

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Protocol Registration System (PRS) Overview and Resource Orientation

Results Database Train-the-Trainer Workshop
October 2012

 <http://ClinicalTrials.gov>

Using the Protocol Registration System (PRS)

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PRS Basics

- Web-based data entry system for summary protocol and results information
 - Requires organizational account, user name, password
- PRS Organizational Accounts
 - Established by an organization
 - Used to enter, review, submit, and update protocol and results information for studies (“records”) sponsored by the organization or conducted by sponsor-investigators at the organization

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PRS Basics (cont.)

- PRS Roles
 - Administrator: organization point of contact
 - Maintains PRS Organizational Account
 - Creates User accounts
 - Has access to all study records
 - Monitors records in account for Problems
 - Approves and releases records when the Organization is the Sponsor and Responsible Party
 - User: creates and edits records
 - Only has access to records in which they are the Record Owner or on the Access List
 - Approves and releases records when a Sponsor-Investigator or Principal Investigator is the Responsible Party

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PRS Basics (cont.)

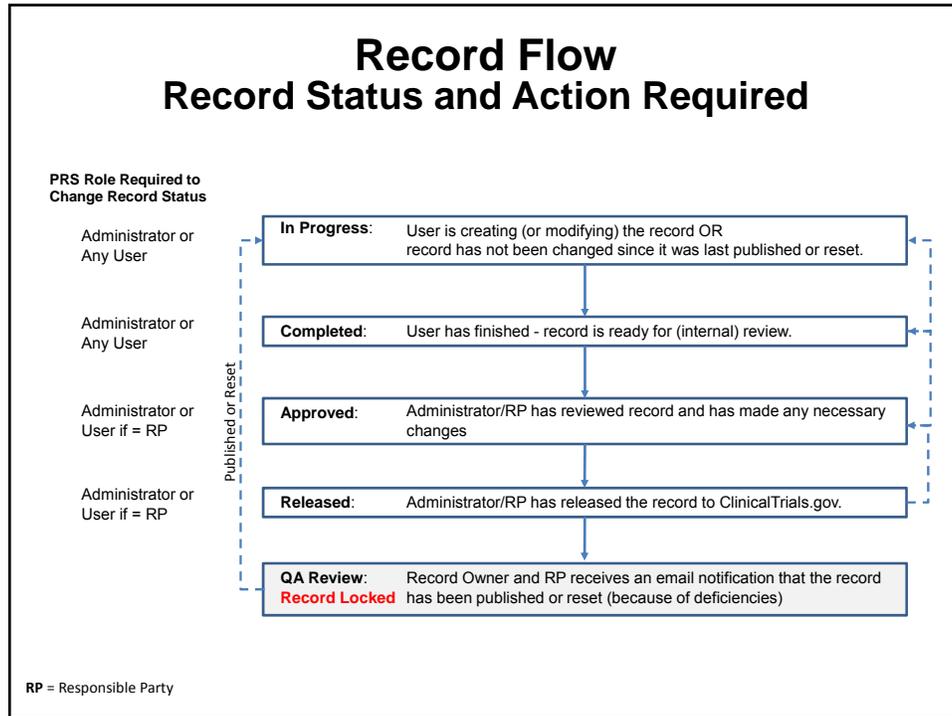
- PRS Roles
 - Record Owner (may be a User or Administrator)
 - Considered the primary contact for a study record
 - Initially assigned to person who created the study record; record ownership can be transferred

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PRS Basics (cont.)

- Required* and optional structured data elements
 - Pull-down menus and/or free text
- Business rules
 -  **ERROR** - Study cannot be released; must be addressed
 -  **WARNING** - FDAAA item; should be addressed
 -  **NOTE** - Helpful hints; may or may not apply
- Review criteria applied by ClinicalTrials.gov Staff
 - Logic and internal consistency
 - Apparent validity
 - Meaningful entries
 - Formatting

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PRS Information Resources

- User's Guide [PRS Main Menu]
- Protocol Registration
 - Data Elements
 - Review Criteria
- Results
 - Data Elements
 - Review Criteria
 - Simple Results Templates
 - Helpful Hints and Common Errors

Items To Consider Before Registering a Protocol

- 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
- Studies must be registered by the Responsible Party (study Sponsor or designated Principal Investigator [PI])

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

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PRS Responsible Party Format

ClinicalTrials.gov
Protocol Registration System



Title Oversight **Sponsor** Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: RP Demo Example: Responsible Party With Old Data Elements ID: 0-rp-demo-old

Responsible Party: ^{FDAAA} NOTE: The **Sponsor** option should be selected, unless the Investigator has been designated as
--Select-- tted under US Public Law 110-85, the FDA Amendments Act (FDAAA).
--Select-- out Responsible Party...

Sponsor: ^{* FDAAA} Test Organization
ty was entered in the old format as Professor Håkan Hanberger, Division of
Principal Investigator tsity Hospital, SE-581 85 Linköping.
Sponsor-Investigator ple Party has not been entered.

Collaborators: (One per line)
Include all additional funding sources.
Enter only the organization names, one per line (no numbers, dashes, bullets, etc.).
Merck

OK Cancel

* 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

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PRS Responsible Party Format

ClinicalTrials.gov
Protocol Registration System

Title: Oversight **Sponsor** Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: RP Demo Example: Responsible Party With Old Data Elements ID: 0-rp-demo-old

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).
[Principal Investigator](#) [About Responsible Party...](#)

Responsible Party: 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 not in list?](#)
[Incorrect name format?](#)

Investigator Official Title:

Investigator Affiliation:

NOTE: Responsible Party was entered in the old format as Professor Håkan Hanberger, Division of Infectious Diseases, Unrversity Hospital, SE-581 85 Linköping.
WARNING: Responsible Party has not been entered.

Sponsor: * FDAAA

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PRS Business Rules: Responsible Party

- Responsible Party must Approve and Release record (but others may still assist with data entry)
 - If RP = Sponsor
 - Administrator “approves” and “releases” record
 - If RP ≠ Sponsor
 - Record is in the Sponsor’s organizational account
 - Investigator must be specified as a User in the PRS and name must be properly formatted (for display on ClinicalTrials.gov)
 - Investigator “approves” and “releases” record
 - Administrator receives notification after release
- See: “Responsible Party FAQ” on PRS Main Menu under Help for more information

<https://register.clinicaltrials.gov/>

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Previewing the Record: Viewing the Public Display

Click "Preview" to see how the entered data will be displayed in the record on the public site.

[Main Menu](#) [Select](#) [Preview](#) [Spelling](#) [Edit All](#) [Problems](#) [Delete](#) [Copy](#) [Downl](#)

Title: Test 1 - Efficacy and Safety Study of DX-88 to Treat Acute Attacks of Heredi..

Next Action: [Approve](#) **Optional Actions:** [Reset to In-Progress](#)

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ClinicalTrials.gov
Protocol Registration System

Protocol Registration Preview

[Continue](#) [Select](#)

Test 1 - Efficacy and Safety Study of DX-88 to Treat Acute Attacks of Hereditary Angioedema (HAE)

This study has been completed.

Sponsor:	PRS Training
Collaborators:	
Information provided by (Responsible Party):	Rebecca Williams, PRS Training
ClinicalTrials.gov Identifier:	

Purpose

The purpose of this study is to determine if a subcutaneous dose of DX-88 (ecallantide, an investigational product) is safe and relieves symptoms of HAE in patients suffering from moderate to severe acute attacks of HAE.

Condition	Intervention	Phase
Hereditary Angioedema (HAE)	Drug: ecallantide Drug: Phosphate Buffer Saline (PBS),	Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Randomized, Efficacy Study

Official Title: A Double-blind, Placebo-controlled Study (72 Patients, Randomized 1:1) Followed by a Repeat-dosing Phase to Assess the Efficacy and Safety of DX-88 (Ecallantide, Recombinant Plasma Kallikrein Inhibitor) for the Treatment of Acute Attacks of Hereditary Angioedema

Further study details as provided by Rebecca Williams, PRS Training:
Enrollment: 91
Study Start Date: December 2005
Study Completion Date: February 2007
Primary Completion Date: December 2005

Arms	Assigned Interventions
Experimental: DX-88 (ecallantide)	Drug: ecallantide
DX-88 (ecallantide) 30 mg given as three 10 mg/mL subcutaneous injections.	dose of 30 mg (10 mg/ml) given as 3 subcutaneous injections.
Placebo Comparator: Placebo	Drug: Phosphate Buffer Saline (PBS),
Phosphate Buffer Saline (PBS), pH 7.0 given as 3 subcutaneous injections.	given as three 1mL subcutaneous injections.

