Trial Registration on www.ClinicalTrials.gov

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CU Clinical Trials Office

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What is ClinicalTrials.gov?

• National registry of federally and privately supported research studies

• Allows the reporting of trials that:
  – Are in conformance with any applicable human subject or ethics review regulations (or equivalent).
  – Are in conformance with any applicable regulations of the national (or regional) health authority (or equivalent).

• Facilitates registration of trials in accordance with the International Committee of Medical Journal Editors (ICMJE) initiative, which requires prior entry of clinical trials in a public registry as a condition for publication
Why is registration important?

• Federally mandated

• Required by FDA for IND/IDE trials (Form 3674)

• Required by ICMJE for journal publication

• Promotes transparency to the public about clinical trials
  – Not all trials are published
  – Publications do not always include all prespecified outcome measures
  – Unacknowledged changes are made to trial protocols that would affect the interpretation of findings

• Beneficial to the research community
  – Assists in enrollment
  – Upholds research integrity by tracking protocol changes
Regulations that govern registration

- **Food and Drug Administration Modernization Act (FDAMA)**
  - **Section 113** required that DHHS, through the NIH, establish a registry of clinical trials for both federally and privately funded trials
  - Initially created to document Investigational New Drug (IND) trials for serious and life-threatening diseases or conditions
  - ClinicalTrials.gov was launched in 2000

- **Food and Drug Administration Amendments Act of 2007 (FDAAA)**
  - [US Public Law 110-85, Title VIII (Section 801)](https://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf) expanded ClinicalTrials.gov and imposed new requirements that apply to certain trials supported by NIH funds (including Results and Adverse Events)
  - Required all NIH grantees to certify in the grant application and progress report forms that all required submissions to ClinicalTrials.gov were completed

- **The International Committee of Medical Journal Editors (ICMJE)**
  - Established a requirement that all clinical trials be entered in a public registry as a condition of consideration for publication
  - Confirms registration with a “NCT” number
FDAAA Enforcement Provisions

• Notices of noncompliance
• Civil monetary penalties (up to $10,000 per day)
• Withholding of NIH and other federal grant funds
Which trials?

• “Applicable Clinical Trial” (Title VIII of FDAAA, PL110-85) includes:

  Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation

  Trials of Devices: Controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric postmarket surveillance studies.

• Not all “applicable clinical trials” are required to be registered and report results
  – Phase 1 (drug) or small feasibility (devices) studies
  – Applicable clinical trials completed before December 26, 2007
Who is responsible for registration?

- The “Responsible Party” is the term used in Title VIII to refer to the entity or individual who is responsible for registering on ClinicalTrials.gov
  - “Sponsor” of the clinical trial (21 CFR 50.3)
  - Principal Investigator (PI) of such clinical trial if so designated by a Sponsor, grantee, contractor, or awardee
  - Sponsor-Investigator (S-I) for IND/IDE trials

- The PI or S-I must be designated as the “Responsible Party” during trial registration
ClinicalTrials.gov Records

• One record per trial

• One “owner” per record (in addition to Investigator)
  – Either Investigator or designated research personnel
  – Ownership can be transferred

• Registration
  – Submitted at trial initiation
  – Must be submitted no later than 21 days from the date of enrollment for first subject

• Results
  – Submitted after trial completion
  – Summarizes trial results

• Protocol Registration System (PRS)
  – Secure Web-based data entry system for providing summary protocol and results information
  – Consists of pull down menus, free-text fields, and other data entry mechanisms
What type of information is reported?

• Descriptive Information
  – Study Type
  – Phase Design
  – Outcomes
  – Enrollment
  – Start and Completion Dates

• Recruitment Information
  – Eligibility Criteria
  – Recruitment Status

• Location and Contact Information
  – Sponsor and/or Responsible Party
  – Facility Name and Contact

• Administrative Data
  – Protocol ID
  – IND/IDE Number (not public)
Record Review Criteria

• Review consists of a check on:
  – Apparent validity
  – Meaningful entries
  – Logic and internal consistency
  – Formatting

• Quality Assurance Review is two-fold
  – Initial review by PRS Administrators at the overseeing organization (i.e., CU)
  – Final review by ClinicalTrials.gov QA team

• Time frame for review
  – Protocol records generally take 2 to 5 business days
  – Results records can take up to 30 days, depending on the complexity of results
Reporting of Results

- Participant Flow
- Baseline and Demographic Characteristics
- Primary and Secondary Outcomes
- Adverse Event information
- Other information
  - “Certain Agreements” related to restrictions on results disclosure
  - “Overall Limitations and Caveats”
  - “Point of Contact” for reported results

NOTE: Results reporting is required within 12 months of (primary) completion date
More information on Results Reporting

PowerPoint presentations are available on the PRS website:

- Results: Participant Flow Module
- Results: Baseline Characteristics Module
- Results: Outcome Measures and Statistical Analyses Module
- Results: Adverse Events Module

Please visit: http://prsinfo.clinicaltrials.gov/webinars/
Recent Update

• Registration of protocols on www.clinicaltrials.gov must now be incorporated into the Informed Consent Forms for all “applicable trials,” in accordance with Section 801 of FDAAA
  – Required for applicable trials initiated on or after March 7, 2012
  – Informs potential study participants of the availability of the clinical trial information on www.clinicaltrials.gov
  – Does not apply retroactively to studies approved by the IRB prior to March 7, 2012 (re-consent is not required)
  – No waivers granted

• Under new 21 CFR 50.25(c), the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials:

  "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time." (FDA Guidance Document available)
Tutorial on Registering and Updating Trials in the Protocol Registration System (PRS)
Access to PRS

- Organizational account for Columbia University already exists
- An account must be created in order to access PRS
  - Individual accounts are linked to the “ColumbiaU” account
  - Only PRS Administrators can create user accounts
  - Applicant must provide UNI and current email address
- Accounts can be modified and deactivated
  - Temporary password must be changed
  - Contact information should be updated on a regular basis
  - Passwords can be reset by the PRS Administrators
Website Address: https://register.clinicaltrials.gov
### Protocol Records
- Create
- Modify
- View

### QA Review Comments
- Problems: je2050 Records
- Undelete

### User Account
- Change password
- Modify Information
- PRS Administrator(s)

### Help
- **Quick Start Guide**
- Frequently Asked Questions (FAQ)
- Responsible Party FAQ
- What's New: Jan 20, 2012
- User’s Guide
- Protocol Data Element Definitions
- Results Data Element Definitions
- Protocol Review Criteria
- Results Review Criteria
- FDAMA 113 Requirements
- Simple Results Forms

### XML Upload
- Upload protocol records
- Check upload status
- Protocol XML Schema
- Results XML Schema
- Results Pick-list Normalization

### Session
- Logout
To avoid duplicate or invalid registration of your study, check the following before proceeding with registration:

1. Section 801 studies may only be registered by the Responsible Party. If this is an applicable clinical trial as defined by US Public Law 110-85, Title VIII, Section 801, ensure that your organization is the Responsible Party as defined by the law before registering the study.

2. IND/IDE studies may only be registered by the IND/IDE holder. If the study is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE), ensure that your organization is the IND/IDE holder before registering the study.

3. For NIH-funded studies, coordinate with the relevant Institute or Center. If this is a US National Institutes of Health (NIH) funded study, registration should be coordinated with the sponsoring NIH Institute or Center to avoid duplicate registration.

4. Multi-site studies are NOT registered by individual sites. If this is a multi-site study it must be registered only once, by the sponsor (primary organization that oversees implementation of study and is responsible for data analysis) or its designated principal investigator (PI).

5. Coordinate with all collaborators before registering. If the study has multiple collaborators, contact the other organizations to confirm that the study has not already been registered and to notify them that your organization, as sponsor or its designated PI, is registering the study.

6. Refer to the ClinicalTrials.gov Review of Protocol Submissions document for a description of items evaluated by ClinicalTrials.gov after protocol information is submitted.
Please specify both a Brief Title and a Unique Protocol Id

<table>
<thead>
<tr>
<th>Field</th>
<th>Required</th>
<th>Example Description</th>
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<tbody>
<tr>
<td>Unique Protocol ID</td>
<td>*</td>
<td>Enter sponsoring organization’s unique identifier</td>
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<tr>
<td>Brief Title</td>
<td>*</td>
<td>Use lay language. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer</td>
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<tr>
<td>Acronym</td>
<td></td>
<td>If there is an acronym or abbreviation used to identify this study, enter it here.</td>
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<tr>
<td>Official Title</td>
<td></td>
<td>Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate</td>
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<tr>
<td>Study Type</td>
<td></td>
<td>Indicate Study Type: Interventional, Observational, Expanded Access</td>
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<tr>
<td>FDA Regulated Intervention</td>
<td></td>
<td>Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulations.</td>
</tr>
<tr>
<td>IND/IDE Protocol</td>
<td></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>
Secondary Identifiers include but are not limited to US NIH grant numbers, other grant funding numbers and identifiers from other clinical trial registries (e.g., ISRCTN).

- Add a Secondary ID to this study

Secondary ID: FDAAA

There are no Study SecondaryIds currently listed for this study.

