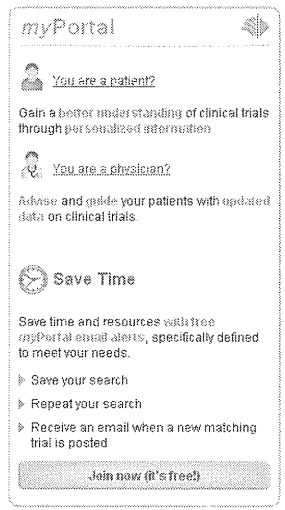
Complicated trial postings are suddenly much easier to understand!

Spelling suggestions



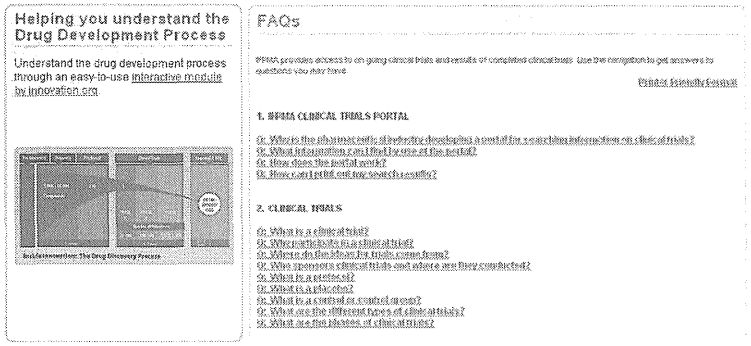
Not sure of the spelling? The Portal will suggest names for disease or medicines specified.

Make Portal yours



- Save your search and receive an email each time a clinical trial is posted in the medical catergory your are interested in.
- You let us do the work and spend less time searching for trials!

Learn more about Clinical Trials



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

Strengthening Healthcare Systems Globally: The Value of Patient Engagement

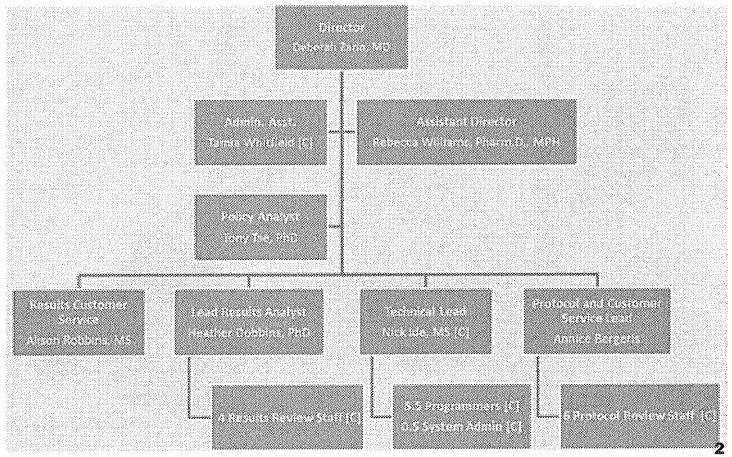
Conclusion

- The IFPMA Clinical Trials Portal is built to help you find information about ongoing/completed clinical trials and clinical trial results:
  - A search engine available in 6 languages
  - A complete set of tools focused on your needs:
    - Search for clinical trials in your country
    - Lay language explanations of technical terms
    - Spelling suggestions
    - Synonyms & Translations
  - A personal account that reduces the time you spend looking for information

ClinicalTrials.gov

Nicholas Ide
ClinicalTrials.gov
National Library of Medicine

ClinicalTrials.gov Onsite Staff



2

[C] = Contractor

Study and Intervention Type (Data as of February 05, 2013)		Number of Registered Studies and Percentage of Total	Number of Studies With Posted Results and Percentage of Total***
Total		140,003	8,077
Interventional		113,527 (81%)	7,530 (93%)
Type of Intervention*	Drug or biologic	76,626	6,436
	Behavioral, other	27,529	806
	Surgical procedure	12,777	312
	Device**	9,743	685
Observational		25,843 (18%)	547 (6%)
Expanded Access		190	N/A

