ClinicalTrials.gov: A Review of Registration Requirements

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Be aware that...

- Any PowerPoint presentation can only be an introduction to a topic.
- This subject is complex – this will point you to many other resources – and I am happy to assist you further.
- PowerPoint bullets are neither the law nor the regulations that apply.
Learning Objectives

- Explain what ClinicalTrials.gov is and what it can do
- Explain why you should register your study
- Identify who is responsible for registration
- Provide practice examples
- Explain how registration works at BCH
- Review the registration process
- Help Resources (institutional & national)
What is ClinicalTrials.gov?

Why should I be concerned?
http://www.ClinicalTrials.gov
Rationale for CT.gov

• Increase research transparency
• Help people find trials

To learn more, visit: http://clinicaltrials.gov/ct2/manage-recs/background
ClinicalTrials.gov is a service of the U.S. National Institutes of Health. ClinicalTrials.gov can be searched in real time to find enrolling and completed studies including:

- Conditions
- Interventions
- Outcome measures
- Sponsors/collaborators
- Locations
- Phases
- Dates (Start and Completion)
- Results
Evolution of Clinical Trial Disclosure Requirements

• 1997: FDAMA establishes ClinicalTrials.gov
• 2000: ClinicalTrials.gov launched
• 2005: ICMJE requires registration of trials (including at ClinicalTrials.gov)
• 2007: FDAAA expands ClinicalTrials.gov to require registration of more studies and results and adds penalties for noncompliance
• 2008: ClinicalTrials.gov adds basic results modules, including adverse events

Source: [http://clinicaltrials.gov/ct2/about-site/history](http://clinicaltrials.gov/ct2/about-site/history)
Why should I register a trial in ClinicalTrials.gov?
# 1 It’s the law!

FDA Amendments Act of 2007 (FDAAA)
Most prospective clinical trials involving regulated drugs, biological products, and devices must be registered on ClinicalTrials.gov. (The law also requires reporting of results and adverse events for a subset of these studies.)

To learn more about FDAAA 801 Requirements, visit: http://clinicaltrials.gov/ct2/manage-recs/fdaaa
FDAAA - Registration

Required for “Applicable Clinical Trials”:

- Interventional studies (drugs, biologics, devices)
- Phase 2 – 4 (not phase 1 drug; not small feasibility device;)
- US FDA jurisdiction (e.g., IND/IDE or US site)
- Studies initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007

When:

- Within 21 days of enrollment of 1st subject
- Update at least every 12 months (30 days for Recruitment Status and Primary Completion Date)

http://clinicaltrials.gov/ct2/manage-recs/fdaaa
FDAAA – Registration Requirements for Drugs/Biologics

• Is it a *Clinical Investigation*?
  – Defined as “any experiment in which a drug is administered or dispensed to one or more human subjects

• Is the clinical investigation *controlled*?
  – Is it designed to permit a comparison of a test intervention with a control to provide a quantitative assessment of the drug effect?
  – Concurrent & Non-concurrent controls

• Is the clinical investigation *other than a phase 1* clinical trial?
  – Per FDAAA, Phase 1 includes initial introduction of an investigational drug into humans, metabolism, and pharmacologic actions of a drug, mechanism of action, and early evidence of effectiveness
FDAAA – Registration Requirements for Devices

• Is it a prospective study of *health outcomes*?
  – FDAAA defines ‘health outcome’ where primary purpose is to evaluate a defined clinical outcome directly related to human health

• Does the study ‘compare an *intervention with a device against a control* in human subjects’?
  – ‘Intervention defined broadly to include various techniques using the device such as (among other things): device regimens and procedures, use of prophylactic, diagnostic, or therapeutic agents’

• Is the clinical study other than:
  – a small clinical trial to determine the feasibility of a device
  – a clinical trial to test prototype devices (primary outcome measure related to feasibility, not to health outcomes)
FDAAA – the details matter

• NIH Elaboration Document:

It’s the law (a final detail)

• Some Phase I trials, though they are not Applicable Clinical Trials under FDAAA, are required to register under FDAMA – the earlier law -- which is still in effect.