* Required by ClinicalTrials.gov
  - FDAAA
    - Required to comply with US Public Law 110-85, Section 801
  - FDAAA
    - May be required to comply with US Public Law 110-85, Section 801
**ClinicalTrials.gov**  
*Protocol Registration System*

**Title**: TEST  
**ID**: AAAJXXXX

**Select one ID Type** and fill in the additional information, if any, for that type.

<table>
<thead>
<tr>
<th>ID Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>US NIH Grant/Contract Award Number</strong></td>
<td>For grant numbers, include activity code, institute code and 6 digit serial number. Examples: R01DA013131, UO1HL066582, 5R01HL123451-01A2</td>
</tr>
</tbody>
</table>
| **Other Grant/Funding Number** | **Grantor or Funder:** 
| **Registry Identifier** | **Registry Name:** |
| **EudraCT Number** | **European Union Drug Regulatory Authorities Clinical Trial System** |
| **Other Identifier** | **Issuing Organization:** |

*Required by ClinicalTrials.gov  
FDAAA  
Required to comply with US Public Law 110-85, Section 801  
May be required to comply with US Public Law 110-85, Section 801*  

[Add number here]
<table>
<thead>
<tr>
<th>Section 801 Clinical Trial?</th>
<th>Delayed Protocol Posting?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>If FDA Regulated Intervention</strong> marked as “yes”</td>
<td><strong>If IND/IDE Protocol</strong> is marked as “yes”</td>
</tr>
</tbody>
</table>

**IND/IDE Grantor:** Select from CBER, CDER, or CDRH.

**IND/IDE Number:** [Enter number] (FDAAA)

**IND/IDE Serial Number:** [Enter number] (FDAAA)

**Has Expanded Access?** Select from options:
- **About expanded access records**

If applicable, enter the ClinicalTrials.gov identifier (NCT number) for the associated Expanded Access record.

---

**Title:** TEST

**Title:** FDA Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links

**ID:** AAA/XXXX

**NOTE:** The information entered on this screen is required for administrative purposes and will not be made public in ClinicalTrials.gov.

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**About Expanded Access Records**

ClinicalTrials.gov expanded access records contain information about the availability of an experimental drug or device outside of a clinical trial protocol. Expanded access records are used to register all types of non-protocol access to experimental treatments, including protocol exceptions, single-patient IND, treatment IND, compassionate use, emergency use, continued access, and parallel track.

- **Unique Protocol Id**
- **Brief Title:** indicates type of protocol exception and the associated treatment.
- **Study Type:** select “Expanded Access”
- **IND/IDE Information:** applicable
- **Overseas Authorities**
- **Lead Sponsor/Collaborators**
- **Brief Summary:** describe the procedure for requesting treatment.
- **Record Verification Data**
- **Expanded Access Status:** select from option menu
- **Interventions**
- **Criteria**
- **Eligibility Criteria:** use Ags Limits to indicate whether the treatment is available to children and/or adults.
- **Central Contact:** if expanded access is available, include telephone or email address for providing information.

Other applicable data elements, such as Detailed Description, Citations and Links may be provided if desired.
As of August 18, 2011
Clinical Trials.gov Protocol Registration System

Title: TEST TEST TEST TEST

ID: AAAJXXXX

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).

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: Columbia University

Will change to Investigator’s name if S-I is selected

“Clinical Professor of…”

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Columbia University Medical Center
Use lay language. Include a statement of the study hypothesis.

Provide a more extensive description, if desired. Avoid duplication of information to be recorded elsewhere, such as eligibility criteria or outcomes.
Tips for Formatting Text

• To format paragraphs, include a blank line between paragraphs.

• To format bulleted lists, start each list item on a new line with a "list item" character, such as an asterisk (*) or hyphen (-).

• To format numbered lists use sequential numbers, starting with "1" (or "1.") as the list item characters. Alternatively, use lower case letters, starting with "a.", as list item characters.

• Bulleted, numbered and lettered lists may be combined in order to create a list within a list. For example: 1. list item one a. list item 1a b. list item 1b - bullet one - bullet two 2. list item two ...

• Use the "Preview" feature to see how the text will appear on ClinicalTrials.gov.
Brief Summary:

Use lay language. Include a statement of the study hypothesis.

*TEST A
*TEST B
*TEST C

-A
-B
-C

Detailed Description:

Provide a more extensive description, if desired. Avoid duplication of information to be recorded elsewhere, such as eligibility criteria or outcome measures.