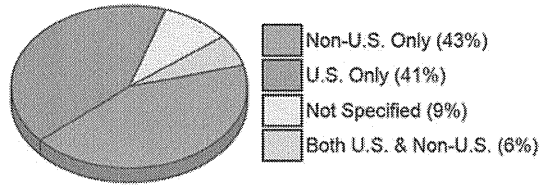
3

Source: http://clinicaltrials.gov/ct2/resources/trends

3

ClinicalTrials.gov Statistics

(as of 1/29/2013)
Locations of Registered Studies



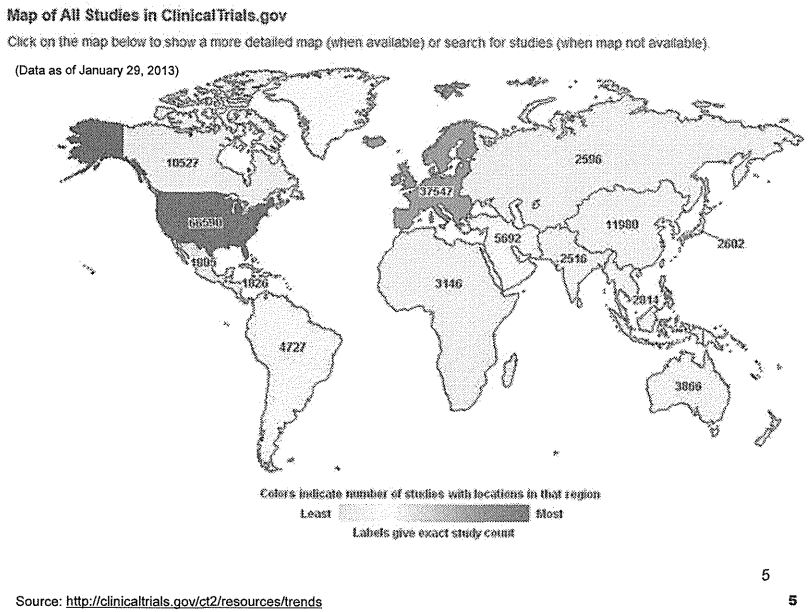
Location	Number of Registered Studies and Percentage of Total
Non-U.S. Only	59,883 (43%)
U.S. Only	57,699 (41%)
Not Specified*	13,107 (9%)
Both U.S. & Non-U.S.	8,891 (6%)
Total	139,590

* Not Specified: The location of the study was not provided by the Sponsor.

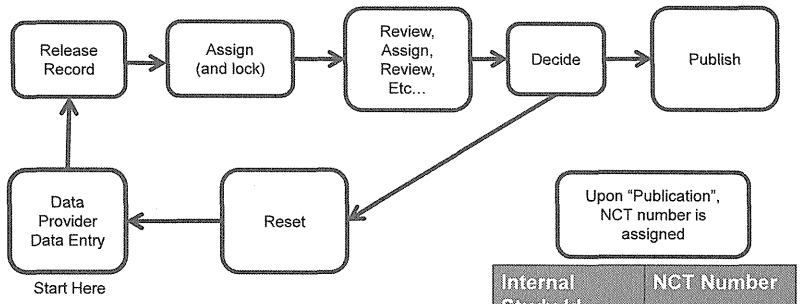
4

Source: http://clinicaltrials.gov/ct2/resources/trends

4

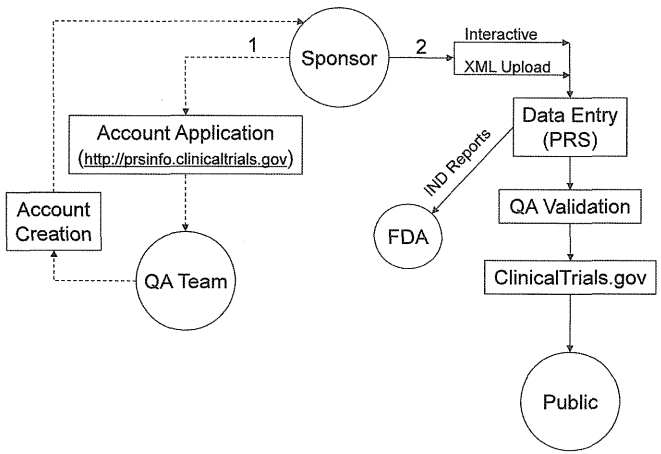


Internal PRS Flow



Internal Study Id	NCT Number
S0000123	NCT0005431
S0000ABC	NCT00004531
S0001212	NCT00121016