• These involve primarily experimental treatments for serious or life-threatening diseases whether using an IND, Group C Cancer drug, or other FDA regulated product.

• Thus, many studies for cancer and other serious and life-threatening diseases must register regardless of Phase.

For more information:
FDAAA – Results Submission

Required for:
- Applicable Clinical Trials
- In which the study product is approved (for any use) by FDA

When:
- Within 12 months of Primary Completion Date (final data collection for primary endpoint)
- If product not approved by Primary Completion Date but is approved later, then results due 30 days after approval
- Delays are possible, primarily for manufacturer or under limited special circumstances
  - Pending publication is NOT considered a good cause for delay

http://clinicaltrials.gov/ct2/manage-recs/fdaaa
#2 You Want to Publish!

International Committee of Medical Journal Editors (ICMJE)

• Requires registration in a publicly available, searchable system.

• Scope is broader than FDAAA (i.e., all clinical trials).

• Includes 1000+ journals that have adopted the ICMJE policy, such as BMJ, JAMA, and NEJM.

Source: [http://www.icmje.org/journals.html](http://www.icmje.org/journals.html)
ICMJE – Registration: Which studies?

Required for Prospective studies that:

• Assign subjects to an intervention with or without concurrent comparison or control groups
• Study the cause/effect relationship between medical intervention and a health outcome.

ICMJE scope is much broader than the scope of FDAAA:

• *Interventions* include *procedures, behavioral treatments, dietary interventions*

• *Health outcomes* include any biomedical or health-related measure obtained in participants, including *pharmacokinetic measures* and adverse events

Source: [http://www.icmje.org/publishing_10register.html](http://www.icmje.org/publishing_10register.html)
ICMJE - Registration

• When to register:
  • Prior to enrollment of 1st subject

• ICJME doesn’t require results submission

• ICMJE will not consider results data posted in the tabular format required by ClinicalTrials.gov to be prior publication

Source: [http://www.icmje.org/publishing_10register.html](http://www.icmje.org/publishing_10register.html)
One more reason to register...
Clinical research billing compliance

- BCH is required to report the 8-digit ClinicalTrials.gov number (NCT#) on insurance claims for items and services that are provided to patients in clinical trials.
- The Clinical Trials Business Office oversees billing and billing compliance for clinical research at BCH.
- Expect to hear more about this office in the near future. Changes to the way study teams report subject visits (to facilitate the billing process) are forthcoming.
- For more information, contact Nick Repucci at 4-4611 or nicholas.repucci@childrens.harvard.edu.
Policy Requirements – Recap

FDAAA Results & AE Reporting

FDAAA and FDAMA Registration

ICMJE Registration
Who is responsible for registering?
Who is responsible for registering the trial?

**ICMJE:**
Anyone can register, but the author is responsible for ensuring complete registration

**FDAAA:**
The **Responsible Party** (RP) defined as...
- The Sponsor (or Sponsor-Investigator):
  - IND/IDE holder
  - If no IND/IDE, the industry, academic institution or other organization that initiated the study
FDAAA: Designation of Responsible Party

• RP can be designated by the Sponsor to a PI who:
  • Is responsible for conducting the study
  • Has access to and control over the data
  • Has the right to publish the trial results, AND
  • Has the ability to meet the requirements

• Example of RP designation
  • PI initiated study at Boston Children’s and is funded by NHLBI
    o BCH is the Sponsor (grant funding recipient)
    o BCH can be the RP, but will designate the PI as the RP (when the above 4 criteria are met)
Who is the RP? Let’s practice...

1. Department funded/ PI initiated research
2. NIH funded research/ Children’s is the grantee institution (no IND/IDE)
3. Pharmaceutical company funded research/ multi-center study including site at Children’s
4. Device company funded research/ Children’s PI is the IDE holder
5. Cooperative Group study
What happens if I don’t register?
Consequences of Noncompliance

FDAAA

• Public notices of noncompliance and violations
• Withholding of NIH funds
• FDA sanctions
• Civil monetary penalties (up to $10,000/day)

ICMJE

• Cannot publish in journals following ICMJE policy, and other select journals
What are my responsibilities for the following studies? Hmmm...
Study #1

Effectiveness of Bupropion for Treating Nicotine Dependence in Young People

• Study Design: Multi-center, Randomized, Efficacy Study
• Interventions: Bupropion, Placebo
• Primary Outcome: Smoking behavior over 6 months

Register for FDAAA and/or ICMJE?
Who is the Responsible Party?
Submit Results?
Study #2

*Effects of Chronic Sleep Restriction in Young and Older People*

- Study Design: Open label, Crossover Assignment
- Interventions: Chronic sleep restriction
- Primary Outcome: Changes in sleep and waking EEG measures, frequent measures of performance, attention, alertness
- Other fact: Two universities collaborating, Dr. A @ AU and Dr. B at BU; Dr. B designed study, but A will enroll more

*Register for FDAAA and/or ICMJE?*  
*Who is the Responsible Party?*  
*Submit Results?*
Study #3

Assess the impact on Quality of Life (QoL) of long term caregivers of patients with multiple sclerosis

• Centers/sample size: Multi-site, 450 subjects
• Intervention/method: Caregivers take QoL survey monthly for 2 years
• Other fact: Funded by Pharmaceutical Co.

Register for FDAAA and/or ICMJE?

Who is the Responsible Party?

Submit Results?
Study #4

*Implantable device designed to relieve the symptoms of heart failure through counter-pulsation technology*

- Study Design: Open Label
- Intervention: Implantable device (IDE obtained)
- Primary outcome: to test the feasibility of the device
- 8 people enrolled, 6 month study

*Register for FDAAA and/or ICMJE?*  
*Who is the Responsible Party?*  
*Submit Results?*
Study #5 – Last one

*Hip Fracture Study*

- Method: Compile data from electronic medical record (EMR) over a two year period for 1700 subjects
- Data elements: smoking status, use of alcohol, bone marrow density, weight, and height
- Primary Outcome: Determine the validity of a new hip fracture risk assessment method compared to FRAX, World Health Organization’s fracture risk tool

*Register for FDAAA and/or ICMJE?*

*Who is the Responsible Party?*

*Submit Results?*
What is the FDAAA requirement for informed consent language?
FDA Mandated Informed Consent Language

• The FDA has added a new element of consent that is required for “applicable clinical trials.” All applicable clinical trials are required to include this new element of consent by March 7, 2012.

• By federal regulation, the required language must be incorporated verbatim and cannot be altered in any way. “A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US 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.”

• Subjects who were consented before March 7, 2012 will NOT have to be re-consented or otherwise sign addendum consent with this language. For more information or questions, contact the Children’s IRB office.
Reasons to Register & Use Informed Consent Language

FDAAA Results & AE Reporting
FDAAA and FDAMA Registration
ICMJE Registration

Looking for Participants
Ok, I’m ready to register. Where do I start?
New User Access

- Provide the following information to your PRS Administrator,

  **Irine Breytburg** ([irine.breytburg@childrens.harvard.edu](mailto:irine.breytburg@childrens.harvard.edu)):
  - BCH Username
  - BCH Employee Number
  - Full name (e.g., John J Smith, MD)
  - Email address

- PRS Administrator sends profile request to ClinicalTrials.gov

- ClinicalTrials.gov emails Investigator/staff notifying of account & provides temporary password (within 2 days)

- You may now log into the ClinicalTrials.gov Protocol Registration System: [https://register.clinicaltrials.gov/](https://register.clinicaltrials.gov/)
Responsibilities of an Owner of Study Records on ClinicalTrials.gov.....

• You are responsible for maintaining the study records associated with your account.

• When you enter information about the study, please ensure the information is correct, readily understood by the public, and updated in a timely manner.

• Only one owner can be assigned to a study record, but the owner can also allow other users to edit the study record. Use the Access List.
ClinicalTrials.gov Login Page

Log in:  https://register.clinicaltrials.gov/

Organization Name = childrensh
ClinicalTrials.gov Menu

After log in:

**Blue Menu box** is what everyone sees.

Check out the Help on the Blue Menu.