1. TEST A
   a. A1
   b. A2
2. TEST B
   a. B1
   b. B2

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FDAAA Required to comply with US Public Law 110-85, Section 801
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<table>
<thead>
<tr>
<th>Oversight Authorities: United States Food and Drug Administration</th>
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<table>
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<tr>
<th>Edit</th>
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<tbody>
<tr>
<td>Brief Summary</td>
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<tr>
<td>1. TEST A</td>
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<tr>
<td>2. TEST B</td>
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<tr>
<td>3. TEST C</td>
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</table>

<table>
<thead>
<tr>
<th>Detailed Description</th>
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</thead>
<tbody>
<tr>
<td>1. TEST A</td>
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<tr>
<td>a. A1</td>
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<tr>
<td>b. A2</td>
</tr>
<tr>
<td>2. TEST B</td>
</tr>
<tr>
<td>a. B1</td>
</tr>
<tr>
<td>b. B2</td>
</tr>
</tbody>
</table>

Provide a more extensive description, if desired. Avoid duplication of information to be recorded elsewhere.

<p>| 1. TEST A |
| a. A1 |
| b. A2 |
| 2. TEST B |
| a. B1 |
| b. B2 |</p>
<table>
<thead>
<tr>
<th>Key Trial Dates</th>
<th>Status</th>
<th>Design</th>
<th>Interventions</th>
<th>Conditions</th>
<th>Eligibility</th>
<th>Locations</th>
<th>Citations</th>
<th>Links</th>
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<tbody>
<tr>
<td><strong>Record Verification Date</strong></td>
<td>–Select–</td>
<td>Year</td>
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<tr>
<td><strong>Overall Recruitment Status</strong></td>
<td>–Select–</td>
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<tr>
<td><strong>Why Study Stopped</strong></td>
<td>Not yet recruiting</td>
<td>Recruiting</td>
<td>Active, not recruiting</td>
<td>Enrolling by invitation</td>
<td>Completed</td>
<td>Terminated (Halted Prematurely)</td>
<td>Withdrawn (No Participants Enrolled)</td>
<td></td>
</tr>
</tbody>
</table>

**ClinicalTrials.gov Protocol Registration System**

- **Record Verification Date**: Must be updated every 6 months.
- **Overall Recruitment Status**: Select the status of the recruitment.
- **Why Study Stopped**: Briefly explain why the study was stopped.
- **Key Trial Dates**:
  - **Study Start Date**: Date that enrollment to the protocol begins.
  - **Primary Completion Date**: The date of the last subject-related research procedure (i.e., visit or intervention).
  - **Study Completion Date**: Final date on which data was (or is expected to be) collected.
- **Final data collection date**: Can select “Actual” or “Anticipated”.

*Required by ClinicalTrials.gov: Required to comply with US Public Law 110-85, Section 801. May be required to comply with US Public Law 110-85, Section 801.*
## ClinicalTrials.gov Protocol Registration System

### NOTE:
These attributes apply to an "Interventional" study. If desired, change the study type to "Observational".

<table>
<thead>
<tr>
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<th>- Select-</th>
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<tbody>
<tr>
<td>Study Phase:</td>
<td>- Select-</td>
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<tr>
<td>Intervention Model:</td>
<td>- Select-</td>
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<tr>
<td>Number of Arms:</td>
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<tr>
<td>Masking:</td>
<td>- Select-</td>
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<tr>
<td>Allocation:</td>
<td>- Select-</td>
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<tr>
<td>Study Endpoint Classification:</td>
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<tr>
<td>Enrollment:</td>
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  May be required to comply with US Public Law 110-85, Section 801
### ClinicalTrials.gov Protocol Registration System

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<th>Title</th>
<th>FDA</th>
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<th>Sponsor</th>
<th>Summary</th>
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<th>Locations</th>
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<th>Links</th>
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#### Design

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<th>Study Phase</th>
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<th>Masking</th>
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<th>Allocation</th>
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<th>Enrollment</th>
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ClinicalTrials.gov
Protocol Registration System

NOTE: These attributes apply to an "Interventional" study. If desired, change the study type to "Observational".

Primary Purpose:  
Study Phase:  
Intervention Model:  
Number of Arms:  
Masking:  
Allocation:  
Study Endpoint Classification:  
Enrollment:  

Continue  Quit

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Required to comply with US Public Law 110-85, Section 801
May be required to comply with US Public Law 110-85, Section 801
NOTE: These attributes apply to an "Interventional" study. If desired, change the study type to "Observational".

Number of intervention groups (enter 1 for single-arm study)

NOTE: Correct # of roles must be checked off
ClinicalTrials.gov
Protocol Registration System

Title: TEST
ID: AAA/XXXX

NOTE: These attributes apply to an "Interventional" study. If desired, change the study type to "Observational".

