ClinicalTrials.gov –
How to Register Your Trial
ClinicalTrials.gov

- Operated by the National Library of Medicine (NLM)
- Each institution has an institutional account
  - Individual investigators/employees are given user profiles on that account
- Each study gets only one record, regardless of number of sites
- Each study should be registered by the Responsible Party (RP)
- Each institutional account can have many records/studies
  - Each user can access many records/studies under his/her profile
  - While users can edit such records, only the RP can release it
- Type of information in ClinicalTrials.gov
  - Registration
  - Results
    - Adverse Events
ClinicalTrials.gov – Registration Information

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

• Recruitment information
  o Eligibility criteria, locations, recruitment status

• Administrative and other information
  o Key dates and contact information

• Helpful links to add
  o MEDLINE publications, consumer health information, FDA information
New User Access to ClinicalTrials.gov

• Provide the following information to your PRS Administrator:
  o Desired user name
  o Full name (e.g., John J Smith, MD)
  o 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/
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 Log in Page

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

Organization Name = Your Institution
ClinicalTrials.gov Menu

To create a new record, click the New Record link in the Quick Links section.

To manage records, update your user account, and find helpful resources, use the drop down menus.

To edit existing records, click the Open link on the Record List.
### Registration in “New Record” View

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organization’s Unique Protocol ID</td>
<td>Required by ClinicalTrials.gov. Unique identifier for the organization.</td>
</tr>
<tr>
<td>Brief Title</td>
<td>Required by ClinicalTrials.gov. Brief title for the study.</td>
</tr>
<tr>
<td>Acronym</td>
<td>If specified, will be included at end of Brief Title in parentheses.</td>
</tr>
<tr>
<td>Study Type</td>
<td>Requires selection.</td>
</tr>
<tr>
<td>Interventional</td>
<td>Participants assigned to intervention(s) based on a protocol.</td>
</tr>
<tr>
<td>Observational</td>
<td>Participants not assigned to intervention(s) based on a protocol; typically in context of routine care.</td>
</tr>
<tr>
<td>Patient Registry</td>
<td>Requires selection.</td>
</tr>
<tr>
<td>Expanded Access</td>
<td>Requires selection.</td>
</tr>
</tbody>
</table>

**FDAAA**
- Required to comply with US FDA Amendments Act
- May be required to comply with US FDA Amendments Act

**Special Characters**
- Used for unique characters that cannot be typed directly.

**Continue**
- Button to proceed with registration.

**Cancel**
- Button to cancel registration.
## Board Approval

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Regulated Intervention</td>
<td>Does this trial involve a drug, biologic or device subject to US Food and Drug Administration (FDA) regulations?</td>
</tr>
<tr>
<td>IND/IDE Protocol</td>
<td>FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?</td>
</tr>
<tr>
<td><strong>Board Approval</strong></td>
<td>Status: --Select--</td>
</tr>
<tr>
<td><strong>Board Name</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Board Affiliation</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Board Contact</strong></td>
<td>Business Phone: [<em><strong>] Extension: [</strong></em>]</td>
</tr>
<tr>
<td></td>
<td>Business Email: [___]</td>
</tr>
<tr>
<td></td>
<td>Business Address: [___]</td>
</tr>
<tr>
<td>Data Monitoring Committee?</td>
<td>--Select--</td>
</tr>
<tr>
<td><strong>Oversight Authorities</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Add Oversight Authority**  
List of oversight authorities

Format (in English) as Country: Organization Name

**Examples:**
- United States: Food and Drug Administration
- Germany: Federal Institute for Drugs and Medicinal Devices
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) – Only 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

### Principal Investigator

Select **Sponsor** unless the Investigator has been designated as Responsible Party per FDAAA.

**For Principal Investigator or Sponsor-Investigator only**, provide:

- **Investigator Name [Username]**:
  - Select the investigator's PRS account.
  - The Investigator Name (i.e., the Full Name from the PRS account record) must be a person's full name for display on ClinicalTrials.gov.
  - **Investigator not in list? Incorrect name format?**

- **Investigator Official Title**:
- **Investigator Affiliation**:

### Sponsor

Primary organization conducting study and associated data analysis (not necessarily a funding source).

### Collaborators

Organization(s) providing support: funding, design, implementation, data analysis or reporting. Enter **only the organization name**.
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](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?
Example of Problematic Primary Outcome Measure
Example of Corrected Primary Outcome Measure*

* Secondary Outcome Measure fields require same information
How to Enter Arms/Interventions Information

**Arms**

- **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) 50 mg tablet by mouth every 6 hours for 7 days.

**Interventions**

- **Intervention**: Drug: Acetaminophen
  Other Names: Tylenol, Anacin-3
  
  **NOTE**: Intervention Description: data not entered.

- **Intervention**: Drug: Tramadol
  Other Names: Ultram, Rybix
  
  **NOTE**: Intervention Description: data not entered.

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

**Cross-Reference**

<table>
<thead>
<tr>
<th>Arms</th>
<th>Interventions</th>
</tr>
</thead>
</table>
| Experimental: Acetaminophen & Tramadol  
  Acetaminophen 325 mg tablet and Tramadol 50 mg tablet by mouth every 6 hours for 7 days. | ![Green Check](checkmark) ![Green Check](checkmark) |
| Active Comparator: Acetaminophen & Placebo  
  Acetaminophen 325 mg tablet and Placebo (for Tramadol) 50 mg tablet by mouth every 6 hours for 7 days. | ![Green Check](checkmark) ![Green Check](checkmark) ![Green Check](checkmark) |

- **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

Completed all fields and Ready to Release your study on ClinicalTrials.gov
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 PRS 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

Find Studies  About Clinical Studies  Submit Studies  Resources  About This Site

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:
  o In Progress: Fields to be completed
  o Entry Completed: Ready for Approval and Release
  o Approved/Released:
    o RP is sole party that can “Approve & Release”

• ClinicalTrials.gov PRS Review

• NCT number assigned

• Posted on ClinicalTrials.gov 2-5 business days
Records can be transferred to other user accounts as staff change.

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

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 “Edit Record”
- Click on “Edit” to open the study
- Click “Edit” next to the Protocol Section
- 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 Study Status box
- Click on the “Save” button at the bottom of the page
- Return to the “Record Summary” Page
- Be sure to click on “Complete” when finished updating

- Study is ready for “Approval” and “Release”
- Know who is responsible for “Approval” and “Release”
General Tips on Updating Your Record

- 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 a study record be deleted from ClinicalTrials.gov?

- 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
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

PRS User's Guide

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. Edit Record
- Protocol-E. View Record
- Protocol-F. Preview Record as it Will Appear 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. Participant Flow
- Results-E. Baseline Characteristics
- Results-F. Outcome Measures
- Results-G. Adverse Events
- Results-H. Limitations and Caveats
- Results-I. More Information
- Results-J. Delete the Results Section
Additional Resources

- General ClinicalTrials.gov information: [http://clinicaltrials.gov/ct2/about-site](http://clinicaltrials.gov/ct2/about-site)
- For specific questions or comments: register@clinicaltrials.gov.
- Instructions for Authors sections of ICMJE journals all have information regarding clinical trial registration
- Local Contacts:
  - ADD “YOUR U” contacts here or on a final slide
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

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