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Protocol Registration System (PRS): Accounts and Registration

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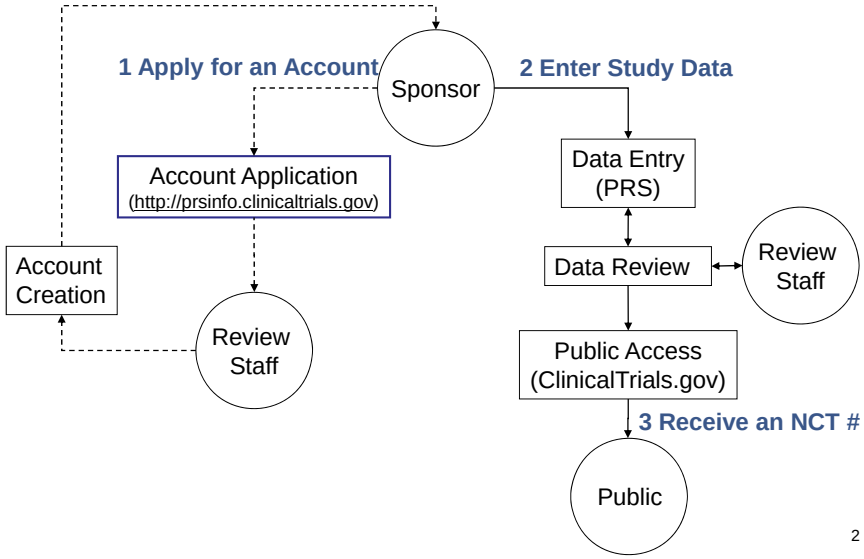
National Library of Medicine

http://ClinicalTrials.gov

ClinicalTrials.gov Data Flow



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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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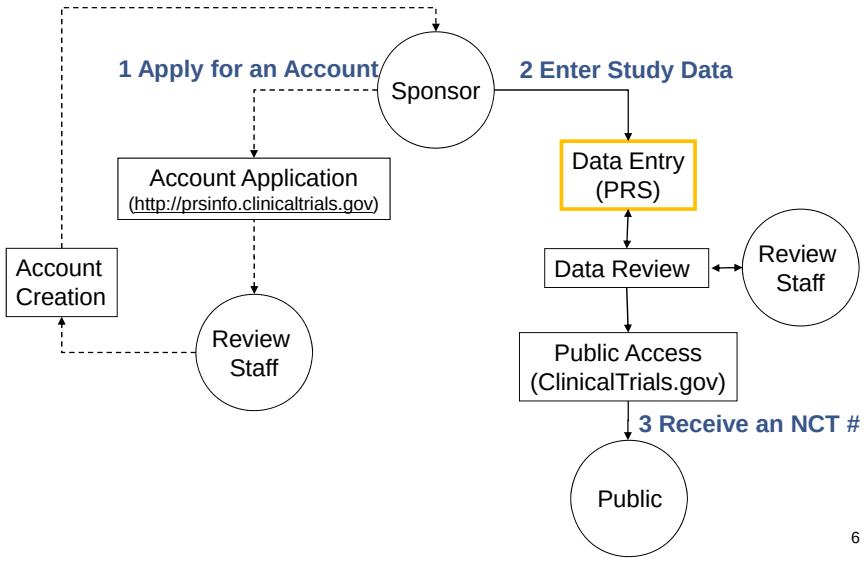
Entering Protocol Data

ClinicalTrials.gov Data Flow



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PRS: Login

http://register.clinicaltrials.gov

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PRS: Main Menu

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PRS: Before You Start

Change Password

Read Quick Start Guide

Read 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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Create a Record

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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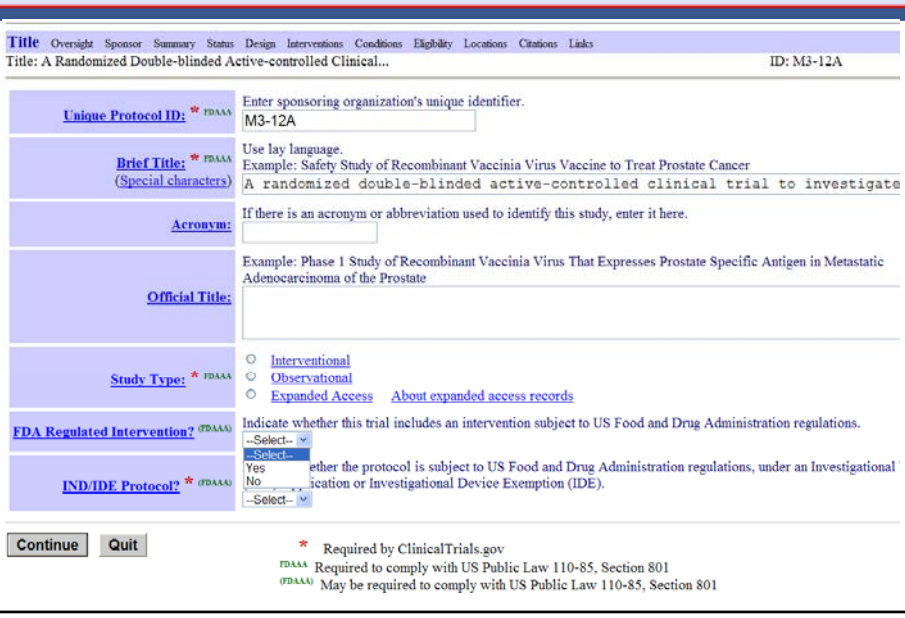
Sample PRS Data Entry Screen



