Background: ClinicalTrials.gov and the database for Aggregate Analysis of ClinicalTrials.gov (AACT)
Background

- What is ClinicalTrials.gov?
- ClinicalTrials.gov history
- Key reporting requirements
- Rationale for reporting clinical trials
- Basic uses of ClinicalTrials.gov
- Creation of AACT database
What is ClinicalTrials.gov?

ClinicalTrials.gov is a web site that provides patients, their family members, and health care professionals easy access to information about clinical studies on a range of diseases and conditions.

Information is provided and updated by the sponsor or principal investigator of a clinical study, and the web site is maintained by the U.S. National Library of Medicine (NLM) at the National Institutes of Health (NIH).
# ClinicalTrials.gov History

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov 21, 1997</td>
<td>Food and Drug Modernization Act of 1997 (FDAMA) section 113 enacted</td>
<td>Mandated the creation of the ClinicalTrials.gov registry for efficacy trials in serious and life-threatening conditions and interventions regulated by the FDA</td>
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<tr>
<td>Feb 29, 2000</td>
<td>First version of ClinicalTrials.gov publicly available</td>
<td></td>
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<tr>
<td>Sept 2004</td>
<td>Internal Committee of Medical Journal Editors’ (ICMJE) policy established</td>
<td>Required studies published in their journals be registered in ClinicalTrials.gov or other equivalent publicly available registries</td>
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<td>Sept 27, 2007</td>
<td>FDA Amendments Act (FDAAA) section 801 enacted</td>
<td>Created a legal requirement for the registration of the trials of drugs, biologics, and devices</td>
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<tr>
<td>Sept 23, 2008</td>
<td>Results reporting launched</td>
<td>Results reporting available, Adverse event reporting optional</td>
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<tr>
<td>Sept 28, 2009</td>
<td>Adverse Event reporting required</td>
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Key Trial Reporting Requirements

- Register at trial initiation for interventional studies of drugs, biologics, and devices
  - (Phase 1 excluded)
- Studies under an IND/IDE or with US site
- To meet ICMJE requirement of registration
- Keep all entries up to date
  - Changes are tracked on public site
Key Trial Results Reporting Requirements

- Report summary results at trial completion for
  - Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation
  - Trials of Devices: Controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric postmarket surveillance studies
Basic uses of ClinicalTrials.gov

- Identify trials of potential interest for specific individual
- Track progress of specific trial including access to summary results
- Identify all trials that are ongoing or completed for a given set of conditions or interventions
- Identify investigators and/or research centers participating in studies for given set of conditions or interventions
Database for the Aggregate Analysis of ClinicalTrials.gov (AACT)

Design

- Download XML dataset of all clinical studies registered with ClinicalTrials.gov as of March 27 and September 27 each year
- Designed and implemented relational database to facilitate aggregate analysis of data

Example Uses of Aggregate Data

- Examine the “Clinical Research Enterprise”
- Provide information to specific user communities
- Examine the quality and completeness of reporting

“Derived funding” used in CTTI AACT Publications

Derived from Sponsor and Collaborators fields in ClinicalTrials.gov*:

<table>
<thead>
<tr>
<th>Lead Sponsor</th>
<th>Collaborators</th>
<th>Derived</th>
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<tr>
<td>Industry</td>
<td>No restrictions</td>
<td>Industry</td>
</tr>
<tr>
<td>Not NIH</td>
<td>At least one from Industry, none from NIH</td>
<td>Industry</td>
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<tr>
<td>NIH</td>
<td>No restrictions</td>
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<tr>
<td>Not industry</td>
<td>At least one from NIH</td>
<td>NIH</td>
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<tr>
<td>Not industry, not NIH</td>
<td>None from industry, none from NIH</td>
<td>Other</td>
</tr>
</tbody>
</table>

*For definitions see: [http://prsinfo.clinicaltrials.gov/definitions.html](http://prsinfo.clinicaltrials.gov/definitions.html)
A ACT Supporting Documents

Points to Consider: guidelines for investigators to consider when planning a statistical analysis using AACT

Comprehensive Data Dictionary: a complete list of data elements from the AACT database, corresponding definitions from NLM’s data element definitions document, and data model and parameters used in the AACT database in five sections: current variables, enumerations, schema, constraints, and record counts.

Readme Files: instructions on how to implement AACT as well as critical info for database administrators and statistical programmers.

State of Clinical Trials

- AACT is available in 3 formats:
  - Oracle dmp, pipe-delimited text files, and SAS CPOR

- For an publications and products about AACT and created using the AACT database: