ClinicalTrials.gov: A Public Database of Clinical Research

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Background (http://clinicaltrials.gov)

- Largest public registry of clinical research studies
- Public access to "basic results" of certain interventional studies
- Reporting required by law— effective as of September 27, 2007 [1]
- Accepts wide range of interventional and observational studies
- Supports many registration and/or results reporting policies (e.g., WHO and medical journal editors [2])

FDA Amendments Act (FDAAA) Requirements

Which Trials are Involved?

- **Drugs and Biologics**: Controlled trials, other than Phase I, of a product regulated by the FDA
- **Devices**: Controlled trials with health outcomes of devices regulated by the FDA (not small feasibility studies) and pediatric postmarket surveillance device studies
- Trials initiated after September 27, 2007
- Trials initiated on or before September 27, 2007 and ongoing as of December 26, 2007

Who Needs to Submit Data?

- Publicly and privately funded trials
- Responsible for registration
  - Sponsor or
  - Principal investigator, if designated

Additional FDAAA Resources

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

Registration at ClinicalTrials.gov

What Data Elements are Included?

- Protocol Description
- Recruitment Information
- Location and Contact Information
- Administrative Data

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

When to Register?

- No later than 21 days after enrollment of the first participant
- [NOTE: Must be *prior to* enrollment of the first participant to fulfill journal editors registration policy]

"Basic Results" Reporting at ClinicalTrials.gov

Which Trials Must be Reported?

- Generally, trials of *FDA-approved* drugs, biologics, and devices that were required to be registered (*see above*)

What Information Is Included?

- Participant Flow (# Started/Completed)
- Baseline Characteristics
- Outcome Measures
- Adverse Events (AEs)
- Results Point of Contact
- Restrictions on PI Publication
- Overall Limitations and Caveats

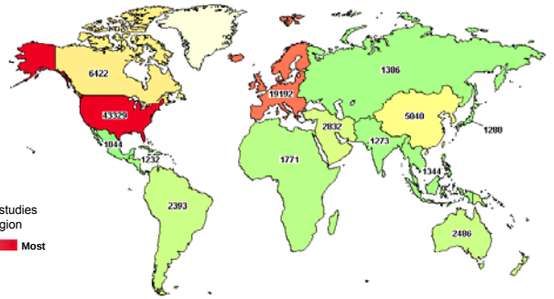
http://prsinfo.clinicaltrials.gov/results_definitions.html

When to Report?

- No later than 1 year after the date of final collection of data for the primary outcome or early study termination
- Requests for delayed submission available
  - Seeking initial approval
  - Seeking approval of a new use
  - Extension for "good cause"

Study Locations (all registered clinical studies; n = 80,513 as of 10/23/09)

170 Countries
(as of 10/23/09)



Colors indicate number of studies with locations in that region

Least — Most

Purposes of Registration and Results Reporting

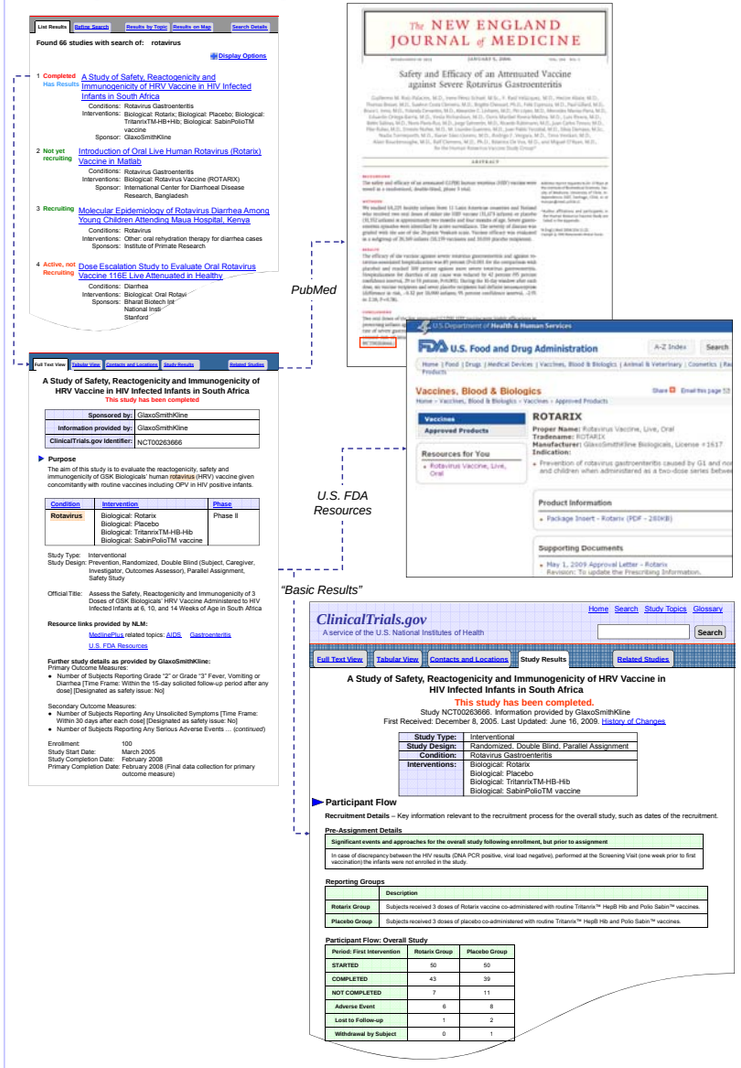
- Promote fulfillment of ethical responsibility to human volunteers – use of research to contribute to medical knowledge
- Provide information to potential participants
- Identify relevant studies reporting harms and efficacy results
- Mitigate "publication" and "outcome measure reporting" bias
- Promote more efficient allocation of resources
- Assist ethical review boards and others in determining appropriateness of studies being reviewed
- Increase transparency in dissemination of clinical research information

Characteristics of Studies

	Number of Studies (Oct 23, 2009)
Total	80,513
Study Type*	
Observational	13,118
Interventional	67,063
Data Provider Category	
Federal (including NIH)	19,192
Industry	25,293
University/Foundation/Other	36,028
Phase (Interventional only)**	
N/A	13,906
I	12,542
II	22,285
III	15,055
IV	8,502
Intervention Type (Interventional)**	
Drug & Biologic	48,966
Device***	4,786
Medical Procedure	8,560
Behavioral, Gene Transfer, Other	8,355

*Additionally, 90 "expanded access" studies; 242 studies not specified
**Not additive – trials may have more than one phase or intervention type
***Does not include 242 trials of devices "not previously cleared or approved" by the FDA, which have been submitted but are not posted (in the "*lock box*")

Using ClinicalTrials.gov



Practical Applications for Researchers

- Identify ongoing and completed studies for particular diseases
- Supplement current literature reviews in a research area
- Scan the horizon for the current research in areas of interest
- Review other research approaches and opportunities for collaboration

[1] FDA Amendments Act of 2007 (FDAAA), Section 801 (Pub L No. 110-85); FDA Modernization Act of 1997 (FDAMA), Section 113 (Pub L No. 105-115)
[2] Laine C, Horton R, DeAngelis CD, Drazen JM, Frizelle FA, et al. Clinical trial registration--looking back and moving ahead. *N Engl J Med*. 2007 Jun 28;356(26):2734-6.
[3] Zarin DA, Tse T. Medicine. Moving toward transparency of clinical trials. *Science*. 2008 Mar 7;319(5868):1340-2