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
  - 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

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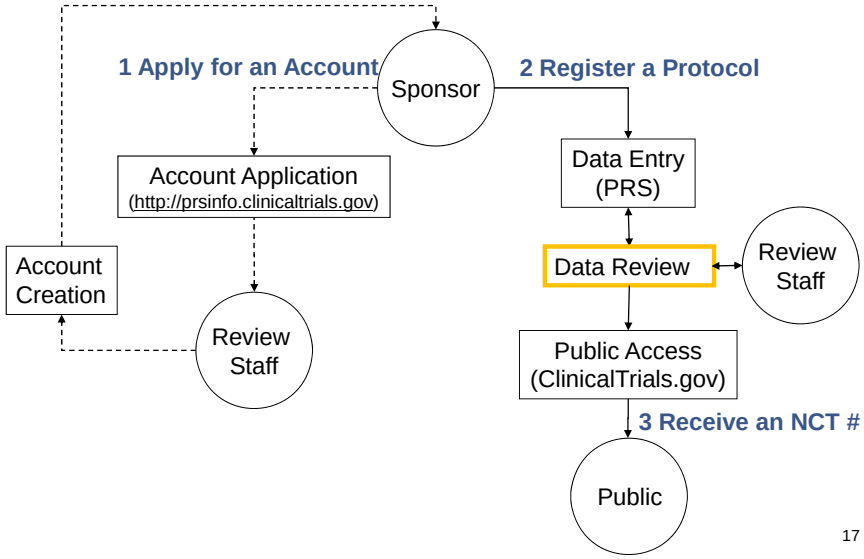
ClinicalTrials.gov Data Flow



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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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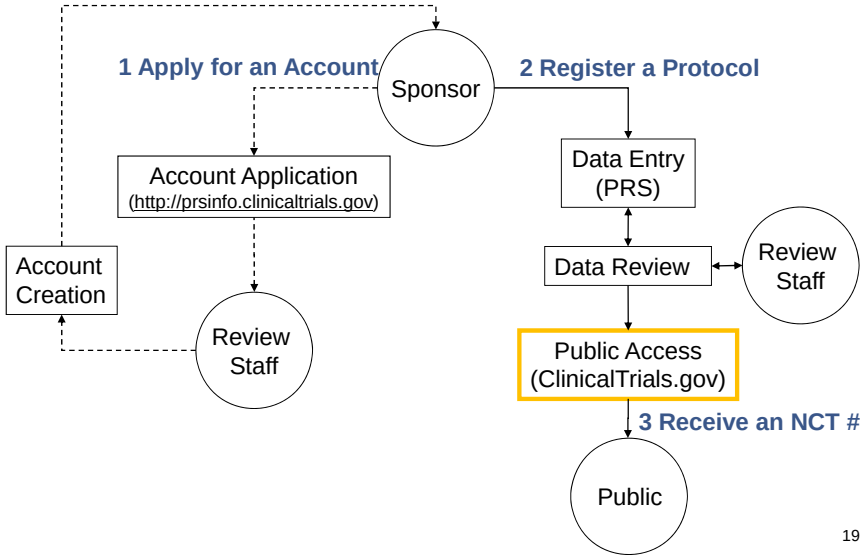
ClinicalTrials.gov Data Flow



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Receive a ClinicalTrials.gov Identifier (NCTxxxxxxxx)

- 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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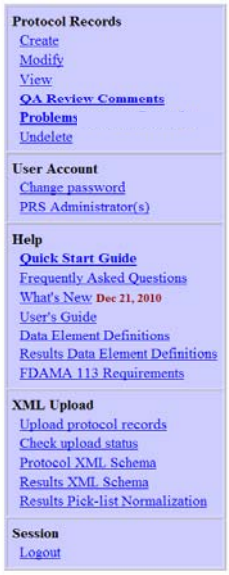
Modify a Record

