FDAAA Title VIII (PL 110-85, Section 801)
Expanded Clinical Trials Registry and Results Database

Status Report on Implementation

Theresa Toigo
Director, FDA Office of Special Health Issues

Ninth Annual Pharmaceutical and Compliance Congress and Best Practices Forum

October 28, 2008
Outline

- Overview of P.L.110-85 Title VIII
- Key Milestones
- Some Statistics
- Trial Registration
- Basic Results Database
- Compliance
- FDA-NIH Collaboration
- Other Provisions
Overview of P.L.110-85
Title VIII–Expanded Clinical Trial Registry Data Bank

• Expansion of clinical trials registry (ClinicalTrials.gov) to require submission of a broader scope of trials and more information for each trial.

• Creation of a results database

• Devices now included

• Failure to comply has consequences

• Link from registry to specified FDA & NIH results information
<table>
<thead>
<tr>
<th>Date</th>
<th>Task</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/26/2007</td>
<td>Linking to FDA information</td>
<td>• Drug Action package for Approval</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Assessment of BPCA/PREA studies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Safety and effectiveness summaries for devices</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Advisory Committee summary document(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Public Health Advisories</td>
</tr>
<tr>
<td>12/26/2007</td>
<td>Linking to NIH information</td>
<td>• Medline citation of published results</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• DailyMed structured product label</td>
</tr>
<tr>
<td>12/26/2007</td>
<td>Expanded Registry Data Elements</td>
<td>• Applicable clinical trials (ACTs) for serious or life-threatening (SLT) diseases/conditions <strong>INITIATED</strong> after 9/27/2007 or <strong>ONGOING</strong> as of 12/26/2007</td>
</tr>
<tr>
<td>12/26/2007</td>
<td>Certification to FDA</td>
<td>• Certification to Accompany Drug, Biological Product, and Device Applications or Submissions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Include NCT numbers where applicable</td>
</tr>
<tr>
<td>12/26/2007</td>
<td>Expanded Registry Scope</td>
<td>For ALL diseases/conditions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FDA-regulated drugs, biologics, and devices</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• For drugs/biologics regulated under section 505 of FDCA or section 351 of PHS Act: controlled trials other than Phase I (i.e., phase II-IV (post marketing))</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• For devices regulated under sections 510(k), 515, or 520(m) of FDCA: prospective study of health outcomes, plus pediatric postmarket surveillance</td>
</tr>
</tbody>
</table>
# Milestones

<table>
<thead>
<tr>
<th>Date</th>
<th>Task</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/27/2008</td>
<td>Basic Results Reporting</td>
<td>• Demographic and Baseline Characteristics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Primary and Secondary Outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Point of Contact, Information on Agreements</td>
</tr>
<tr>
<td>9/27/2008</td>
<td>Expanded Registry Scope</td>
<td>• Expanded data elements for <strong>NON-SLT</strong> trials ONGOING as of 9/27/2007</td>
</tr>
</tbody>
</table>
## Milestones

<table>
<thead>
<tr>
<th>Date</th>
<th>Task</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/27/2009 (or)</td>
<td>Adverse Events (for drugs subject to Basic Results requirements)</td>
<td>• Rulemaking (or)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Default</td>
</tr>
<tr>
<td>9/27/2009</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/27/2009</td>
<td>Public Meeting to discuss regulations to be issued regarding expanded registry and results data bank</td>
<td>• Unapproved products?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Summaries of trial and results (if not misleading or promotional)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Protocol/information?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Timing of reporting results</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• And more</td>
</tr>
</tbody>
</table>
## Milestones

<table>
<thead>
<tr>
<th>Date</th>
<th>Task</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/27/2010</td>
<td>Expansion of registry and results data bank by Rulemaking</td>
<td>• Unapproved products?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Summaries of trial and results (if not misleading or promotional)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Protocol/information?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Timing of reporting results</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• And more</td>
</tr>
</tbody>
</table>
ClinicalTrials.gov Statistics
(as of 9/15/2008)

