

Protocol Registration System (PRS):
Accounts and Registration

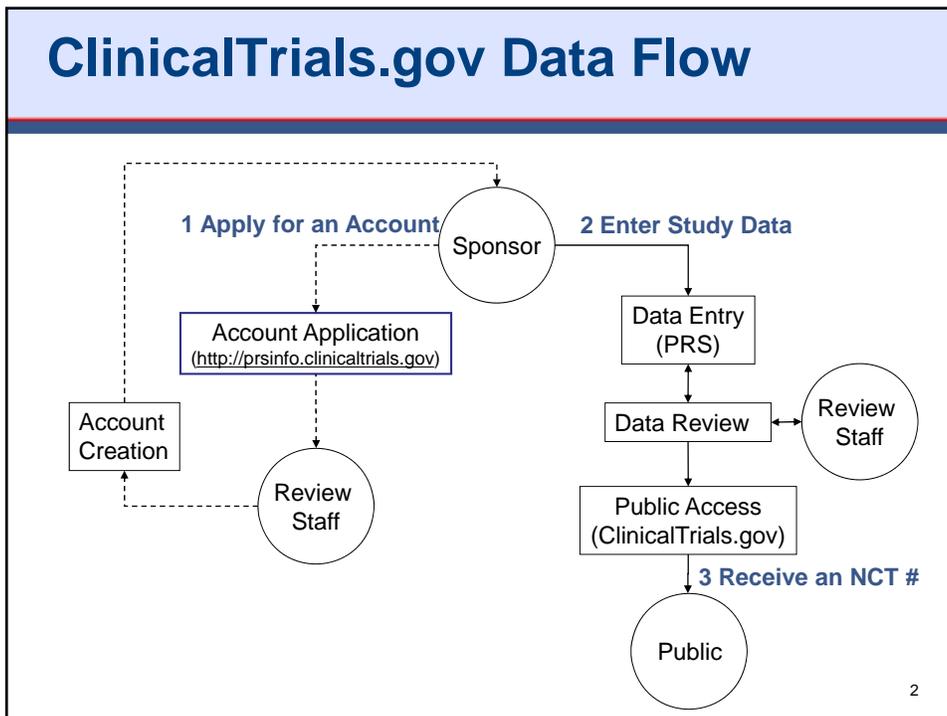
ClinicalTrials.gov
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Protocol Registration System (PRS): Accounts and Registration

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National Library of Medicine



<http://ClinicalTrials.gov>



Apply for a PRS Account

- Go to PRS information page
 - <http://prsinfo.clinicaltrials.gov>
- Determine whether you need to apply for a PRS account
 - If your organization already has a PRS account, contact your organization's PRS administrator to obtain login information
- Log into the PRS (<https://register.clinicaltrials.gov>)
- Review the available documentation:
 - Quick Start Guide and User's Guide

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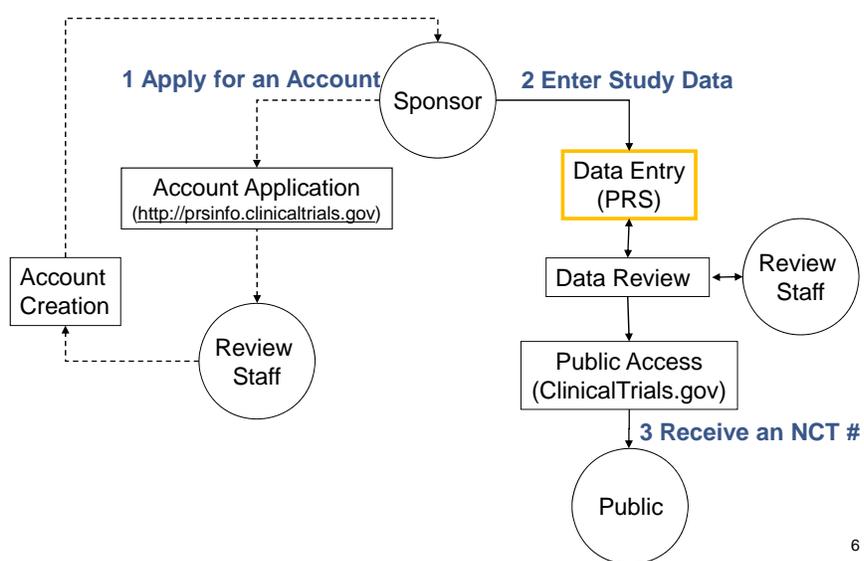
PRS User Roles and Responsibilities