<table>
<thead>
<tr>
<th>Protocol Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create</td>
</tr>
<tr>
<td>Modify</td>
</tr>
<tr>
<td>View</td>
</tr>
<tr>
<td>QA Review Comments</td>
</tr>
<tr>
<td>Problems: aleishachappell Records</td>
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<tr>
<td>Undelete</td>
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<table>
<thead>
<tr>
<th>User Account</th>
</tr>
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<tbody>
<tr>
<td>Change password</td>
</tr>
<tr>
<td>Modify Information</td>
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<tr>
<td>PRS Administrator(s)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Help</th>
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<tbody>
<tr>
<td>Quick Start Guide</td>
</tr>
<tr>
<td>Frequently Asked Questions (FAQ)</td>
</tr>
<tr>
<td>Responsible Party FAQ</td>
</tr>
<tr>
<td>What’s New Jul 23, 2012</td>
</tr>
<tr>
<td>User’s Guide</td>
</tr>
<tr>
<td>Protocol Data Element Definitions</td>
</tr>
<tr>
<td>Results Data Element Definitions</td>
</tr>
<tr>
<td>Protocol Review Criteria</td>
</tr>
<tr>
<td>Results Review Criteria</td>
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<tr>
<td>FDAMA 113 Requirements</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>XML Upload</th>
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</thead>
<tbody>
<tr>
<td>Upload protocol records</td>
</tr>
<tr>
<td>Check upload status</td>
</tr>
<tr>
<td>Protocol XML Schema</td>
</tr>
<tr>
<td>Results XML Schema</td>
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<tr>
<td>Results Pick-list Normalization</td>
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<tr>
<td>Upload from NCI CTRP</td>
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<tr>
<th>Session</th>
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<tbody>
<tr>
<td>Logout</td>
</tr>
</tbody>
</table>

To Create a new protocol record, Click on “Create”
ClinicalTrials.gov –
Basic Registration Information

• Description of study
  – Study type, Phase, Design, Outcome measures

• Recruitment information
  – Eligibility criteria, locations, recruitment status

• Administrative and other information
  – Key dates and contact information

Have your study protocol handy!
# Registration in Create/Modify View

<table>
<thead>
<tr>
<th><strong>Unique Protocol ID:</strong> <em>FDAAA</em></th>
<th>Enter sponsoring organization's unique identifier.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brief Title:</strong> <em>FDAAA</em></td>
<td>Use lay language. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer</td>
</tr>
<tr>
<td><em>(Special characters)</em></td>
<td></td>
</tr>
<tr>
<td><strong>Acronym:</strong></td>
<td>If there is an acronym or abbreviation used to identify this study, enter it here.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Official Title:</strong></td>
<td>Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Study Type:</strong> <em>FDAAA</em></td>
<td>○ Interventional</td>
</tr>
<tr>
<td></td>
<td>○ Observational</td>
</tr>
<tr>
<td></td>
<td>○ Expanded Access. About expanded access records</td>
</tr>
<tr>
<td><strong>FDA Regulated Intervention?</strong> <em>FDAAA</em></td>
<td>Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulations.</td>
</tr>
<tr>
<td><strong>IND/IDE Protocol?</strong> <em>FDAAA</em></td>
<td>Indicate whether the protocol is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE).</td>
</tr>
</tbody>
</table>
Board Approval

If review board approval has been granted, enter the approval number below. If the board does not assign numbers, enter date in mm/dd/yyyy format. Please send a signed board approval letter to ClinicalTrials.gov (address and instructions).

Status: --Select--  Approval Number: 

Committee on Clinical Investigation

Boston Children’s Hospital

NOTE: Incomplete review board information may delay publication of the trial on ClinicalTrials.gov.

Business Phone: 617-355-7052  Extension: 
Business Email: cci@childrens.harvard.edu
Business Address: 

300 Longwood Avenue
Boston, MA 02115

Has a group been appointed to monitor safety and scientific integrity of the study?