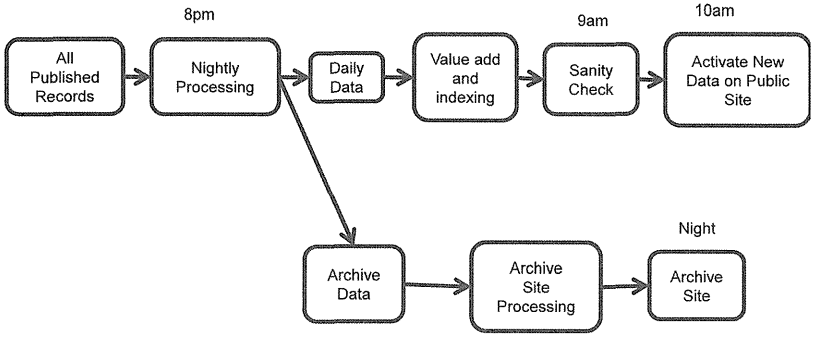
Data Flow



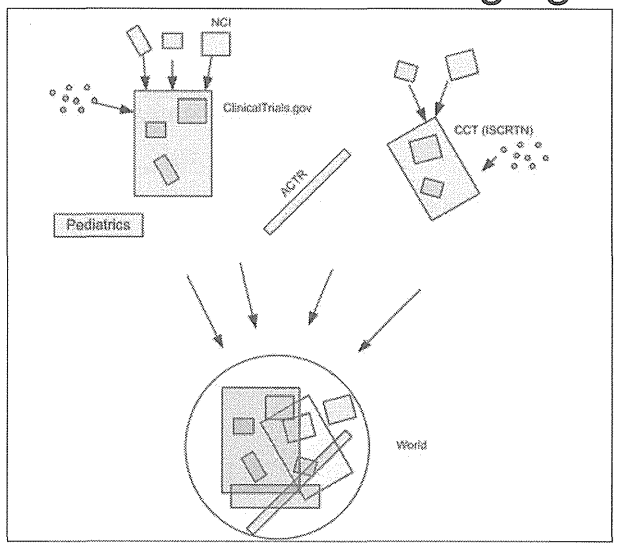
Quality Assurance

- Protocol Registration System (PRS)
  - Organizational accounts
  - Automated validation (e.g., required fields)
- QA team manual review
  - Internal consistency
  - Duplicate registrations
- Evidence of IRB approval
  - Contact information
  - IRB approval letter submission
- We don't have the trial protocol

Daily Flow



Uncoordinated Merging



Global System of Trial Registration

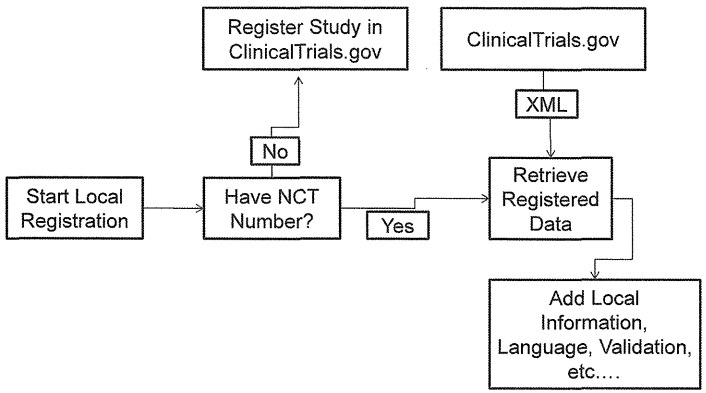
1. Incentives – policies, legislation
2. Communication – outreach, guidelines
3. Data Collection – the database
4. Validation – correct and complete
5. Dissemination – available to constituents

Collaborative Models: Data Collection

Collaboration is essential and complicated

- Register in primary *then* secondary
  - Record primary identifier in secondary register
- Opportunities for country specific additions and validation

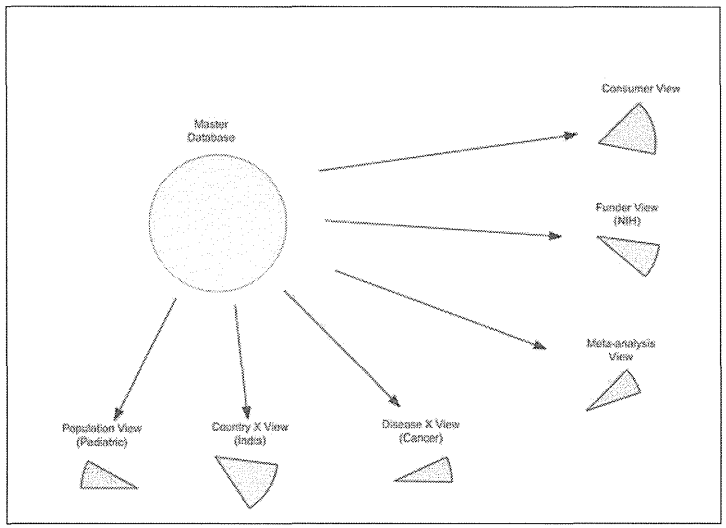
Collaborative Data Collection



Components of Global System

	ClinicalTrials.gov	Registry Partner X	WHO
Incentives	U.S. FDAMA, ICMJE, Other laws,		
Communication	Some **Need Help !**		
Database	Done		
Validation	Some **Need Help !**		
Dissemination	Done **English Only!**		