Primary Purpose: [Select]
Study Phase: [Select]
Intervention Model: [Select]
Number of Arms: [Select]
Masking: [Select]
Allocation: [Select]
Study Endpoint Classification: [Select]
Enrollment: [Select]

* Required by ClinicalTrials.gov
Required to comply with US Public Law 110-85, Section 801
May be required to comply with US Public Law 110-85, Section 801
NOTE: These attributes apply to an "Interventional" study. If desired, change the study type to "Observational".

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Purpose</td>
<td>[Select]</td>
</tr>
<tr>
<td>Study Phase</td>
<td>[Select]</td>
</tr>
<tr>
<td>Intervention Model</td>
<td>[Select]</td>
</tr>
<tr>
<td>Number of Arms</td>
<td>[Select]</td>
</tr>
<tr>
<td>Masking</td>
<td>[Select]</td>
</tr>
<tr>
<td>Allocation</td>
<td>[Select]</td>
</tr>
<tr>
<td>Study Endpoint Classification</td>
<td>[Select]</td>
</tr>
<tr>
<td>Enrollment</td>
<td>[Select]</td>
</tr>
</tbody>
</table>

*FDA.gov Protocol Registration System*
For "completed" trials, the enrollment # must be set as ACTUAL.

For "withdrawn" trials, the enrollment # must be entered as "0."
Provide the primary and secondary outcome measures associated with the protocol, along with the associated time frames.

Add a primary outcome measure to this study.
Add a secondary outcome measure to this study.

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

Primary Outcome Measure

There is no primary outcome measure specified for this study.

Secondary Outcome Measures

There are no secondary outcome measures specified for this study.

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FDAAA
Required to comply with US Public Law 110-85, Section 801
FDAAA
May be required to comply with US Public Law 110-85, Section 801
### 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>Enter only one distinct outcome measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time Frame</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>Safety Issue</td>
<td>Does this outcome measure assess a safety issue?</td>
</tr>
</tbody>
</table>

---

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FDAAA: Required to comply with US Public Law 110-85, Section 801

FDAAA: May be required to comply with US Public Law 110-85, Section 801
Outcome Measures

• **Primary Outcome Measure**: Specific key measurement(s) or observation(s) used to measure the effect of experimental variables
  – Quantitative, not qualitative (i.e., “Increase in QOL Score” vs. “Quality Improvement”)
  – WHAT will be measured, not why it is measured (e.g., “A decrease in…” vs. “To decrease…”)
  – Verbs are generally excluded from the title

• **Secondary Outcome Measures**: Other key measures that will be used to evaluate the intervention(s) or, for observational studies, that are a focus of the study
Outcome Measures (continued)

Time Frame: estimated period of time (maximum) over which the event will be assessed

– Most outcome measures will have one time point
– Will depend on the title of the outcome measure
  • Name of the Outcome Measure – Requires the maximum amount of time required to collect all data (e.g., “…up to 12 months…”)
  • “Change” Outcome Measures – Generally two time points are entered to indicate the time period over which the change occurred (e.g., “baseline and 8 weeks”)
– May also include information on how the event will be determined and over what estimated period of time (e.g., “…from date of randomization”)
– Multiple time points are allowed for pharmacokinetic (PK) outcome measures (e.g., “0, 1, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96 hours post-dose”)
ClinicalTrials.gov
Protocol Registration System

Specify the arms, if any, and their associated interventions (How to Specify Study Arms and Interventions).

Study Arms

<table>
<thead>
<tr>
<th>Arm: * (IDAAA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no arms currently listed for this study.</td>
</tr>
</tbody>
</table>

Interventions

<table>
<thead>
<tr>
<th>Interventions: * (IDAAA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no Interventions currently listed for this study.</td>
</tr>
</tbody>
</table>

ERROR: At least one Intervention must be specified for an Interventional study.
ERROR: An IND/IDE study must have at least one intervention of type: Drug, Device, Biological, Vaccine, Radiation or Genetic.

* Required by ClinicalTrials.gov
Required to comply with US Public Law 110-85, Section 801
May be required to comply with US Public Law 110-85, Section 801
<table>
<thead>
<tr>
<th>Arm Type: Select</th>
<th>Arm Description:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>-</td>
</tr>
<tr>
<td>Active Comparator</td>
<td>-</td>
</tr>
<tr>
<td>Placebo Comparator</td>
<td>-</td>
</tr>
<tr>
<td>Sham Comparator</td>
<td>-</td>
</tr>
<tr>
<td>No Intervention</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>-</td>
</tr>
</tbody>
</table>

**Name of the group. For example, “Drug X”**

**Group/Cohorts:**
Explanation of the nature of the study group

**Arms:** Brief description of the arm
*May want to add specifics of treatment (e.g., Drug X 100mg PO BID...)*
Specify the arms, if any, and their associated interventions (How to Specify Study Arms and Interventions).