Sample PRS Edit Record Screen

ClinicalTrials.gov
Protocol Registration System

Edit Protocol Record

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

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]

[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
Official Title:	Phase II Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate

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Annotations:
- A green box points to the "Complete" button with the text: "After reviewing entered data, click 'Complete'".
- A green box points to the "In Progress" status with the text: "Track the status of the record".

Release Confirmation

ClinicalTrials.gov
Protocol Registration System

Release Protocol

Title: Test 1 - Efficacy and Safety Study of DX-88 to Treat Acute Attacks of Heredi... Org: PRSTraining ID: Test 1

Release protocol record Test 1 to the ClinicalTrials.gov Coordinating Center?

Protocol Records are made available to the public through the ClinicalTrials.gov web site within 2 to 5 days of release, following system validation and quality assurance review. Records that contain Results may take up to 30 days. Previous versions of trial data will be available to the public, although the default view will be the most recent version.

Tip: To help ensure prompt publication, proof read the information carefully and [check spelling](#) before releasing the record.

This protocol record was last verified in April 2010.
Overall Recruitment Status: Completed

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Protocol Registration Receipt

ClinicalTrials.gov
Protocol Registration System

clm3443



Protocol Registration Receipt
11/04/2011

[Continue](#) [Download PDF](#)

Protocol Records are made available to the public through the ClinicalTrials.gov web site within 2 to 5 days of release, following system validation and quality assurance review. Records that contain Results may take up to 30 days. The ClinicalTrials.gov identifier (NCT number) will be assigned at that time, and will then be visible in the PRS.

Tip: Use the "Download PDF" link to get a printable record confirming the registration of this trial.

Test 1 - Efficacy and Safety Study of DX-88 to Treat Acute Attacks of Hereditary Angioedema (HAE)

This study has been completed.

Sponsor:	PRS Training
Collaborators:	
Information provided by (Responsible Party):	Rebecca Williams, PRS Training
ClinicalTrials.gov Identifier:	

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ClinicalTrials.gov
Protocol Registration System



Protocol Registration Receipt
11/04/2011

Grantor: CDER IND/IDE Number: 12345 Serial Number: 01

Test 1 - Efficacy and Safety Study of DX-88 to Treat Acute Attacks of Hereditary
Angioedema (HAE)

This study has been completed.

Sponsor:	PRS Training
Collaborators:	
Information provided by (Responsible Party):	Rebecca Williams, PRS Training
ClinicalTrials.gov Identifier:	

► Purpose

The purpose of this study is to determine if a subcutaneous dose of DX-88 (ecallantide; an investigational product) is safe and relieves symptoms of HAE in patients suffering from moderate to severe acute attacks of HAE.

Condition	Intervention	Phase
Hereditary Angioedema (HAE)	Drug: ecallantide Drug: Phosphate Buffer Saline (PBS),	Phase 3

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New Registrations: ClinicalTrials.gov Identifier (NCT Number)

- Records should be available on ClinicalTrials.gov within **2 to 5 business days** of release
- Where to find the ClinicalTrials.gov Identifier
 - **Email:** Sent to the RP and “record owner” (if different)
 - **PRS Account:** Appears in the “ClinicalTrials.gov ID” field
 - **ClinicalTrials.gov:** Search using 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)
 - Initial Release Date will be reported on public site
- Some studies will be “reset” without public posting
- Check the public site to ensure that a study is properly registered

RP = Responsible Party

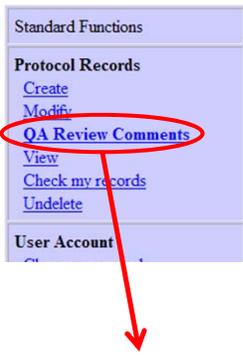
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Review Comments