Collaborative Dissemination



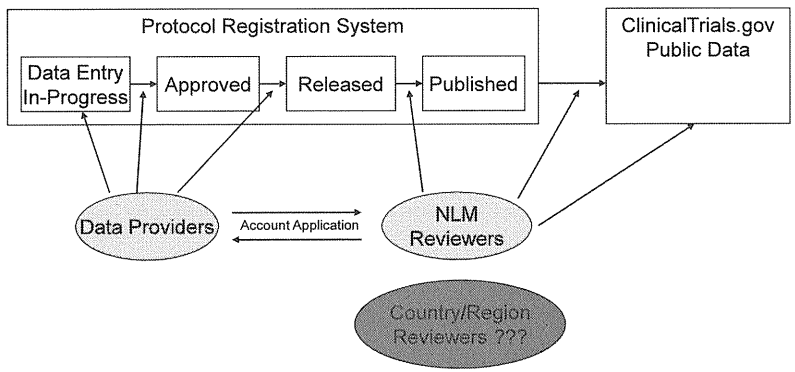
Options on Language Issues

- Parallel Registration
  - Register in English site, capture identifier, then register in language specific registry with cross links between the registries
    - Data provider does the translation
- Capture multiple languages in one database
- Translated Site
  - Using software and human translators, translate some or all of the English data to the target language
- Data Entry Assistance for non-English
  - Is this something the countries could help with ?

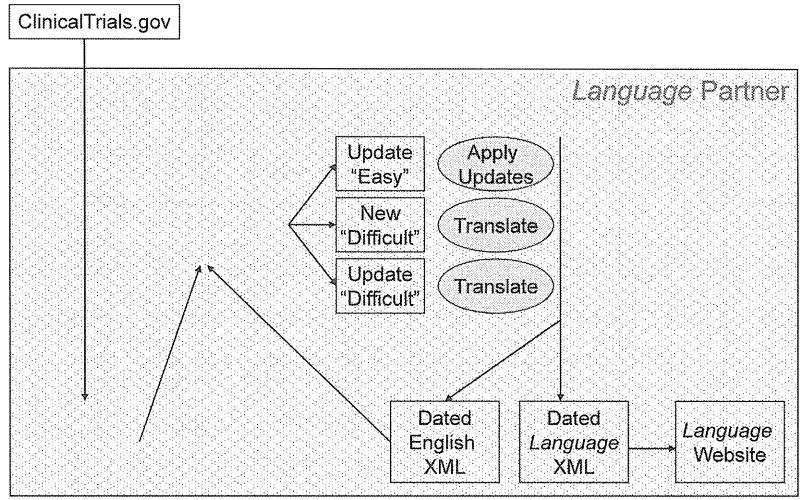
Partner Models

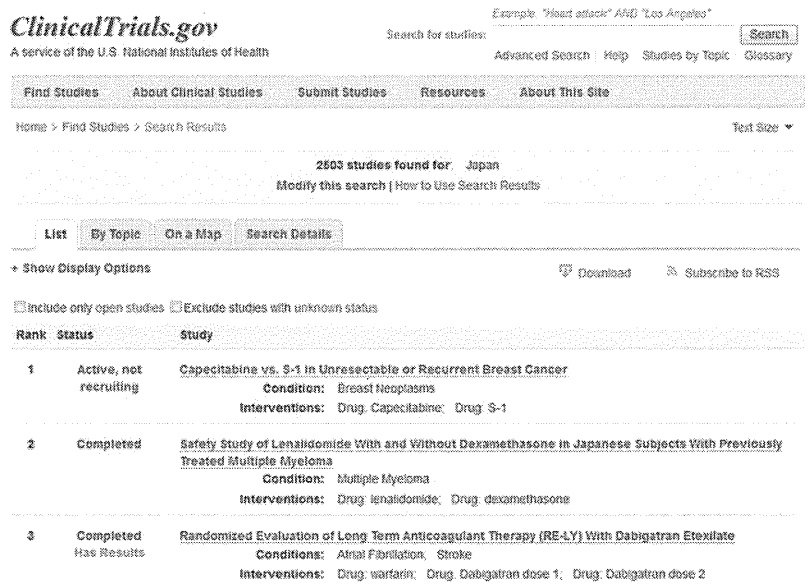
- Content Validation Partner
  - Assist ClinicalTrials.gov with validation activities for studies conducted outside of the United States
- Content Dissemination Partner
  - Take data from ClinicalTrials.gov,
  - translate portions of the data,
  - make information available in other language

