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Key FDAAA Issues

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http://ClinicalTrials.gov

FDAAA
Sec. 801. Expanded Clinical Trial Registry Data Bank

Enacted on September 27, 2007

- ☑ Expanded Registry [Dec 26, 2007]
- ☑ Link to Existing Results [Dec 26, 2007]
- ☑ Basic Results Database [Sept 27, 2008]
- ☑ Public Meeting [April 2009]
- ☑ Adverse Events Module [Sept 27, 2009]
- ☐ Expansion by Rulemaking [Ongoing]

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FDAAA Trial Reporting Provisions

Registration Requirements

- **Which trials?** ("applicable clinical trials"*)
  - Interventional studies of drugs, biologics, and devices
  - Not phase 1 drug or not small feasibility device
  - U.S. FDA jurisdiction (e.g., IND/IDE or U.S. site)
  - Initiated on or after 9/27/07 or ongoing as of 12/26/07
- **When must trials be registered?**
  - Register at trial initiation, but not later than 21 days after enrollment of the first participant

* http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf

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Registration Requirements (cont'd)

- **Who?**
  - Responsible party (RP)
    - Study sponsor OR
    - Sponsor-designated principal investigator (PI)
- **What information?**
  - ClinicalTrials.gov-required data elements AND
  - WHO/ICMJE*-required data elements (e.g., Primary and Secondary Outcome Measures)
- **Where?**
  - Web-based Protocol Registration System (PRS)
- **How?**
  - Online data entry or XML file upload

*World Health Organization/International Committee of Medical Journal Editors

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Basic Results Reporting Requirements

- **Which trials?**
  - "Applicable clinical trials" of **FDA-approved** medical products and registered under FDAAA
- **When must summary results be reported?**
  - Generally, submission within 12 months of the earlier of estimated OR actual trial completion date (of primary outcome)
  - Delayed Submission of Results
    - Seeking initial approval
    - Seeking approval of a new use
    - Extensions for "good cause"

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Basic Results Reporting Requirements (cont'd)

What Information?

- Participant Flow
- Baseline and Demographic Characteristics
- Primary and Secondary Outcomes
  - Scientifically appropriate tests of statistical significance
- Adverse Event Information
- Point of Contact (for scientific information)
- Certain Agreements (restrictions on PI to discuss or publish results after trial completion date)

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FDAAA Enforcement Provisions

- Notices of noncompliance
- Civil monetary penalties (up to $10,000/day)
- Withholding of NIH grant funds

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Key Considerations

Determining If the Trial Is an ACT

- Is it an interventional study?
  - Are the interventions being given as part of the research protocol?
  - Would the participants have received the interventions in the same manner and intensity, whether or not they were in the study?
- Does it include a device?
  - FDA regulatory definitions apply
  - Includes diagnostic devices (e.g., CT scan, x-ray)

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FDAAA Definition: "Responsible Party"

(I) "[T]he sponsor of the clinical trial" (as defined in FDA regulations at 21 CFR 50.3)

(II) "[T]he [PI] of such clinical trial **if so designated by a sponsor, grantee**…, so long as the [PI] is

- responsible for conducting the trial
- has access to and control over the data…
- has the right to publish the results…, and
- has the ability to meet all of the requirements…"

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Current Thinking: "Responsible Party"

- Who is the sponsor?
  - IND/IDE holder
  - NIH grantee
  - "Initiator of trial"
  - **Only one per trial!**
- Sponsor may designate the PI (under some conditions)
- RP has legal responsibilities for FDAAA
  - Others may help
  - **Only one per trial!**

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FDAAA Definition: "Completion Date"

- "Primary Completion Date" Data Element
  - "The date that the final subject was examined or received an intervention for the purposes of final collection of data for the **primary outcome**, whether the clinical trial concluded according to the prespecified protocol or was terminated."
- Issues
  - More than one primary outcome

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Additional Information

General ClinicalTrials.gov information:
http://prsinfo.clinicaltrials.gov

FDAAA-related information:
http://prsinfo.clinicaltrials.gov/fdaaa.html

Office of Extramural Research:
http://grants.nih.gov/Clinicaltrials_fdaaa/

Questions?
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