**ERROR:** No interventions have been assigned to arm 'Drug X'.

**ERROR:** At least one Intervention must be specified for an Interventional study.

**ERROR:** An IND/IDE study must have at least one intervention of type: Drug, Device, Biological Vaccine, Radiation or Genetic.
Generic name here

Brand name here, such as “Drug X”

VS.
Specify the arms, if any, and their associated interventions. (How to Specify Study Arms and Interventions)

Add an arm.

Study Arms

<table>
<thead>
<tr>
<th>Arm</th>
<th>*Experimental: Drug X</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Drug X 100mg POED.</td>
</tr>
</tbody>
</table>

Interventions

<table>
<thead>
<tr>
<th>Interventions</th>
<th>*Drug Formula 11089B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Drug X 100mg POED for 3 months</td>
</tr>
<tr>
<td></td>
<td>Arms: Drug X</td>
</tr>
<tr>
<td></td>
<td>Other Names: Drug X</td>
</tr>
</tbody>
</table>

* Required by ClinicalTrials.gov
  Required to comply with US Public Law 110-85, Section 801
  May be required to comply with US Public Law 110-85, Section 801
**Experimental:** An arm or group in which an experimental drug or regimen is being administered.

**Active comparator:** An arm or group in which active drugs are given.

**Placebo comparator:** An arm or group in which ONLY a placebo is given.

**Sham comparator:** An arm or group in which ONLY a mock therapy that is not a drug is administered.

**No intervention:** An observational arm or group.

**Other:** An arm or group which does not fall into any of the above.
**Interventions**

<table>
<thead>
<tr>
<th><strong>Intervention Type</strong></th>
<th>Drug</th>
</tr>
</thead>
</table>

**Intervention Name**

For a drug, use the generic equivalent name if it has been established.

Acetaminophen

**Intervention Description**

Key details, e.g., for drugs include dosage form, dosage, frequency and duration.

Tylenol Xmg PO BID

**Arms**

- Experimental: Drug X
- Active Comparator: Standard of Care

**Other Names**

Include brand names, serial numbers and code names, if applicable. Other names are used to improve search results on the ClinicalTrials.gov website.

Tylenol

---

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May be required to comply with US Public Law 110-85, Section 801
Specify the arms, if any, and their associated interventions (How to Specify Study Arms and Interventions).

### Study Arms

<table>
<thead>
<tr>
<th>Arm</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Drug X</td>
<td>Drug X 100mg PO BID</td>
</tr>
<tr>
<td>Active Comparator: Standard of Care</td>
<td>Tylenol</td>
</tr>
</tbody>
</table>

### Interventions

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Drug: Formula 11083B</th>
<th>Drug X 100mg PO BID for 3 months</th>
<th>Arms: Drug X</th>
<th>Other Names: Drug X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventions</td>
<td>Drug: Acetaminophen</td>
<td>Tylenol 325mg PO BID</td>
<td>Arms: Standard of Care</td>
<td>Other Names: Tylenol</td>
</tr>
</tbody>
</table>
### Conditions or Focus of Study

Enter only conditions (no numbers, dashes, bullets, etc.), one per line. If there are no conditions under study, enter focus of study instead.

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Enter</th>
<th>Focus of Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Headaches</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Keywords

Enter only keywords (no numbers, dashes, bullets, etc.), one per line.

<table>
<thead>
<tr>
<th>Keywords</th>
<th>Enter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Headaches</td>
<td></td>
</tr>
<tr>
<td>Migraines</td>
<td></td>
</tr>
<tr>
<td>Tylenol</td>
<td></td>
</tr>
<tr>
<td>Drug X</td>
<td></td>
</tr>
</tbody>
</table>

---

* Required by ClinicalTrials.gov

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- May be required to comply with US Public Law 110-85, Section 801
Eligibility Criteria:

Inclusion Criteria:
- Occurrence of at least 1 headache in the past month
- Between the ages of 18 and 45 years

Exclusion Criteria:
- Regular use of Drug Y
- Patients with a history of seizures...

Gender: Both

Age Limits: Minimum 18 Years, Maximum 45 Years

Accepts Healthy Volunteers: No

NOTE: Number 18

Minimum Age without units (years/months/weeks etc.) - treated as no limit

Required to comply with US Public Law 110-85, Section 801
May be required to comply with US Public Law 110-85, Section 801
Specify the Central Contact with overall recruiting responsibility for this study.
Specify the Study Officials Investigators with overall scientific responsibility for this study.
Add a location to this Study.
Copy locations from a master list, extracted from this organization's records.