Content Validation



Content Dissemination





PRS Organizations from Japan

- Sample of organizations providing data to ClinicalTrials.gov:

AbbottJapan	Abbott Japan Co.,Ltd	INDUSTRY
ADVANCED-J	Advanced-J	OTHER
AichiCC	Aichi Cancer Center	OTHER
AichiGakuinU	Aichi Gakuin University	OTHER
AkitaUH	Akita University Hospital	OTHER
Anaeropharma	Anaeropharma Science, Inc.	INDUSTRY
AnGes	AnGes	INDUSTRY
Arigen	aRigen Pharmaceuticals, Inc.	INDUSTRY
ArtistSG	ARTIST Study Group	OTHER
AsahiKasei	Asahi Kasei Pharma Corporation	INDUSTRY
AsahiKKM	Asahi Kasei Kuraray Medical Co.,Ltd.	INDUSTRY
AshikagaRCH	Ashikaga Red Cross Hospital	OTHER
AshiyaU	Ashiya University	OTHER
AssociationsEEI	Associations for Establishment of Evidence in Interventions	OTHER

PRS Organizations from Japan

- >>>>> many removed from middle of list for presentation purposes <<<<<<<

UShizuoka	University of Shizuoka	OTHER
UToyama	University of Toyama	OTHER
UYamanashi	University of Yamanashi	OTHER
Valish	VALISH study	OTHER
VulnerablePS	Vulnerable Plaque Society	NETWORK
WakayamaMU	Wakayama Medical University	OTHER
WJapanThoracicOG	West Japan Thoracic Oncology Group	OTHER
YakultHonsha	Yakult Honsha CO.,LTD	INDUSTRY
Yamagatau	Yamagata University	OTHER
YamaguchiUH	Yamaguchi University Hospital	OTHER
YodakuboH	Yodakubo Hospital	OTHER
YokohamaCUMC	Yokohama City University Medical Center	OTHER
YoshinoNC	Yoshino Neurology Clinic	OTHER
YubariKibounomori	Yubari Kibounomori	OTHER
ZenyakuKogyo	Zenyaku Kogyo Co., Ltd.	INDUSTRY
Zeria	Zeria Pharmaceutical	INDUSTRY

- Total of 252.

PRS Organizations from Japan

Benesis	Benesis Corporation	INDUSTRY
Biomedis	Biomedis International Ltd.	OTHER
BiotronikJapan	Biotronik Japan, Inc.	INDUSTRY
BoocsClinic	Boocs Clinic	OTHER
CanBas	CanBas Co. Ltd.	INDUSTRY
ChemoSero	The Chemo-Sero-Therapeutic Research Institute	INDUSTRY
ChibaU	Chiba University	OTHER
ChugaiPharmaceutical	Chugai Pharmaceutical	INDUSTRY
Chugai_Pharma	Chugai Pharma USA	INDUSTRY
CitizenSystems	Citizen Systems Japan Co., Ltd.	INDUSTRY
COLMSRO	COLM Study Research Organization	OTHER
CopeTG	COPE Trial Group	OTHER
Cosmos	Cosmos Technical Center	INDUSTRY
CSHOT	Center for Supporting Hematology-Oncology Trials	OTHER
CSPOR	Comprehensive Support Project for Oncology Research	OTHER
CTAISSG	Combination Therapy for Acute Ischemic Stroke Study Group	OTHER

Thank you

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

ClinicalTrials.gov

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http://ClinicalTrials.gov

Outline

- Rationale for clinical trial registration and results reporting
- Background – ClinicalTrials.gov
- Key policies and laws
- Basics of registration and results reporting
- Finding Results Submitted to ClinicalTrials.gov
- Uses of ClinicalTrials.gov

Evidence Based Medicine (EBM)

- Clinical and policy decisions informed by evidence regarding the benefits, risks and other burdens associated with all possible alternatives.
- Clinical trials are a key component of the scientific evidence that must be used to make decisions.
- Most decision makers currently depend on summary data from journal articles

Three Key Problems

- Not all trials are published in the literature
- Publications do not always include all prespecified outcome measures
- Unacknowledged changes are made to the trial protocol that would affect the interpretation of the findings
  - e.g., changes to the prespecified outcome measures

The New York Times
nytimes.com

June 2, 2004

New York Sues Maker of Antidepressant Drug Paxil

By KENNETH N. GILPIN

The New York State attorney general accused the British drug giant GlaxoSmithKline of consumer fraud today, asserting that the company had withheld negative information and misrepresented data about the efficacy and safety of prescribing the antidepressant drug Paxil to children.

