Protocol Registration System (PRS): Accounts and Registration

Annice M. Bergeris
Information Research Specialist, ClinicalTrials.gov
National Library of Medicine

ClinicalTrials.gov Data Flow

1 Apply for an Account
   Account Application (http://prsinfo.clinicaltrials.gov)
   Account Creation
   Review Staff

2 Enter Study Data
   Data Entry (PRS)
   Data Review
   Public Access (ClinicalTrials.gov)
   Public

3 Receive an NCT #
Apply for a PRS Account

- Go to PRS information page
  - [http://prsinfo.clinicaltrials.gov](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](https://register.clinicaltrials.gov))
- Review the available documentation:
  - Quick Start Guide and User’s Guide

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
Entering Protocol Data

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**PRS: Login**

![PRS: Login Image]

**PRS: Main Menu**

![PRS: Main Menu Image]
### PRS: Before You Start

- Change Password
- Read Quick Start Guide
- Read User’s Guide

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**Protocol Registration System (PRS):**

**Before You Start**

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**Protocol Records**
- Create
- Modify
- View
- QA Review Comments
- Problem
- Undelete

**User Account**
- Change password
- PRS Administrator(s)

**Help**
- Quick Start Guide
- Frequently Asked Questions
- What’s New: Sep 23, 2019
- User Guide
- Data Element Definitions
- Results Data Elements
- FDAAA-112 Specifications

**XML Upload**
- Uploaded protocol records
- Check upload status
- Protocol XML Schema
- Results XML Schema
- Results Data Element Normalization

**Session**
- Logout

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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

(https://prsinfo.clinicaltrials.gov/fdaaa.html)
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.

Sample PRS Data Entry Screen

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Enter the title of the protocol.</td>
</tr>
<tr>
<td>Brief Title</td>
<td>Enter the brief title of the protocol.</td>
</tr>
<tr>
<td>Objective</td>
<td>Enter the objective of the protocol.</td>
</tr>
<tr>
<td>Study Type</td>
<td>Select the type of study (interventional, observational).</td>
</tr>
<tr>
<td>FDA Regulated</td>
<td>Indicate whether the study is regulated by the FDA.</td>
</tr>
<tr>
<td>IND/IDE Protocol</td>
<td>Indicate whether the protocol is subject to IND/IDE regulations.</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
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**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** - FDAA\* item; should be addressed
  - **NOTE** - Helpful hints
- Review entry for consistency with Protocol Detailed Review Items ([prsinfo.clinicaltrials.gov/fdaa.html](prsinfo.clinicaltrials.gov/fdaa.html))
- When your review is complete, click on “Next Action: Complete”
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

Sample PRS Edit Record Screen

After reviewing entered data, click “Complete”

Track the status of the record
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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 (NCTxxxxxxxxx)

- 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
To edit an existing record, click on “Modify”

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

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

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
**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

**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”
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”)

Entering Arms and Interventions
1. Specify Each Study Arm (3x)

<table>
<thead>
<tr>
<th>Arm Label</th>
<th>Arm Type</th>
<th>Drug Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Drug X, 5 mg daily + Penicillin 1 to 2 million units 14 days.</td>
</tr>
</tbody>
</table>

Active Comparator: Low Dose
Drug X, 5 mg daily + Penicillin 1 to 2 million units IV every 4 hours 6 days.

Experimental: High Dose
Drug X, 5 mg daily + Penicillin 1 to 2 million units IV every 4 hours 6 days.

Placebo Comparator: Control
Placebo + Penicillin 1 to 2 million units IV every 4 hours for up to 10 days.
Entering Arms and Interventions

1. Specify Each Study Arm (3x)

- **Arm Label:**
  - Drug X
  - Penicillin 1 to 2 million units in 16 days

2. Specify Each Intervention (4x)

- **Intervention:**
  - Drug X

3. Assign Each Intervention to One or More Study Arms

- **Intervention Type:**
  - Drug
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Displaying Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention 1</th>
<th>Intervention 2</th>
<th>Intervention 3</th>
<th>Intervention 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm 1</td>
<td>Active Comparator: Low Dose</td>
<td>Drug X, 1 mg daily</td>
<td>Drug X, 1 mg daily</td>
<td>Drug X, 1 mg daily</td>
</tr>
<tr>
<td>Arm 2</td>
<td>Experimantal: High Dose</td>
<td>Drug X, 5 mg daily</td>
<td>Drug X, 1 mg daily</td>
<td>Drug X, 1 mg daily</td>
</tr>
<tr>
<td>Arm 3</td>
<td>Placebo Comparator: Control</td>
<td>Placebo, 2 mg daily</td>
<td>Placebo, 2 mg daily</td>
<td>Placebo, 2 mg daily</td>
</tr>
</tbody>
</table>

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