- PRS User
 - Enters study data
 - Ensures that the data are correct
 - Updates records in a timely manner, as needed
- PRS Administrator
 - Reviews data for errors
 - Releases records for posting on ClinicalTrials.gov
 - Oversees the PRS account on behalf of their organization (e.g., creates user accounts)
 - Serves as a point of contact for ClinicalTrials.gov

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Entering Protocol Data

ClinicalTrials.gov Data Flow



Protocol Registration System (PRS): Accounts and Registration

PRS: Login

ClinicalTrials.gov
Protocol Registration System



Login

Welcome to the ClinicalTrials.gov Protocol Registration System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 04/30/2012
[Euler-Gen Statement](#)

Organization:
User Name:
Password: [Forgot password](#)

Login

[PRS account registration information](#)
[Send email to ClinicalTrials.gov Administration](#)

<http://register.clinicaltrials.gov> 7

PRS: Main Menu

Protocol Records Create Modify View QA Review Comments Problems: create resolve Undelete
User Account Change password PRS Administrator(s)
Help Quick Start Guide Frequently Asked Questions What's New Dec 21, 2010 User's Guide Data Element Definitions Results Data Element Definitions FDAMA 113 Requirements
XML Upload Upload protocol records Check upload status Protocol XML Schema Results XML Schema Results Pick-list Normalization
Session Logout

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PRS: Before You Start

The screenshot shows a vertical navigation menu with the following sections and links:

- Protocol Records**
 - Create
 - Modify
 - View
 - QA Review Comments
 - Problems
 - Undelete
- User Account**
 - Change password
 - PRS Administrator(s)
- Help**
 - Quick Start Guide
 - Frequently Asked Questions
 - What's New Dec 21, 2010
 - User's Guide
 - Data Element Definitions
 - Results Data Element Definitions
 - FDAMA 113 Requirements
- XML Upload**
 - Upload protocol records
 - Check upload status
 - Protocol XML Schema
 - Results XML Schema
 - Results Pick-list Normalization
- Session**
 - Logout

Three red arrows point from the following text on the left to the corresponding links in the menu:

- Change Password → Change password
- Read Quick Start Guide → Quick Start Guide
- Read User's Guide → User's Guide

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Items To Consider Before Registering a Protocol

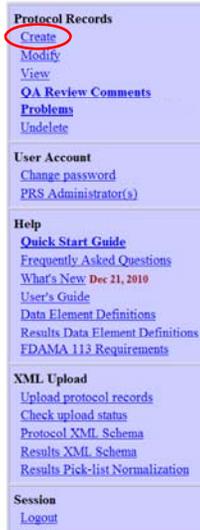
- Studies subject to FDAAA must be registered by the Responsible Party (study sponsor or designated principal investigator [PI])
- Each protocol can only be registered once
 - Avoid duplicate registrations (i.e., multiple records for same study)
 - Agree on the sponsor and the responsible party ahead of time
 - Multisite studies are NOT registered by each individual site
 - Multi-collaborator/funder studies need to designate a single entity to register the study
- See the “Protocol Detailed Review Items” document for hints on preparing a registration record

<http://prsinfo.clinicaltrials.gov/fdaaa.html>

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Protocol Registration System (PRS): Accounts and Registration