The civil lawsuit, filed in New York State Supreme Court, says that starting in 1998, Glaxo suppressed the results of four studies that did not find the drug effective in treating children and adolescents and that suggested a possible increased risk of suicidal thinking and acts.

"By concealing critically important scientific studies on Paxil, GlaxoSmithKline impaired doctors' ability to make the appropriate prescribing decision for their patients and may have jeopardized their health and safety," the attorney general, Eliot Spitzer, said in a statement.

5

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

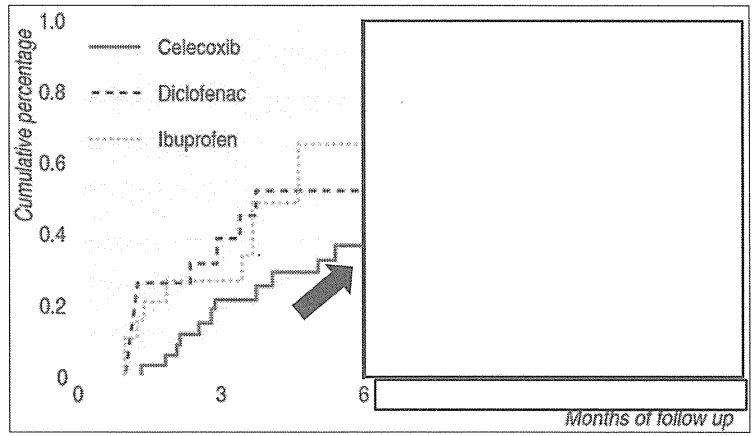
Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy

Erick H. Turner, M.D., Annette M. Matthews, M.D., Eftihia Linardatos, B.S., Robert A. Tell, L.C.S.W., and Robert Rosenthal, Ph.D.

N Engl J Med. 2008 Jan 17;358(3):252-60.

6

Kaplan-Meier estimates for ulcer complications according to traditional definition. Results are truncated after 12 months, no ulcer complications occurred after this period. Adapted from Lu 2001.



Jüni P, Rutjes AW, Dieppe PA. *BMJ*. 2002 Jun 1;324(7349):1287-8.

7

Avandia (Rosiglitazone)

The Washington Post

CAN DRUG RESEARCH STILL BE TRUSTED?

Even in the most respected of medical journals, firms' influence over studies opens door to bias

Jeffrey M. Drazen to editor in chief of the New England Journal of Medicine, which has repeatedly taken steps to apply its own set standard of ethics.

Sunday November 25, 2012

In 2007:
"…[Nissen] discovered the summaries of 42 trials — 35 of them unpublished. Most of them had been sponsored by Glaxo.

After analysis, the results were stark: Avandia raised the risks of heart attack by 43 percent and of death from heart problems by 64 percent."

BMJ

BMJ 2011;344:d7292 doi: 10.1136/bmj.d7292 (Published 3 January 2012)

RESEARCH

Publication of NIH funded trials registered in ClinicalTrials.gov: cross sectional analysis

OPEN ACCESS

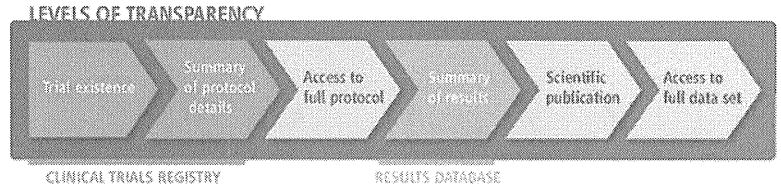
Joseph S Ross *assistant professor of medicine*[1 2], Tony Tse *program analyst at ClinicalTrials.gov*[3], Deborah A Zarin *director of ClinicalTrials.gov*[3], Hui Xu *postgraduate house staff trainee*[4], Lei Zhou *postgraduate house staff trainee*[4], Harlan M Krumholz *Harold H Hines Jr professor of medicine and professor of investigative medicine and of public health*[2 5 6]

[1]Section of General Internal Medicine, Department of Medicine, Yale University School of Medicine, New Haven, CT, USA; [2]Center for Outcomes Research and Evaluation, Yale-New Haven Hospital, New Haven, CT; [3]Lister Hill National Center for Biomedical Communications, National Library of Medicine, National Institutes of Health, Bethesda, MD, USA; [4]Fuwai Hospital and Cardiovascular Institute, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; [5]Robert Wood Johnson Clinical Scholars Program and Section of Cardiovascular Medicine, Department of Medicine, Yale University School of Medicine, New Haven, CT; [6]Section of Health Policy and Administration, Yale University School of Epidemiology and Public Health, New Haven, CT

Summary of Findings

- Fewer than half of NIH funded trials registered at ClinicalTrials.gov after September 2005 and completed by December 2008 were published in a peer reviewed biomedical journal indexed by MEDLINE within 30 months of trial completion
- After a median of 51 months after study completion, a third of NIH-funded trials in the sample remained unpublished

Levels of "Transparency"



Zarin DA, Tse T. *Science*. 2008 Mar 7;319(5868):1340-2.