--Select--

Enter, in English, country followed by organization name.  [List of oversight authorities]

Examples:
United States: Food and Drug Administration
Germany: Federal Institute for Drugs and Medicinal Devices

IND/IDE = FDA
No IND/IDE = IRB
Responsible Party versus Owner

Anyone can be the owner of a study. Owners are often Study Coordinators or study team members, and assist the Responsible Party with data entry.

The Responsible Party (RP) is **legally** responsible for registering their study record on ClinicalTrials.gov, ensuring accuracy, and making sure that the content is up-to-date. An RP must “Approve” and “Release” a study record onto ClinicalTrials.gov.

• Identification of RP
  – Sponsor – Organization that *initiates* the study, or
  – Principal Investigator (PI), *IF* designated as the RP by the Sponsor Organization, or
  – Sponsor-Investigator – Individual who both initiates and conducts

Owners and RP must be Protocol Registration System (PRS) users of the organizational account.
Responsible Party Designation

NOTE: The Sponsor option should be selected, unless the Investigator has been designated as Responsible Party as permitted under US Public Law 110-85, the FDA Amendments Act (FDAAA).

Principal Investigator ▼ About Responsible Party...

For Principal Investigator or Sponsor-Investigator only, provide:

Select the PRS account of the investigator. The Full Name from the selected account must be a person's name. It will be displayed on ClinicalTrials.gov.

Investigator Name [Username]: ▼ --Select--

Investigator Official Title:

Investigator Affiliation:

Sponsor ▼ FDAAA

Include all additional funding sources.

Enter only the organization names, one per line (no numbers, dashes, bullets, etc.).
Tips:

- Brief Title and Summary should be in lay language

- Overall Recruiting Status and Recruiting Status in the locations must match

- Dates are needed for Study Start Date, and Primary and Study Completion Dates

- Change the Verification Date to the current month and year (this updates the record)
Observational: Studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.

Interventional: Studies in human beings in which individuals are assigned based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.

Hints:
- Randomized studies are interventional.
- Studies with investigational drugs or devices are likely to be interventional.

Definitions above are from ClinicalTrials.gov Protocol Data Element Definitions:
https://register.clinicaltrials.gov/prs/html/definitions.html
How to Enter Outcome Measures

Outcome measure information:
Please be as specific as possible.

- **Title:** include the name of the specific measure. Avoid using verbs, that is, do not put “To determine…”

- **Time Frame:** must have a time point at which the outcome is assessed for the specific metric used (hours, days, weeks, years) Hint: specify which study day it is measured - do not use “until the end of study or death.”

- **Description:** describes what will be measured, not why it is measured. If the outcome measure is a questionnaire or scale, provide the range and what low or high scores mean.

- **Safety Issue:** Is this outcome measure assessing a safety issue?

- **Guidance on outcome measure timeframes**
Example of Problematic Primary Outcome Measure

<table>
<thead>
<tr>
<th><strong>Title:</strong> Enter only one distinct outcome measure.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Time Frame:</strong> During schedule treatment period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea Scale</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Safety Issue?</strong> Does this outcome measure assess a safety issue?</th>
</tr>
</thead>
<tbody>
<tr>
<td>--Select--</td>
</tr>
</tbody>
</table>

Tip: Refer to the [Protocol Review Criteria](#) to avoid problems with specification of Outcome Measures.
**Example of Corrected Primary Outcome**

### Primary Outcome Measure

Tip: Refer to the Protocol Review Criteria to avoid problems with specification of Outcome Measures.

<table>
<thead>
<tr>
<th>Title: *</th>
<th>Number of Participants improved on the nausea scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time Frame: (FILL)</td>
<td>8 weeks</td>
</tr>
<tr>
<td>Description:</td>
<td>Nausea scale range: 1 (severe) to 10 (none). Change: score at 8 weeks minus score at baseline. &quot;Improved&quot; = greater than 3 point difference in nausea scale.</td>
</tr>
<tr>
<td>Safety Issue? (FILL)</td>
<td>No</td>
</tr>
</tbody>
</table>