<table>
<thead>
<tr>
<th>Organization</th>
<th>Number of Records</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH and other Federal</td>
<td>17,580</td>
<td>29%</td>
</tr>
<tr>
<td>Industry</td>
<td>18,624</td>
<td>30%</td>
</tr>
<tr>
<td>Other organizations</td>
<td>25,461</td>
<td>41%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>61,665</strong></td>
<td></td>
</tr>
</tbody>
</table>
# ClinicalTrials.gov Statistics

*(as of 9/15/2008)*

<table>
<thead>
<tr>
<th>Type of Trial*</th>
<th>Number of Records</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>61,665</td>
<td>100%</td>
</tr>
<tr>
<td>Observational</td>
<td>9,577</td>
<td>16%</td>
</tr>
<tr>
<td>Intervventional</td>
<td>51,982</td>
<td>84%</td>
</tr>
<tr>
<td>Drug &amp; Biologic</td>
<td>39,182</td>
<td></td>
</tr>
<tr>
<td>Surgical Procedure</td>
<td>8,032</td>
<td></td>
</tr>
<tr>
<td>Device</td>
<td>3,342</td>
<td></td>
</tr>
<tr>
<td>Behavioral, Gene Transfer, Other</td>
<td>6,921</td>
<td></td>
</tr>
</tbody>
</table>

* 106 records missing Study Type Information
## ClinicalTrials.gov Statistics
*(as of 9/15/2008)*

<table>
<thead>
<tr>
<th>International Sites</th>
<th>Number of Records</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>US Only</td>
<td>30,247</td>
<td>50%</td>
</tr>
<tr>
<td>Non-US Only</td>
<td>20,487</td>
<td>33%</td>
</tr>
<tr>
<td>US and Non-US mixed</td>
<td>4,592</td>
<td>7%</td>
</tr>
<tr>
<td>Missing</td>
<td>6,339</td>
<td>10%</td>
</tr>
</tbody>
</table>
Which Trials Must Be Registered?

Applicable Drug Clinical Trial

“(I) IN GENERAL – The term ‘applicable drug clinical trial’ means a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

“(II) CLINICAL INVESTIGATION – For purposes of subclause (I), the term ‘clinical investigation’ has the meaning given that term in section 312.3 of title 21, Code of Federal Regulations (or any successor regulation).

“(III) PHASE I – For purposes of subclause (I), the term ‘phase I’ has the meaning given that term in section 312.21 of title 21, Code of Federal Regulations (or any successor regulation).
Which Trials Must Be Registered?

ii) APPLICABLE DEVICE CLINICAL TRIAL – The term ‘applicable device clinical trial’ means—

“(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial 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); and”

“(II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.”

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110
Who is Required to Register?

“Responsible party:”

(1) The sponsor of the clinical trial (as defined in 21 CFR 50.3); or

(2) The principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this subsection for the submission of clinical trial information.

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110
Basic Results Information
Statutory Requirements

• Demographic & baseline characteristics of patient sample
  – Table of values, overall and for each arm
  – Including # of patients dropped out & # excluded from analysis

• Primary and secondary outcomes (as submitted to registry)
  – Table of values for each primary & secondary outcome measure, by arm
  – Results of scientifically appropriate tests of the statistical significance

• Point of contact (for scientific information about results)

• Certain agreements (restrictions on PI to discuss or publish results after trial completion date)

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110
If the Secretary fails to issue regulation by 24 months after the date of enactment [September 27, 2009]

SERIOUS ADVERSE EVENTS
- Table of anticipated & unanticipated serious adverse events
- Grouped by organ system
- Number and frequency of event in each clinical trial arm

FREQUENT ADVERSE EVENTS
- Table of anticipated & unanticipated adverse events not included in “serious adverse events” table
- Exceed a frequency of 5 percent within any trial arm
- Grouped by organ system
- Number and frequency of event in each trial arm
Finding Results at ClinicalTrials.gov

• From Homepage (http://clinicaltrials.gov) go to “Advanced Search”
  – Select “Studies with Results” from the menu for the Study Results field
  – Select study record from results list
  – Click “Study Results” tab

• Step-by-step screen shots on next slides
Fill in any or all of the fields below.

Click on a label to the left for further explanation or read the Help.