- When record “**reset**”, the Responsible Party and Record Owner (if different) will receive email
- Comments can be accessed from PRS Main Menu and within each record
- Specific comments are co-located in the section where the issue was identified
- May be pre-formatted “comment stamp” or customized comment for specific issue

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Accessing Review Comments From the PRS Main Menu



Protocol ID	ClinicalTrials.gov ID	Brief Title	has Results	Comment Date	Release Date
03-154	NCT00145249	Amphotericin Alone or in Combination with Fluconazole for AIDS-Associated Meningitis	Results	06/22/2010	09/16/2010

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Review Comments Data Provider Perspective

[Collapse Section](#)

	AmphoB Standard	AmphoB+Fluc400	AmphoB + Fluc800
STARTED	47 ^[1]	48 ^[2]	48 ^[3]
COMPLETED	36	33	31
Not Completed	11	15	17

[1] 47 subjects randomized; 45 subjects treated
 [2] 48 subjects randomized; 47 subjects treated
 [3] 48 subjects randomized; 45 were study eligible and 49 were treated

Comments:

The Enrollment number in the protocol section conflicts with the number of participants Started in the Participant Flow module. Please verify and correct either or both of these data elements, as necessary.

Please provide an explanation for the last footnote. Specifically, it is not clear how the number of participants treated was more than the number of participants randomized.

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Review Comments Reviewer Perspective

▶ Participant Flow

Recruitment Details [Collapse Section](#)

Subjects were recruited at 13 medical centers in Latin America and participated between January 2007 and July 2008.

Pre-Assignment Details

160 subjects were screened and evaluated for inclusion/exclusion criteria; 121 were assigned to open-label treatment.

Reporting Groups

Description	
Pregabalin	Dose adjustment phase: Week 1: 75mg BID (150 mg/day) all subjects; Week 2 through Week 4: subjects were assessed on a weekly basis for dose adjustment from 75 mg BID (150 mg/day) to 150 mg BID (300 mg/day), and to 300 mg BID (600 mg/day) if needed based on pain relief and tolerability. 8 week dose maintenance phase (Week 5 to Week 12): subjects continued with their final pregabalin dosage: 75mg BID (150 mg/day) to 300 mg BID (600 mg/day) based on individual pain response and tolerability.

Comments:

-- Add Comment Stamp --

Please review entire record and expand all acronyms and abbreviations (and include acronyms in parentheses) at least the first time used in both the Protocol and Results section.

Overall Study [Collapse Section](#)

	Pregabalin
STARTED	121
COMPLETED	99

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Review Comments Reviewer Perspective

▶ Participant Flow

Recruitment Details [Collapse Section](#)

Subjects were recruited at 13 medical centers in Latin America and participated between January 2007 and July 2008.

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Comments:

-- Add Comment Stamp --

Acronyms and Abbreviations - Spell Out
 Arm Titles not Informative
 Cross-over Study
 Detailed Review of Results Submission
 Earlier Comments
 Irrelevant Information
 None or N/A
 Not Understandable
 Number Started Inconsistent with Protocol Enrollment
 Pending Records Require Review
 Results Helpful Hints and Common Errors
 Results Pre-submission checklist
 Spelling

and abbreviations (and time used in both the Protocol

Overall Study [Collapse Section](#)

COMPLETED	99
-----------	----

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Review Comments (cont.)

- If record reset without public posting, then major review findings must be addressed
 - Modify record to address comments and re-release record
- Email register@clinicaltrials.gov if questions on content of comments
 - Include NCT Number (or Unique Protocol ID prior to posting), date of comments, and description of question w/ any supporting info
 - May also request teleconference

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Review Comments - Protocol

- Insufficient Outcome Measures are the primary reason protocol records are reset
 - Be familiar with the Protocol Review Criteria for Outcome Measure Title, Description, and Time Frame

<http://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf>

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Caveats Regarding Posting at ClinicalTrials.gov

- **Responsible Party must ensure that records meet review criteria**
 - Responsible parties should assess their records using available review criteria prior to releasing the records
- Posting does **not** ensure that all review criteria were met
- Comments may still be provided “suggesting” improvements
- ClinicalTrials.gov may note issues and request revisions after record posted publicly

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PRS Tools for Administrators

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Creating User Accounts

Administrative Functions

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User Registration

Organization: TestOrg

Group: [none]

Access Level: Normal

User Login Name:

Full User Name:

Other User Information: Include phone number.