* Secondary Outcome Measure fields require same information
### Study Arms

| Arm: *(FDAAA)* | Experimental: Acetaminophen & Tramadol  
Acetaminophen 325 mg tablet and Tramadol 50 mg tablet by mouth every 6 hours for 7 days |
| Arm: *(FDAAA)* | Active Comparator: Acetaminophen & Placebo  
Acetaminophen 325 mg tablet and Placebo (for Tramadol) tablet by mouth every 6 hours for 7 days |

### Interventions

**Tip:** If the same intervention is administered in multiple arms, only enter information for that intervention once. The Cross-Reference is used to specify each arm in which the intervention is administered.

| Intervention: *(FDAAA)* | Drug: Acetaminophen  
Other Names:  
Tylenol  
Anacin-3 |
| NOTE: Intervention Description: data not entered. |

| Intervention: *(FDAAA)* | Drug: Tramadol  
Other Names:  
Ultram  
Rybix |
| NOTE: Intervention Description: data not entered. |

| Intervention: *(FDAAA)* | Drug: Placebo (for Tramadol)  
Sugar pill manufactured to mimic Tramadol 50 mg tablet |
| NOTE: Intervention Other Names have not been specified |

### Arm/Intervention Cross-Reference

| Cross-Reference: *(FDAAA)* |
| Armes | Interventions |
| Drug: Acetaminophen | Drug: Tramadol | Drug: Placebo (for Tramadol) |
| Experimental: Acetaminophen & Tramadol | ✔ | ✔ |
| Acetaminophen 325 mg tablet and Tramadol 50 mg tablet by mouth every 6 hours for 7 days | ✔ | ✔ |
| Active Comparator: Acetaminophen & Placebo | ✔ | |
| Acetaminophen 325 mg tablet and Placebo (for Tramadol) tablet by mouth every 6 hours for 7 days | ✔ | ✔ |

✔ - Intervention is administered to patients in this Arm.
Central Contact:

• Please list the person providing centralized coordinated recruitment information.

Locations:

• Please list all sites if the study is multi center.
• Recruitment Status should match the Overall Recruiting Status above.

Note: Please fill this section in completely. This information will give participants the correct information on whom to contact.
Please ensure you have thoroughly reviewed your study record...

- All fields should be completely filled out and in lay language (where possible)
- All red errors must be corrected
- Any misspelled words should be corrected
- Acronyms and abbreviations should be spelled out
Almost there...”Next Action”

**Complete:** The person updating or owner of the record will click on “Complete” to indicate that the study is ready for the “Approve” and “Release” actions.

**Approve and Release:** The Responsible Party (Administrator, if Sponsor; PI, if Sponsor-Investigator or designated PI) of the study needs to click on “Approve” and “Release” for the study to go through Quality Assurance (QA) review and be published on ClinicalTrials.gov website.
ClinicalTrials.gov does a manual review

- If there are QA issues, the record owner and RP will receive notification from ClinicalTrials.gov with comments.
- The study will be reset to “In Progress”. Study Owner/RP will corrected the issues and re-release it.
- If there are no QA issues, the study is assigned an NCT number and published on the “public” side of the database.
- This process takes about 2-5 business days.
Published Registration

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Search for studies: [Search]
Advanced Search | Help | Studies by Topic | Glossary

Home > Find Studies > Search Results > Study Record Detail

Trial record 1 of 1 for: nct00191282
Previous Study | Return to List | Next Study

Hyperglycemia and Cardiovascular Outcomes With Type 2 Diabetes (IONM)

This study has been completed.

Sponsor:
Eli Lilly and Company

Information provided by:
Eli Lilly and Company

ClinicalTrials.gov Identifier:
NCT00191282

First received: September 12, 2005
Last updated: January 18, 2011
Last verified: January 2011

History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record
Summary of Registration Process

• Fill out Registration ("Create" a record)
• Actions:
  – In progress: Fields to be completed
  – Completed: Ready for Approval and Release
  – Approved/Released:
    • RP is sole party that can “Approve & Release”
• ClinicalTrials.gov QA
• NCT number assigned
• Posted on ClinicalTrials.gov 2-5 business days
Ongoing Responsibilities of an Owner of Study Records on ClinicalTrials.gov:

- Records can be transferred to other user accounts as staff change – email Irine

- Records must be updated every 6 months – unless Overall Recruitment Status changes, then you should update the record within 30 days.