Create a Record



Protocol Records
[Create](#)
[Modify](#)
[View](#)
[QA Review Comments](#)
[Problems](#)
[Undelete](#)

User Account
[Change password](#)
[PRS Administrator\(s\)](#)

Help
[Quick Start Guide](#)
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[What's New Dec 21, 2010](#)
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[Results Pick-list Normalization](#)

Session
[Logout](#)

To enter your protocol into the system, click on "Create"

This will take you into a Web-based data entry system where you can enter information on your trial

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Sample PRS Data Entry Screen

Title	Oversight	Sponsor	Summary	Status	Design	Interventions	Conditions	Eligibility	Locations	Citations	Links
Title: A Randomized Double-blinded Active-controlled Clinical...											ID: M3-12A
Unique Protocol ID: * FDAAA	Enter sponsoring organization's unique identifier. M3-12A										
Brief Title: * FDAAA (Special characters)	Use lay language. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer A randomized double-blinded active-controlled clinical trial to investigate										
Acronym:	If there is an acronym or abbreviation used to identify this study, enter it here.										
Official Title:	Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate										
Study Type: * FDAAA	<input type="radio"/> Interventional <input type="radio"/> Observational <input type="radio"/> Expanded Access About expanded access records										
FDA Regulated Intervention? FDAAA	Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulations. --Select-- <input type="radio"/> Yes <input type="radio"/> No										
IND/IDE Protocol? * FDAAA	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). --Select-- <input type="radio"/> Yes <input type="radio"/> No										
<input type="button" value="Continue"/>	<input type="button" value="Quit"/>										

* 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

Key Registry Data Elements*

- Protocol Information
 - Title/Protocol ID
 - Brief Summary
 - Study Type and Design
 - **# Participants**
 - Condition
 - Intervention
 - Study Arms/Description
 - Outcome Measures
- Dates
 - Start Date
 - **Completion Date**
- Recruitment Information
 - **Recruitment Status**
 - Eligibility Criteria
 - **Facility Location(s)**
- Administrative
 - Sponsor
 - Investigators
 - IND/IDE Information
 - Human Subjects Review
 - **Expanded Access**

*Data elements expected to change during conduct of the trial are **highlighted**.

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After Data Entry Is Finished

- Review the information on the Edit Protocol screen for accuracy and completeness
 - **STOP ERROR** - Study cannot be released, must be addressed
 - **WARNING** - FDAAA* item; should be addressed
 - **NOTE** - Helpful hints
- Review entry for consistency with Protocol Detailed Review Items (prsinfo.clinicaltrials.gov/fdaaa.html)
- When your review is complete, click on “Next Action: Complete”

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After Data Entry Is Finished (cont'd)

- PRS administrator will “approve” and “release” the record to be displayed publicly at ClinicalTrials.gov
- After the record is “released,” ClinicalTrials.gov staff will review the record for consistency with minimum quality review criteria

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Sample PRS Edit Record Screen

The screenshot shows the 'Edit Protocol Record' interface. At the top left is the 'ClinicalTrials.gov Protocol Registration System' logo. On the right are logos for the Department of Health and Human Services and the FDA. A navigation menu includes 'Main Menu', 'Select', 'Preview', 'Spelling', 'Edit', 'Delete', and 'Download XML'. A red box highlights the 'Next Action: Complete' link and a tip: 'Tip: Remember to update Record Verification Date when reviewing or updating a protocol record.' Below this, the 'Record Status' section shows 'In Progress' selected, with other options 'Completed', 'Approved', and 'Released'. It also displays 'Owned by: User', 'Last updated: 01/14/2011 09:42 by User', and 'Initial release: [not yet released]'. A green box points to the 'Record Log' section, which is currently empty. Another green box points to the 'XML Upload: Allowed' status. The bottom section contains fields for 'Unique Protocol ID: 11110000', 'ClinicalTrials.gov ID:', 'Brief Title: Pilot Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer', and 'Official Title: Phase II Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate'.