Locations:
There are no Locations currently listed for this study.

* Required by ClinicalTrials.gov
  FDAAA Required to comply with US Public Law 110-85, Section 801
  FDAAA May be required to comply with US Public Law 110-85, Section 801
ClinicalTrials.gov
Protocol Registration System

Title: TEST

Central Contact is the person with overall recruitment responsibility for this study.
If contact information is provided for all recruiting locations, Central Contact may be left blank.

Central Contact: * (FDA)

First: [ ] [ ] [ ] [ ] [ ] Last: [ ] [ ] [ ] [ ] Degree: [ ]
Phone: [ ] Ext: [ ] Email: [ ]

Central Contact Backup:

First: [ ] [ ] [ ] [ ] [ ] Last: [ ] [ ] [ ] [ ] Degree: [ ]
Phone: [ ] Ext: [ ] Email: [ ]

* Required by ClinicalTrials.gov
(FDA) Required to comply with US Public Law 110-85, Section 801
(FDA) May be required to comply with US Public Law 110-85, Section 801

Continue  Quit
ClinicalTrials.gov
Protocol Registration System

<table>
<thead>
<tr>
<th>Title</th>
<th>FDA</th>
<th>Oversight</th>
<th>Sponsor</th>
<th>Summary</th>
<th>Status</th>
<th>Design</th>
<th>Interventions</th>
<th>Conditions</th>
<th>Eligibility</th>
<th>Locations</th>
<th>Citations</th>
<th>Links</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title: TEST</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ID: AAA/XXXX</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Study officials, including the principal investigator, are the persons responsible for the overall scientific leadership of the protocol.

Add a Study Official to this study.

There are no Study Officials currently listed for this study.

NOTE: Study Official is required by the WHO and ICMJE.

* Required by ClinicalTrials.gov

- Required to comply with US Public Law 110-85, Section 801
- May be required to comply with US Public Law 110-85, Section 801
Study Official’s Name:
First: [Field]
Mi: [Field]
Last: [Field]
Degree: [Field]

Organizational Affiliation:
Select: [Dropdown]
- Study Chair
- Study Director
- Study Principal Investigator

Columbia University

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FDAAA
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FDAAA
May be required to comply with US Public Law 110-85, Section 801

Columbia University Medical Center
Definition: bibliographic reference in NLM’s MEDLINE format (Limit: 2000 characters)

Example: Barza M; Pavan PR; Doft BH; Wisniewski SR; Wilson LA; Han DP; Kelsey SF. Evaluation of microbiological diagnostic techniques in postoperative endophthalmitis in the Endophthalmitis Vitrectomy Study. Arch Ophthalmol 1997 Sep;115(9):1142-50
## ClinicalTrials.gov

**Protocol Registration System**

<table>
<thead>
<tr>
<th>Title</th>
<th>Sponsor</th>
<th>Status</th>
<th>Design</th>
<th>Interventions</th>
<th>Conditions</th>
<th>Eligibility</th>
<th>Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEST</td>
<td>TEST</td>
<td>TEST</td>
<td>TEST</td>
<td>TEST</td>
<td>TEST</td>
<td>TEST</td>
<td>TEST</td>
</tr>
</tbody>
</table>

**Citations**

Provide the unique PubMed Identifier (PMID) for the citation.

*Search for a citation* in MEDLINE, using the PubMed browser.

**MEDLINE Identifier:**

Enter PubMed Identifier (PMID)

**Results Reference:**

Does the publication report on results of this study?

*Select*:

- Select

If the publication was not found in MEDLINE, *enter the citation text*.

**OK**  **Cancel**
### ClinicalTrials.gov Protocol Registration System

#### Title: TEST

**Use this screen to provide pointers to web pages directly relevant to the protocol. Provide up to 5 suggested links.**

**Continue**  **Quit**  **Add a Link to a related web page to this study, if applicable.**

**Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.**

<table>
<thead>
<tr>
<th>Links</th>
<th>There are no Links to related web pages currently listed for this study.</th>
</tr>
</thead>
</table>
Protocol Record Completed

ClinicalTrials.gov
Protocol Registration System

Protocol Record Completed

Title: TEST

ID: AAAJXXXX

You have reached the last data entry screen. Proceed to the next screen (Edit Protocol) to review the entire record.

Note that the data that you have entered are automatically validated by the system. Messages describing problems of varying severity (Errors, Alerts, or Notes) are included on the Edit Protocol screen, beneath the relevant fields. Review each message and take the appropriate action.

Once the record is ready for review by your administrator, click on the "Complete" link near the top of the Edit Protocol Record screen to mark the record as completed. Your administrator must then "Approve" and "Release" the record, in order for the record to be submitted for final Quality Assurance review and publication on the ClinicalTrials.gov web site.