**Search Terms:**

**Recruitment:** All Studies

**Study Results:** Studies With Results

**Study Type:**
- All Studies
- Studies With Results
- Studies Without Results

**Targeted Search:**

**Conditions:**

**Interventions:**

**Sponsors:**

**Study IDs:**

**Locations:**

1. **State:** --- Optional ---
   **Country:** --- Optional ---

2. **State:** --- Optional ---
   **Country:** --- Optional ---

3. **State:** --- Optional ---
   **Country:** --- Optional ---

**Location Terms:**

**Additional Criteria:**
Found 1 study with search of: Studies With Results

Hide studies that are not seeking new volunteers.

1 Completed
Has Results

Bimatoprost 0.03% Versus Travoprost 0.004% in Patients Currently on Latanoprost 0.005%

Conditions: Glaucoma; Ocular Hypertension

Interventions: Drug: bimatoprost 0.03% eye drops; Drug: travoprost 0.004% eye drops

RSS Feed for studies found by your search that were received in the last 14 days

Download Options
Bimatoprost 0.03% Versus Travoprost 0.004% in Patients Currently on Latanoprost 0.005%

This study has been completed.

**Purpose**

Patients with glaucoma or ocular hypertension currently being treated with latanoprost 0.005%, and in need of additional IOP lowering, will be randomized to receive either bimatoprost 0.03% or travoprost 0.004% in place of latanoprost 0.005%.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glaucoma</td>
<td>Drug: bimatoprost 0.03% eye drops</td>
<td></td>
</tr>
<tr>
<td>Ocular Hypertension</td>
<td>Drug: travoprost 0.004% eye drops</td>
<td></td>
</tr>
</tbody>
</table>

**Genetics Home Reference** related topics: early-onset glaucoma

**MedlinePlus** related topics: Glaucoma, High Blood Pressure

**ChemIDplus** related topics: Latanoprost, Tetrahydrozoline, Tetrahydrozoline hydrochloride, Travoprost, Bimatoprost

**U.S. FDA Resources**

Study Type: Interventional
Study Design: Treatment, Randomized, Single Blind (Investigator), Active Control, Parallel Assignment, Safety/Efficacy Study
Bimatoprost 0.03% Versus Travoprost 0.004% in Patients Currently on Latanoprost 0.005%

This study has been completed.

Study NCT00440011. Last updated on September 25, 2008. Information provided by Allergan

| Study Type: | Interventional |
| Study Design: | Randomized, Single Blind (Investigator), Active Control, Parallel Assignment |
| Conditions: | Glaucoma, Ocular Hypertension |
| Interventions: | Drug: bimatoprost 0.03% eye drops, Drug: travoprost 0.004% eye drops |

► Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

No text entered.

Reporting Groups
Compliance

• Reporting requirements (registration and results)

• Certification of compliance with law
  – HHS Grants
  – FDA drug/biologic/device applications/submissions

• Prohibited Acts
  – Failure to submit certification
  – Knowingly submitting false certification
  – Failure to submit or submitting false or misleading clinical trial information

• Failure to comply may result in:
  – Withholding remaining or future grant funding
  – Public notice of failure in registry/results data bank
  – Civil monetary penalties
# Compliance: Some FDA Considerations

<table>
<thead>
<tr>
<th>Task</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop Certification Form</td>
<td>12/21/07 posted on FDA.gov</td>
</tr>
<tr>
<td>Prepare Burden Document</td>
<td>FR Notices 12/7/07 and 3/5/08</td>
</tr>
<tr>
<td>Notify FDA Grantees</td>
<td>12/21/07 via email</td>
</tr>
<tr>
<td>Develop Definitions in collaboration with NIH (ACTs, responsible party)</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Develop Guidance on certification requirement</td>
<td>FR Notice 4/18/08 (draft guidance)</td>
</tr>
<tr>
<td>Informed Consent-- Update IND regulations to require (in informed consent documents and process) a statement that clinical trial information has been or will be submitted to registry</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Add paragraph to investigational and marketing application/submission letters (acknowledgement and approval)</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>
Compliance Certification Form and Draft Guidance

Federal Register Notice
http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.pdf (pdf)

Certification Form (Form FDA 3674 1/08)