To edit an existing record, click on "Modify"



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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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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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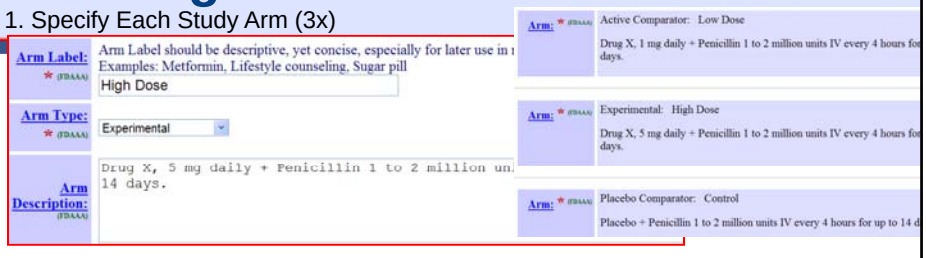
Entering Arms and Interventions

1. Specify Each Study Arm (3x)



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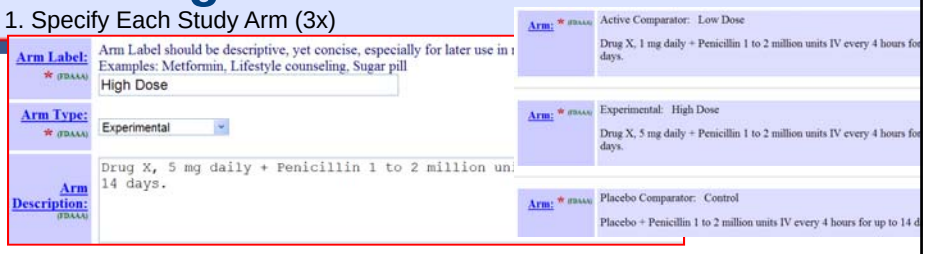
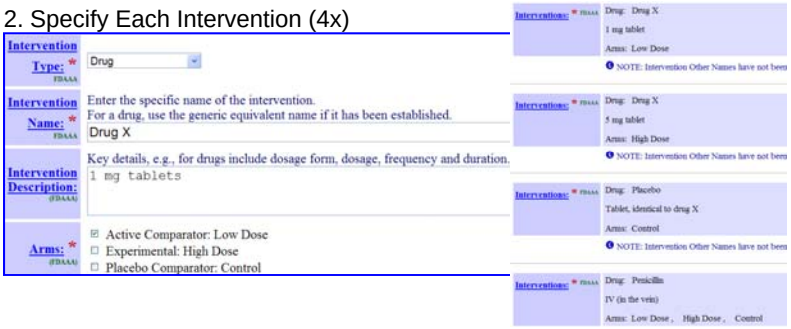


2. Specify Each Intervention (4x)



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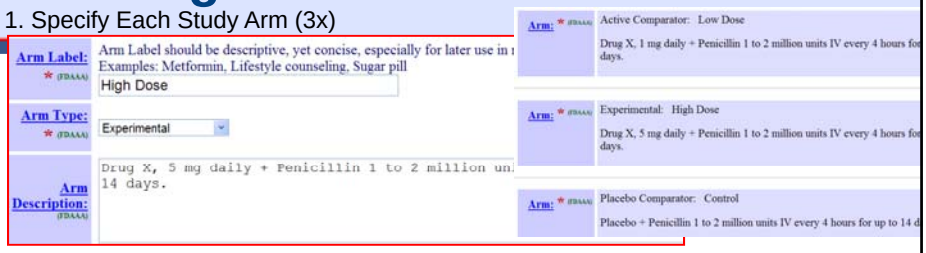

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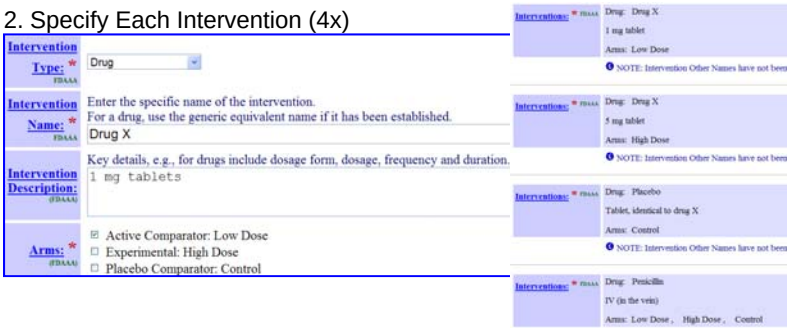

3. Assign Each Intervention to One or More Study Arms

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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
		Drug: Penicillin IV (in the vein)	Intervention 2
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