Reasons to Register Clinical Trials and Report Results

- Human Subject Protections
  - Allows potential participants to find studies
  - Assists ethical review boards during review of study
  - Promote fulfillment of ethical responsibility to human volunteers – contribution to medical knowledge
- Research Integrity
  - Facilitates tracking of protocol changes
  - Increases transparency of research enterprise
- Evidence Based Medicine
  - Facilitates tracking of studies and outcome measures
  - Allows for more complete identification of relevant studies
- Allocation of Resources
  - Promotes more efficient allocation of resources

ClinicalTrials.gov Background

What is ClinicalTrials.gov?

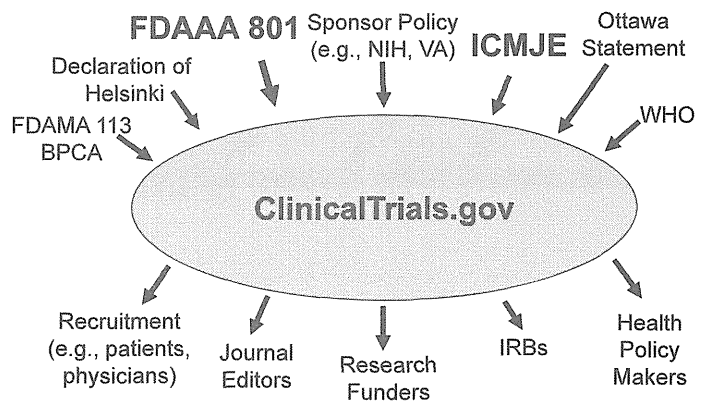
A registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

History of ClinicalTrials.gov

- FDAMA* 113 (1997) mandates registry
  - Investigational New Drug application (IND) trials for serious and life-threatening diseases or conditions
- ClinicalTrials.gov launched in February 2000
- Calls for increased transparency of clinical trials
  - Maine State Law; State Attorneys General
  - International Committee of Medical Journal Editors (ICMJE) statement (2004)
- ClinicalTrials.gov accommodates other policies
- FDAAA† Section 801 (2007): Expands registry & adds results reporting requirements

* Food and Drug Administration Modernization Act of 1997
† Food and Drug Administration Amendments Act of 2007

Policies and Users



ClinicalTrials.gov Visitors by "Role"
(n = 2,216)

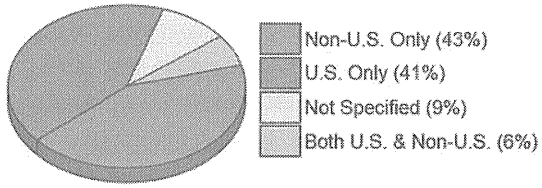
Patient	28%
Scientist/Researcher	18%
Family/Friend	14%
Health Care Provider	8%
Other	7%
Clinical Trial Staff	6%
Clinical Research Support	5%
Student/Educator	4%
Medical Communications	3%
Librarian/Information Prof.	2%
IRB or Ethics	<1%

Source: American Customer Satisfaction Index (ACSI) Online Consumer Survey; 4th Quarter 2012

17

ClinicalTrials.gov Statistics
(as of 12/9/2012)

Locations of Registered Studies



Location	Number of Registered Studies and Percentage of Total
Non-U.S. Only	58,484 (43%)
U.S. Only	56,806 (41%)
Not Specified*	12,960 (9%)
Both U.S. & Non-U.S.	8,857 (6%)
Total	137,107

* Not Specified: The location of the study was not provided by the Sponsor.