Draft Guidance
http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html

FDAAA Web site
http://www.fda.gov/oc/initiatives/advance/fdaaa.html
If Form 3674 is not included, you will see language in the acknowledgement letters. For example,

Please note that you are responsible for complying with the applicable provisions of sections 402(j) and 402(j) of the Public Health Service Act (PHS Act) (42 USC §§ 282(j) and (j)), which was amended by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law No. 110-85, 121 Stat. 904). Title VIII of FDAAA amended the PHS Act by adding new section 402(j) (42 USC § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. FDAAA requires that, at the time of submission of an application under section 505 of the FDCA, the application must be accompanied by a certification that all applicable requirements of 42 USC § 282(j) have been met. Where available, the certification must include the appropriate National Clinical Trial (NCT) control numbers. 42 USC 282(j)(5)(B). You did not include such certification when you submitted this application. You may use Form FDA 3674, Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank, to comply with the certification requirement. The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/default.html.

In completing Form FDA 3674, you should review 42 USC § 282(j) to determine whether the requirements of FDAAA apply to any clinical trials referenced in this application. Additional information regarding the certification form is available at: http://internet-dev.fda.gov/cder/regulatory/FDAAA_certification.htm. Additional information regarding Title VIII of FDAAA is available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html. Additional information on registering your clinical trials is available at the Protocol Registration System website http://prsinfo.clinicaltrials.gov/.
Certification Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(8)(B), with
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

<table>
<thead>
<tr>
<th>SPONSOR / APPLICANT / SUBMITTER INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. NAME OF SPONSOR/APPLICANT/SUBMITTER</td>
</tr>
<tr>
<td>2. DATE OF THE APPLICATION/SUBMISSION IN WHICH THIS CERTIFICATION ACCOMPANIES</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRODUCT INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. FOR DRUG/DEVICE: Include Any/All Common, Proprietary, and/or Common/Proprietary/Diagnostic/Therapeutic Product Name(s)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>FOR SERVICE: Include Any/All Common, Proprietary, or/and Model Name(s), Classification, Traits or Proprietary or Model Name(s) and/or Model Number(s)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>APPLICATION / SUBMISSION INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. TYPE OF APPLICATION/SUBMISSION IN WHICH THIS CERTIFICATION ACCOMPANIES</td>
</tr>
<tr>
<td>IND</td>
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<table>
<thead>
<tr>
<th>SERIAL NUMBER AS OF 10-14-06</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. INCLUDE INDIANAMERINDIANA510(k) PPD/OTHER NUMBER (If number previously assigned)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CERTIFICATION STATEMENT / INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)</td>
</tr>
<tr>
<td>A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.</td>
</tr>
<tr>
<td>B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.</td>
</tr>
<tr>
<td>C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>NCT Number(s):</th>
</tr>
</thead>
</table>

FDA-NIH Collaboration: Working Groups

- FDA Notification to NIH
- Pilot Quality Control Study
- NIH Linking to FDA Documents
- Compliance/Enforcement
- Public Meeting
- Results Databases
- Risk Communication
FDA-NIH Collaboration: FDA Notification to NIH

• FDA Commissioner to inform Director, NIH of certain actions on applications/submissions that were accompanied by a certification form

• For such applications/submissions seeking initial approval/clearance/licensure of drug/biologic/device, at time of:
  – approval
  – licensure
  – clearance

• For such applications/submissions seeking approval of new use for previously approved/cleared/licensed drug/biologic/device, at time of:
  – approval of new use
  – licensure of new use
  – clearance of new use
  – issuance of letter, such as a complete response letter, not approving, not clearing, not approvable, not substantially equivalent
  – application or premarket notification withdrawn without resubmission for no less than 210 days

Note: actions that trigger FDA notice to NIH also trigger requirements to submit results information to the results data bank.
FDA-NIH Collaboration: Quality Control

Pilot Study

• NIH and FDA to conduct pilot study to determine optimal method of verification to help to ensure submitted clinical trial information is non-promotional and not false or misleading.