After reviewing entered data, click “Complete”

Next Action: [Complete](#) Tip: Remember to update [Record Verification Date](#) when reviewing or updating a protocol record.

Record Status: [In Progress](#) | [Completed](#) | [Approved](#) | [Released](#) XML Upload: Allowed

Owned by: [User](#) Last updated: 01/14/2011 09:42 by [User](#)

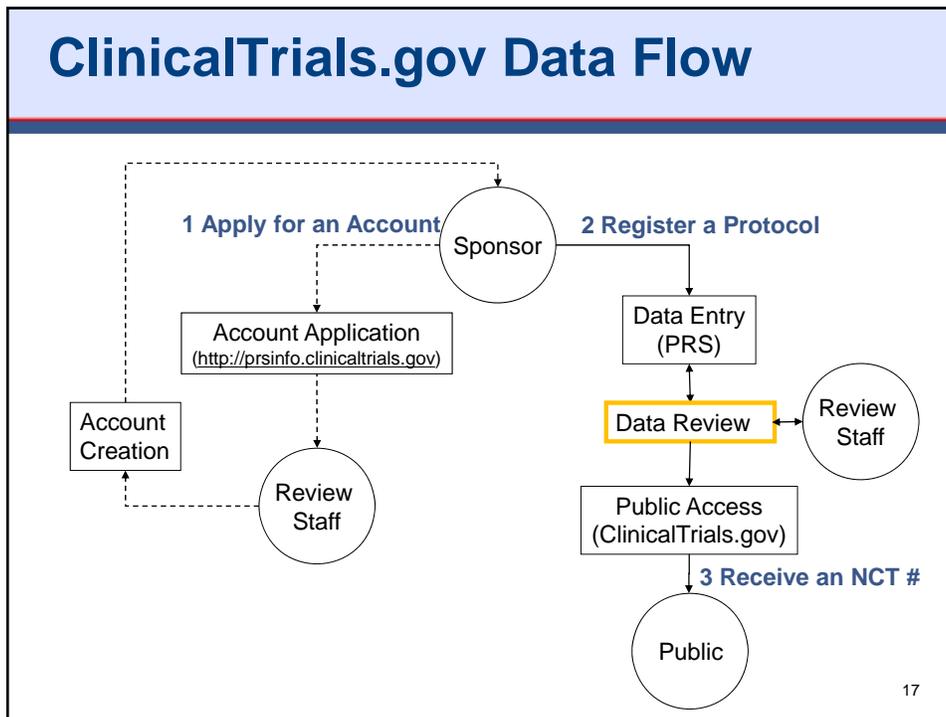
Initial release: [not yet released]