18
18

ClinicalTrials.gov Statistics
(as of 12/9/2012)

50 million pages views *monthly*
65,000 unique visitors *daily*

	Registration	Results
Total	137,107	7,617
Type of Trial		
Observational	25,232 (18%)	517 (6%)
Interventional*	111,253 (81%)	7,100 (93%)
- Drug & Biologic	75,412	6,078
- Behavioral, Other	26,442	746
- Surgical Procedure	12,533	291
- Device**	9,450	637

* Intervention types not additive; study record may include more than one type of intervention
**436 applicable device clinical trials submitted, but qualify for "delayed posting" under FDAAA

19

Key Policies and Laws

20

Two Disclosure Policies

- ICMJE – Journal Editors Policy (2004)
  - Prospective registration of all clinical trials as a precondition for publication of the study results
  - Effective Date: September 13, 2005
- FDA Amendments Act, Section 801 (2007)
  - Enacted on September 27, 2007
  - Expanded Trial Registration Requirements (FDAMA)
  - Added New Results Reporting Requirement
  - Added Enforcement Provisions: e.g.,
    - Civil monetary penalties (up to $10,000/day)
    - Withholding of NIH grant funds
  - Current Status: Rulemaking

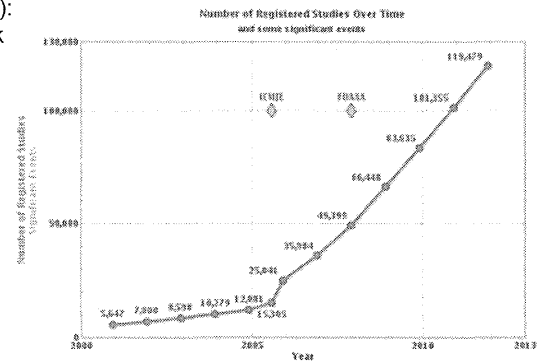
21 21

	ICMJE	FDAAA
Why?	Required for journal publication	Required by US federal law
Which Trials?	Interventional Studies -All Phases -All Intervention Types	Interventional Studies -Not Phase 1/Feasibility -Drugs, Biologics, Devices
Who?	Author	Sponsor or designated PI
When to Register?	Prior to enrollment of first participant	Within 21 days of enrollment of first participant
What to Register?	WHO Data Items	ClinicalTrials.gov and FDAAA Data Elements
Where to Register?	ClinicalTrials.gov or WHO Primary Registry	ClinicalTrials.gov
When to Submit Results?	Not Applicable	Within 12 months of final data collection for the primary outcome

22

Rate of New Registrations

- After FDAMA (2000):
  25 – 30 registrations per week
- After ICMJE (2005):
  200 – 250 per week
- After FDAAA (2007):
  300 – 350 per week



FDAAA Results Requirements

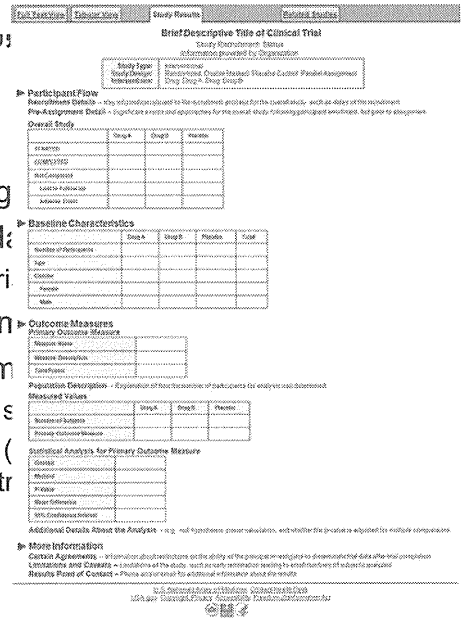
- **Which Trials?**
  - Same as registration for FDA approved or cleared drugs, biologics, devices
  - Initiated on or after 9/27/07 or ongoing as of 12/26/07
- **When Must Results be Reported?**
  - Within 12 months of (primary) completion date; OR
  - ≤ 30 days of approval or clearance
  - Delays possible
    - Seeking approval of a new use
    - Extensions for "good cause"

24 24

http://prsinfo.clinicaltrials.gov/fdaaa.html

FDAAA "Basic"

- Participant Flow
- Baseline and Demog
- Primary and Second
  - Scientifically appropri
- Adverse Event Inform
- Administrative Inform
  - Point of Contact (for s
  - Certain Agreements (publish results after tr



http://prsinfo.clinicaltrials.gov/fdaaa.html

Clarifications about Results Reporting Requirements

- Summary results at the end of the trial
  - No interim or "real time" reporting
  - No participant level reporting
- Information currently targeted at readers of the medical literature
  - "Tables" of information; "just the facts"
  - No conclusions or discussion

Results Submission and Journal Publication

- Deadlines for reporting to ClinicalTrials.gov are independent of publication status
- Submitting results to ClinicalTrials.gov will not interfere with publication*
  - But failing to register before the first participant is enrolled will!
- ClinicalTrials.gov records are linked, via NCT number, to publications

* Laine C, Horton R, DeAngelis C, et al. *Ann Intern Med.* 2007; http://www.icmje.org/faq_clinical.html