OK
ClinicalTrials.gov
Protocol Registration System

Edit Protocol Record

Errors in protocol or results data. See messages below.
Additional information may be required per US Public Law 110-85. See WARNING messages below.

Title: TEST
ID: AAAJXXXX

Next Action: Complete
Tip: Remember to update Record Verification Date when reviewing or updating a protocol record.

Record Status: In Progress
Owned by: jc2050
Last updated: 02/09/2012 16:29 by jc2050
Initial release: [not yet released]

Unique Protocol ID: AAAJXXXX
ClinicalTrials.gov ID:
Brief Title: TEST

NOTE: Titles should be in proper title case.

ERROR: A title this short cannot be sufficiently descriptive.

Official Title:

NOTE: Official Title is required by the WHO and ICMJE.

Study Type: Observational
Edit Protocol Record - Windows Internet Explorer provided by Columbia University Medical Center

WARNING: Study Start Date has not been entered.

Primary Completion Date:

WARNING: Primary Completion Date has not been entered.

Study Completion Date:

NOTE: Study Completion Date has not been entered.

Study Design:

Primary Purpose:
Study Phase:
Intervention Model:
Number of Arms:
Masking:
Allocation:
Enrollment:

ERROR: Study Characteristics must be specified.

WARNING: Enrollment has not been entered.

Outcome Measures:

Primary Outcome Measure:
Secondary Outcome Measures

WARNING: Primary Outcome Measure has not been entered.

Conditions:
Chronic Headaches

Keywords:
Chronic Headaches
Migraines
Tylenol
Drug X

Arms:
Drug X
Drug X 100mg PO BID...
Standard of Care
Tylenol...

ERROR: Arm Type is a required field.
ERROR: Arm Type is a required field.

Interventions:
Drug Drug X
Next Action: Complete

Record Status: In Progress | Completed | Approved | Released

ID: AAAJXXXX

Unique Protocol ID: AAAJXXXX

ClinicalTrials.gov ID:

Brief Title: TEST TEST TEST TEST TEST

Note: Titles should be in proper title case.
Note: A title this short may not be sufficiently descriptive.

Official Title: TEST TEST TEST TEST TEST

Note: Official Title is required by the WHO and ICMJE.

Study Type: Interventional

FDA Regulated Intervention? Yes
Function is reserved for PRS Administrators or PI/S-I
Release of a Record

1. Once the record is released, the information is locked.

2. The record will then be reviewed by the QA staff at ClinicalTrials.gov.

3. Once the review has been completed (~2 to 5 business days), an email will be sent to the data provider notifying them.
   - If significant errors have been detected, the record will be reset and sent back to the data provider for review.
   - If no significant errors have been detected, the record will be posted publicly at ClinicalTrials.gov.

4. If the record is to be posted on the website, a NCT number is issued, and the owner of the record will receive an email.
Updates

• Updates are required at a *minimum* of every 6 months
  – Overall recruitment status
  – Facility contact
  – Facility information (including recruitment status)

• Record Verification Date should be updated for every change made to a record
<table>
<thead>
<tr>
<th><strong>Data Monitoring Committee?</strong></th>
<th>No</th>
</tr>
</thead>
</table>
| **Oversight Authorities:**   | United States: Food and Drug Administration  
United States: Institutional Review Board |
| **Brief Summary:**            | • TEST A  
• TEST B  
• TEST C |
| **Detailed Description:**     | 1. TEST A  
a. A1  
b. A2  
2. TEST B  
a. B1  
b. B2 |
| **Record Verification Date:** | February 2012 |
| **Overall Status:**           | Not yet recruiting |
| **Study Start Date:**         | February 2012 |
| **Primary Completion Date:**  | February 2014 [Anticipated] |
| **Study Completion Date:**    | February 2015 [Anticipated] |
| **Study Design:**             | Primary Purpose: Treatment  
Study Phase: Phase 1  
Intervention Model: Parallel Assignment  
Number of Arms: 2  
Masking: Open Label  
Allocation: Randomized  
Endpoint Classification: Safety/Efficacy Study  
Enrollment: 10 [Anticipated] |
| **Outcome Measures:**         | Primary Outcome Measure  
Secondary Outcome Measures: |
How to Contact Us?

PRS Administrators at Columbia University:

Jane Cho, MS
T: (212) 342-2763
E: jc2050@columbia.edu

Fatoumatta N’Dure
T: (212) 342-1643
E: fn2151@columbia.edu

QA Team at ClinicalTrials.gov:

E: register@clinicaltrials.gov

THANK YOU!