Record Log: None

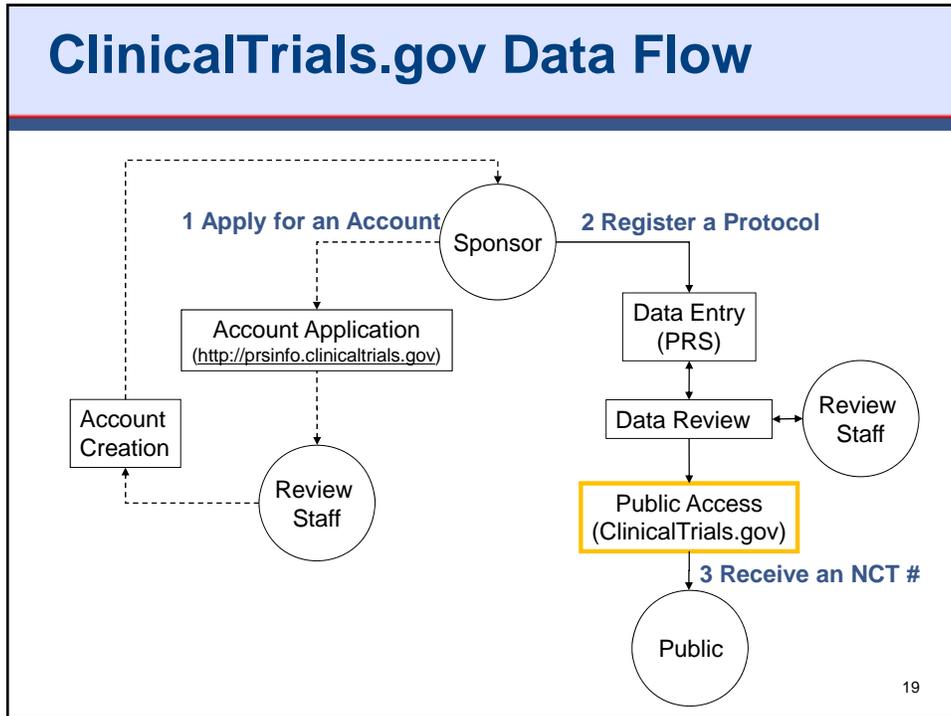
Track the status of the record

Unique Protocol ID: 11110000
ClinicalTrials.gov ID:
Brief Title: Pilot Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer
Official Title: Phase II Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate

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- ### General Review Criteria
- Protocol record must be clear and informative
 - Review focuses on:
 - Logic and internal consistency
 - Apparent validity
 - Meaningful entries
 - Formatting
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Receive a ClinicalTrials.gov Identifier (NCTxxxxxxx)

- Records should be available at ClinicalTrials.gov within **2 to 5 business days** of release by the administrator
- Where to find the ClinicalTrials.gov Identifier
 - **Email:** Sent to the “record owner” once QA reviewer has posted it
 - **PRS Account:** Appears in the “ClinicalTrials.gov ID” field
 - **ClinicalTrials.gov:** Search using your Unique Protocol ID; the NCT number is listed at the top
- A study is not registered until it receives a ClinicalTrials.gov Identifier (NCT number)
- Check the public site to ensure that your study is properly registered

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Modify a Record

To edit an existing record, click on "Modify" →



The screenshot shows a vertical menu with the following sections:

- Protocol Records**
 - [Create](#)
 - [Modify](#)
 - [View](#)
 - [QA Review Comments](#)
 - [Problem](#)
 - [Undelete](#)
- User Account**
 - [Change password](#)
 - [PRS Administrator\(s\)](#)
- Help**
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 - [Results XML Schema](#)
 - [Results Pick-list Normalization](#)
- Session**
 - [Logout](#)

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Modify a Record

- Click "Modify" on the Main Menu and select the record to be modified
- Make changes to the relevant section of the record and save changes by clicking "OK"
- Review record for ERRORS, WARNINGS, NOTES and check against review criteria
- Update Record Verification Date
- Click on "Next Action: Complete"

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Protocol Registration System (PRS): Accounts and Registration

ClinicalTrials.gov
Protocol Registration System



Edit Protocol Record

[Main Menu](#) [Select](#) [Preview](#) [Spelling](#) [Edit All](#) [Delete](#) [Download XML](#)

Optional Actions: [Reset to In-Progress](#)

Record Status: In Progress | **Completed** | Approved | Released **XML Upload:** Allowed
Owned by: [tsetony](#) **Last updated:** 01/14/2011 10:15 by tsetony
Initial release: [not yet released]

[Add](#) **Record Log:** None

Edit	Unique Protocol ID: 11110000
	ClinicalTrials.gov ID:
	Brief Title: Pilot Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer
	Full Title: Phase II Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate

Click "Edit" to modify the entries for the data elements that appear to the right (e.g., Brief Title).