![Record Verification Date: * FDAAA July Year: 2012](image)

- Records must be updated within 30 days after the completion date.

- Failure to update information on ClinicalTrials.gov can result in penalties
Updating Your Record

• Log into ClinicalTrials.gov
• Click on “Modify”
• Click on “Edit” to open the study. Make appropriate changes by clicking on “Edit” along the side in the study record.
• If no changes have occurred in the last 6 months, update the Record Verification Date by clicking the “Edit” button next to the field.

• Be sure click on “Complete” when finished updating.

• Study is ready for “Approval” and “Release”
• Know who is responsible for “Approval” and “Release”
Tips on Updating Records

- Complete all fields
- Use **spelling tool** for spelling errors
- Spell out acronyms and abbreviations
- Use the EDIT links to make changes or “Edit All” link at top
- Check for errors and warnings
- Check for notes (optional to address)
Can I delete a study record?

- Only if the study record has never been published on ClinicalTrials.gov
- Otherwise, No.
- ClinicalTrials.gov serves as a long-term public registry. Once a study record is published, it remains in the system even after a trial has closed.
- If you find a duplicate, contact ClinicalTrials.gov at register@clinicaltrials.gov.
Checking your Problem Records

PRS System identifies current ‘Problem Records’

• Records that have not been marked as completed
• Active studies that have not been updated in the past 6 months
• Records missing one or more data elements required by FDAAA, such as: Responsible Party, Study Start Date, Primary Completion Date and Primary Outcome Measure
• Records that appear to be overdue for registration of results per FDAAA
ClinicalTrials.gov - Help

Procedures for Protocol

- Protocol-A. Log In to PRS
- Protocol-B. Create a ClinicalTrials.gov Record
- Protocol-C. Submit Record to Your Administrator
- Protocol-D. Modify Record
- Protocol-E. View Record
- Protocol-F. Preview Record as it Appears on ClinicalTrials.gov
- Protocol-G. Delete Record
- Protocol-H. Change Your Password

Procedures for Results

- Results-A. Requirements
- Results-B. Create a Results Section
- Results-C. Navigate the Results Section
- Results-D. Results Point of Contact
- Results-E. Certain Agreements
- Results-F. Participant Flow
- Results-G. Baseline Characteristics
- Results-H. Outcome Measures
- Results-I. Limitations and Caveats
- Results-J. Adverse Events
- Results-K. Preview Results as it Appears on ClinicalTrials.gov
- Results-L. Delete the Results Section
What if I have more questions?
Additional Resources

• General ClinicalTrials.gov information:
  http://clinicaltrials.gov/ct2/about-site
• FDAAA related information:
  http://clinicaltrials.gov/ct2/manage-recs/fdaaa
• For specific questions or comments: register@clinicaltrials.gov.
• Office of Extramural Research (OER):
  http://grants.nih.gov/Clinicaltrials_fdaaa/
• Frequently Asked Questions for NIH Grantees:
  http://grants.nih.gov/Clinicaltrials_fdaaa/faq.htm
• Instructions for Authors sections of ICMJE journals all have
  information regarding clinical trial registration
• Local Contacts:
  – Christina McCarthy  X4-2777 (content)
  – Irine Breytburg  X5-3205 (technical, account access)
Help for Registering Studies on ClinicalTrials.gov

• “Submit Studies” at http://clinicaltrials.gov/ct2/manage-recs
• “For Researchers” at http://clinicaltrials.gov/ct2/help/for-researcher
• “For Study Record Managers” at http://clinicaltrials.gov/ct2/help/for-manager
This slide set was made possible by a collaboration of CTSA organizations (Mayo Clinic, Partners, University of Michigan Medical School, University of Rochester) and the National Library of Medicine.

The Clinical and Translational Science Awards Program (CTSA) is part of the Roadmap Initiative, Re-Engineering the Clinical Research Enterprise and is funded by the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH).