ClinicalTrials.gov

FDAAA 801

On the Agenda Today

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History

- 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)
- 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

Why register and submit results?

- Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) requires responsible parties to register and submit study results of clinical trials with ClinicalTrials.gov. It's the law.

- FDAAA 801 establishes penalties for responsible parties who fail to comply. These penalties include civil monetary penalties (up to $10,000/day), and for federally funded studies, the withholding of grant funds.

- The International Committee of Medical Journals Editors (ICMJE) requires trial registration as a condition for the publication of research results generated by a clinical trial.

- To enhance patient enrollment and provide a mechanism to track progress of clinical trials.

What is an Applicable Clinical Trial?

- Trials initiated after September 27, 2007 or that were initiated on or before that date and were still ongoing as of December 26, 2007
- Controlled clinical trials (other than Phase I) of FDA regulated drugs or biologics
- Controlled trials with health outcomes of FDA regulated devices and pediatric postmarket surveillance (excludes small feasibility studies)

Applicable Clinical Trials (cont'd)

- Generally include studies with one or more arms of FDA-regulated drugs, biologics, or devices that meet one of the following conditions:
  - Have more than one site in the US
  - Are conducted under an FDA investigational new drug application (IND) or investigational device exemption (IDE)
  - Involve drugs, biologics, or devices that are manufactured in the US or its territories and are exported for research

Which studies are excluded?

- Phase 1 drug trials including studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes
- Small clinical trials to determine the feasibility of a device or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes
- Trials that do not include drugs, biologics, or devices (such as behavioral interventions)
- Non-interventional (observational) clinical research, such as cohort or case-control studies
- Trials that were ongoing as of September 27, 2007, and reached the Completion Date (date that the final subject was examined or received an intervention) before December 26, 2007

Who is the Responsible Party?

- Sponsor of a clinical trial
- Principal Investigator (PI)

Registration

- ClinicalTrials.gov establishes one Protocol Registration System (PRS) account for an organization. All investigators from that organization are designated as users in this single PRS account. The organization should designate one or more PRS administrators to manage the account and create logins for additional users.

- To avoid duplicate registration, studies should be registered only by the Responsible Party (sponsor or PI)

- The Responsible Party must submit information no later than 21 days after enrollment of first participant. If a study is submitted prior to obtaining IRB approval, the recruitment status must be listed as "Not yet recruiting" until IRB approval is obtained.

Registration (cont'd)

- PRS Basics
  - Web-based data entry system for summary protocol and results information
  - Requires organizational account, user name and password
  - Contact organizational account "administrator" or email register@clinicaltrials.gov

- PRS Roles
  - Administrator: creates user accounts, edits and approves records, point of contact
  - User: creates, edits and modifies records

- For basic help with the PRS there is a Quick Start Guide in the Help section of the PRS main menu. There is also a useful presentation at the link below.
  http://prsinfo.clinicaltrials.gov/webinars/module3/resources/PRSQA_Handouts.pdf

Registration Process at USF

- Once you have determined that it is appropriate to register a study in ClinicalTrials.gov, a designated user can create a new submission.
- If you need a user account, contact Tony Marshall at amarsha7@usf.edu.
- If the submission is complete and without errors, the USF administrator will forward the submission for quality assurance (QA) review by ClinicalTrials.gov staff. They may send the submission back to you for revisions.
- Once the QA review is approved, the Responsible Party can release the record. If the Sponsor is listed as the Responsible Party, the USF Administrator will release the record.

Editing and Updating a Record

- Required Registration Updates
  - When there is a change in recruitment status or to the completion date, the record must be updated within 30 days of the change.
  - Other changes to the protocol or record must be made at least every 12 months. It is recommended that the Record Verification Date be updated at least every 6 months, even if there were no changes to the record, for studies that are not yet completed
- You may edit a record at any time by clicking on "Modify" under the Protocol Records heading in the PRS main menu. After you finish making changes, you will need to re-release (resubmit) the record to ClinicalTrials.gov for review and processing.

Submitting Results

- Generally the results of a trial involving a drug, biologic, or device that is approved, licensed, or cleared by FDA must be submitted by the Responsible Party no later than 12 months after the Completion Date (date final subject was examined or received an intervention)

- It is possible to delay the submission of results by submitting a certification but only for a certain time period and under specific circumstances. http://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhenDoINeedToRegister

- It is also possible to request an extension under certain circumstances.

Informed Consent Regulations

- In accordance with FDAAA 801, Applicable Clinical Trials are required to include a statement in the informed consent regarding the availability of clinical trial information on ClinicalTrials.gov.

  Example: "A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

Additional Information (cont'd)

Training Materials

http://clinicaltrials.gov/ct2/manage-recs/present

- Online Presentations
  - Overview of ClinicalTrials.gov and Related Policies
  - Applying for a PRS account and registering a Clinical Trial
  - Submitting Results Data

- Results Database Train-The Trainer Workshop
  - Workshop Slides
  - Example Studies for Results Data Entry (examples of study and results submissions)

Additional Information (cont'd)

- General ClinicalTrials.gov information:
  http://prsinfo.clinicaltrials.gov
- FDAAA related information:
  http://clinicaltrials.gov/ct2/manage-recs/fdaaa
- NIH Office of Extramural Research:
  Includes flowcharts for identifying applicable clinical trials and responsible parties
  http://grants.nih.gov/Clinicaltrials_fdaaa
- Frequently Asked Questions:
  http://clinicaltrials.gov/ct2/manage-recs/faq

- All information provided in this presentation can be found on ClinicalTrials.gov.

Contact: register@clinicaltrials.gov

Thank You