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Review Criteria

General Issues

- English is used (possible exception: Official Title)
- Acronyms and abbreviations are explained in parentheses first time used
- No spelling errors exist
 - Hint: Use the Spelling Tool on “View Protocol Record” page
- No formatting problems found, including unreadable characters or symbols
 - Hint: Use Unicode, UTF-8 format
- Brief Title is in lay language and includes the condition and intervention evaluated in the study

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Internal Consistency

Information must be consistent throughout record

- Overall recruiting status with:
 - Study Start Date
 - Primary Completion Date
 - Study Completion Date
- Study Type with other information in the record
- Intervention Names—consistent throughout record
- Study Design data elements with Official Title and other information in the record

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Outcome Measures (OMs)

- **Specific** (Primary and Secondary)
Outcome Measure Titles and Descriptions
 - Describes WHAT will be measured and assessed, **not** WHY it will be measured
 - Name of the specific measure (e.g., “systolic blood pressure”)
 - Description of the metric that will be used to characterize the measure (e.g., “change in systolic blood pressure”)
- Note: General terms such as “safety,” “tolerability,” and “feasibility” are not sufficient

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Outcome Measure Time Frame

- General—Time Frame must be specific
 - “At follow-up” or “end of study” is not specific
 - At a minimum, the Time Frame should include the maximum length of follow-up that is currently planned (e.g., “up to 3 years”)
- Most OMs will have one time point
- Each unique combination of OM and Time Frame should be entered as separate OMs
 - “Hamilton Depression Rating Scale at 8 weeks” and “Hamilton Depression Rating Scale at 12 weeks”

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OM Time Frame (cont'd)

- “Change” Outcome Measures
 - Time Frame indicates time period over which change occurred
 - Generally, two time points should be entered (e.g., “baseline and 8 weeks”)
- “Time-to-Event” Outcome Measures
 - At a minimum, include the estimated period of time over which the event will be assessed (e.g., “up to 100 weeks”)

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Entering Arms and Interventions

1. Specify Each Study Arm (3x)

Arm Label: * (BAAU)	Arm Label should be descriptive, yet concise, especially for later use in: Examples: Metformin, Lifestyle counseling, Sugar pill High Dose	Arm: * (BAAU) Active Comparator: Low Dose Drug X, 1 mg daily + Penicillin 1 to 2 million units IV every 4 hours for days.
Arm Type: * (BAAU)	Experimental	Arm: * (BAAU) Experimental: High Dose Drug X, 5 mg daily + Penicillin 1 to 2 million units IV every 4 hours for days.
Arm Description: (BAAU)	Drug X, 5 mg daily + Penicillin 1 to 2 million units IV every 4 hours for up to 14 days.	Arm: * (BAAU) Placebo Comparator: Control Placebo + Penicillin 1 to 2 million units IV every 4 hours for up to 14 days.

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Entering Arms and Interventions

1. Specify Each Study Arm (3x)

Arm Label: * (FDA/AAU) Arm Label should be descriptive, yet concise, especially for later use in... Examples: Metformin, Lifestyle counseling, Sugar pill
High Dose

Arm Type: * (FDA/AAU) Experimental

Arm Description: (FDA/AAU) Drug X, 5 mg daily + Penicillin 1 to 2 million un... 14 days.

Arm: * (FDA/AAU) Active Comparator: Low Dose
Drug X, 1 mg daily + Penicillin 1 to 2 million units IV every 4 hours for days.

Arm: * (FDA/AAU) Experimental: High Dose
Drug X, 5 mg daily + Penicillin 1 to 2 million units IV every 4 hours for days.

Arm: * (FDA/AAU) Placebo Comparator: Control
Placebo + Penicillin 1 to 2 million units IV every 4 hours for up to 14 d

2. Specify Each Intervention (4x)

Intervention Type: * (FDA/AAU) Drug

Intervention Name: * (FDA/AAU) Enter the specific name of the intervention. For a drug, use the generic equivalent name if it has been established.
Drug X

Intervention Description: (FDA/AAU) Key details, e.g., for drugs include dosage form, dosage, frequency and duration.
1 mg tablets

Arms: * (FDA/AAU) Active Comparator: Low Dose
 Experimental: High Dose
 Placebo Comparator: Control