• Study to use publicly available information and other information available to Department to verify accuracy of information submitted to Basic Results data bank
FDA-NIH Collaboration: Linking

- Secretary shall ensure that, for trials that form the primary basis of an efficacy claim or are conducted post-approval/clearance, registry includes links to results information on such trials
  - from FDA Advisory Committee summaries
  - FDA assessments under 505A and B (BPCA and PREA)
  - Public Health Advisories
  - action packages for approval (for drugs)
  - safety and effectiveness summaries (for devices)
FDA-NIH Collaboration: Linking

FDA Resources on Drugs and Devices

Drug and Device Information from the US Food and Drug Administration

CDER - Center for Drug Evaluation and Research
CDRH - Center for Devices and Radiological Health
CBER - Center for Biologics Evaluation and Research

Drug Action Packages
Drugs@FDA - drug products approved by CDER at FDA
Approved Biologics - drug products approved by CBER at FDA

Device Approval Packages
PMA CDER - device premarket approval applications
PMA CBER - biologic device premarket approval applications
510(k) CDRH - device premarket notifications
510(k) CBER - biologic device premarket notifications

Drug and Device Safety Information
MedWatch - FDA safety information and adverse event reporting program
Public Health Advisories - drug-related warning statements
Drug Safety Initiative - variety of information about drug safety issues
Medical Device Safety - device recalls, alerts, and other safety information
Device Public Health Notifications - risks associated with the use of medical devices
Biologics Safety Information - safety notifications by CBER

Purpose
RATIONALE: Chemoprevention therapy is the use of certain drugs to try to prevent the development of cancer. Anastrozole may be effective in preventing breast cancer.

PURPOSE: This randomized clinical trial is studying how well anastrozole works in preventing breast cancer in postmenopausal women who are at increased risk for the disease.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Cancer</td>
<td>Drug: anastrozole</td>
</tr>
<tr>
<td></td>
<td>Procedure: aromatase inhibition therapy</td>
</tr>
<tr>
<td></td>
<td>Procedure: chemoprevention</td>
</tr>
</tbody>
</table>

Genetics Home Reference related topics: breast cancer
MedlinePlus related topics: Breast Cancer

U.S. FDA Resources
Study Type: Interventional
Study Design: Prevention, Randomized, Double-Blind, Placebo Control

Other Relevant Information
Advisory Committee Materials - may discuss efficacy and safety of drugs and devices and summarize results of clinical trials
Section 506A Reviews - summaries of reviews of pediatric studies
Pediatric Exclusivity Labelling - pediatric exclusivity labelling changes
Section 506A Labelling Changes - Pediatric Research Equity Act (PREA) labelling changes

http://clinicaltrials.gov/ct2/info/fdalinks
FDA-NIH Collaboration: Linking
What’s so complicated?

• For trials that form the primary basis of an efficacy claim, the registry should include links to results information on such trials
  – from FDA Advisory Committee summaries
  – FDA assessments under 505A and B (BPCA and PREA)
  – Public Health Advisories
  – action packages for approval (for drugs)

• FDA documents do not currently include NCT numbers
What are some IT implications for Certification, Notification and Linking?

- NCT numbers provide a framework for linking between the FDA and the NIH websites.
- FDA databases are not yet equipped to capture NCT numbers and certification form information…not so easy.
- How can we use FDA document tracking systems to support project tasks?
- Industry and Academia have some IT challenges, too.
FDA-NIH Collaboration: Public Meeting

Public meeting within 18 months to solicit input from interested parties regarding regulations. Regulations to address:

- Standard Format
- Nontechnical summary of trial and results for patients (if can be included without being misleading or promotional)
- Procedures to ensure that data elements are not false or misleading and are non-promotional
- Results required for unapproved/not cleared products?
- Full protocol?
- Changes in timing/updates for submissions?
Additional Information

FDA

- General FDAAA information

- Questions?
  - FDAAACLINICALTRIALS@FDA.HHS.GOV

NLM

- Email LISTSERV and other FDAAA information:
  - [http://prsinfo.clinicaltrials.gov/fdaaa.html](http://prsinfo.clinicaltrials.gov/fdaaa.html)

- Other general information:
  - [http://prsinfo.clinicaltrials.gov](http://prsinfo.clinicaltrials.gov)

- Questions?
  - prsinfo@clinicaltrials.gov
Thank You

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