Intervention: * (FDA/AAU) Drug: Drug X
1 mg tablet
Arms: Low Dose
NOTE: Intervention Other Names have not been

Intervention: * (FDA/AAU) Drug: Drug X
5 mg tablet
Arms: High Dose
NOTE: Intervention Other Names have not been

Intervention: * (FDA/AAU) Drug: Placebo
Tablet, identical to drug X
Arms: Control
NOTE: Intervention Other Names have not been

Intervention: * (FDA/AAU) Drug: Penicillin
IV (in the vein)
Arms: Low Dose, High Dose, Control

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Entering Arms and Interventions

1. Specify Each Study Arm (3x)

Arm Label: * (FDA/AAU) Arm Label should be descriptive, yet concise, especially for later use in... Examples: Metformin, Lifestyle counseling, Sugar pill
High Dose

Arm Type: * (FDA/AAU) Experimental

Arm Description: (FDA/AAU) Drug X, 5 mg daily + Penicillin 1 to 2 million un... 14 days.

Arm: * (FDA/AAU) Active Comparator: Low Dose
Drug X, 1 mg daily + Penicillin 1 to 2 million units IV every 4 hours for days.

Arm: * (FDA/AAU) Experimental: High Dose
Drug X, 5 mg daily + Penicillin 1 to 2 million units IV every 4 hours for days.

Arm: * (FDA/AAU) Placebo Comparator: Control
Placebo + Penicillin 1 to 2 million units IV every 4 hours for up to 14 d

2. Specify Each Intervention (4x)

Intervention Type: * (FDA/AAU) Drug

Intervention Name: * (FDA/AAU) Enter the specific name of the intervention. For a drug, use the generic equivalent name if it has been established.
Drug X

Intervention Description: (FDA/AAU) Key details, e.g., for drugs include dosage form, dosage, frequency and duration.
1 mg tablets

Arms: * (FDA/AAU) Active Comparator: Low Dose
 Experimental: High Dose
 Placebo Comparator: Control

Intervention: * (FDA/AAU) Drug: Drug X
1 mg tablet
Arms: Low Dose
NOTE: Intervention Other Names have not been

Intervention: * (FDA/AAU) Drug: Drug X
5 mg tablet
Arms: High Dose
NOTE: Intervention Other Names have not been

Intervention: * (FDA/AAU) Drug: Placebo
Tablet, identical to drug X
Arms: Control
NOTE: Intervention Other Names have not been

Intervention: * (FDA/AAU) Drug: Penicillin
IV (in the vein)
Arms: Low Dose, High Dose, Control

3. Assign Each Intervention to One or More Study Arms

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Displaying Arms and Interventions

Arms	Assigned Interventions	
Arm 1 { Active Comparator: Low Dose Drug X, 1 mg daily + Penicillin 1 to 2 million units IV every 4 hours for up to 14 days.	Drug: Drug X 1 mg tablet	} Intervention 1 } Intervention 2
	Drug: Penicillin IV (in the vein)	
Arm 2 { Experimental: High Dose Drug X, 5 mg daily + Penicillin 1 to 2 million units IV every 4 hours for up to 14 days.	Drug: Drug X 5 mg tablet	} Intervention 3
	Drug: Penicillin IV (in the vein)	
Arm 3 { Placebo Comparator: Control Placebo + Penicillin 1 to 2 million units IV every 4 hours for up to 14 days.	Drug: Placebo Tablet, identical to drug X	} Intervention 4
	Drug: Penicillin IV (in the vein)	

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Additional Information

General ClinicalTrials.gov information:

<http://prsinfo.clinicaltrials.gov>

FDAAA related information:

<http://prsinfo.clinicaltrials.gov/fdaaa.html>

Office of Extramural Research:

http://grants.nih.gov/Clinicaltrials_fdaaa/

Questions?

register@clinicaltrials.gov