User Email: Enter email address carefully. Login information, including initial password, is sent to this address.

Send automatic (PRS-generated) email messages
 Subscribe to PRS Announcements (email)

[Create](#) [Cancel](#)

- Select Access Level
 - “Normal” for Users
 - “Administrator”
- Enter information
- Click “Create”

Modifying User Information

Administrative Functions

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User Information

Organization: TestOrg

Group: [none]

Access Level: Administrator

Username: JSmith

Full Name: Example: John J Smith, MD
Jane Smith

Email Address: Enter the full email address. Example: jsmith@mail.nih.gov
jsmith@nlm.nih.gov

Send automatic (PRS-generated) email messages
 Subscribe to PRS Announcements (email)

Important messages from ClinicalTrials.gov will be sent to this address.

Other User Information: Include phone number.

[Modify](#) [Disable](#) [Cancel](#)

The new password must have at least 8 characters.
The new password must use at least 2 out of the following:

- Letters [A..Z, a..z]
- Numbers [0..9]
- Other non-blank characters

New Password:

Repeat New Password:

[Change Password](#)

- Edit Information
- Click “Modify” to save edits

Resetting Passwords

Administrative Functions

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User Information

Organization: TestOrg
 Group: [none] v
 Access Level: Administrator v
 Username: JSmith
 Example: John J Smith, MD
 Full Name: Jane Smith
 Email Address: Enter the full email address. Example: jsmith@mail.nih.gov
 jsmith@nlm.nih.gov
 Send automatic (PRS-generated) email messages
 Subscribe to PRS Announcements (email)
Important messages from ClinicalTrials.gov will be sent to this address.

Other User Information: Include phone number.

The new password must have at least 8 characters.
 The new password must use at least 2 out of the following:

- Letters [A..Z, a..z]
- Numbers [0..9]
- Other non-blank characters

New Password:
 Repeat New Password:

- Enter new password
- Click "Change Password"

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Enabling/Disabling User Accounts

Administrative Functions

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Disable User

Organization	User Name	Access Level	Full Name
TestOrg	SmithJ	Normal	Jane Smith

Disable user account?

Enable User

Enable user account?

Organization	User Name	Access Level	Full Name
TestOrg	SmithJ	Normal	Jane Smith

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Changing Record Ownership

Administrative Functions

	Org	Group	Protocol ID	ClinicalTrials.gov ID	Results Status	Sort by Brief Title
Problems: TestOrg	TestOrg	[none]	11110000			Study of Investigational New D Disease
Validate all records						
Release all records			1234 1234			
Check release st						
Change owner						
Publication Rep						

Change Owner

Title: Study of Investigational New Device for Heart Disease

Current Owner: tsetony

New Owner:

User Name:

Allow XML upload for this record? Yes No

- Click "Ownership" next to record
- Enter login name of new user
- Click "OK"

User Accounts

[Create](#)

[Modify](#)

[Enable/disable](#)

Organization Account

[View](#)

[Groups](#)

[Email Address](#)

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Listing of All Published Records

Administrative Functions

Protocol Records

[Problems: TestOrg Rec](#)

[Validate all records](#)

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[Check release status](#)

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Published Trials Selection Criteria

Select the desired parameters to limit the number of trials listed.

Publication Status: Overall Status:

Published Trials

[Main Menu](#) [Change Selection Criteria](#) [Download](#)

NOTE: This screen shows information pertaining to protocols as they are currently (or soon to be) published on the ClinicalTrials.gov web site. New records are not reflected in this report until after they have been reviewed by ClinicalTrials.gov. Publication Status Key: [R] Results [DR] Delayed Results

1063 records found matching selection criteria: Publication Status: Published

NCT ID	Publication Status	Unique Protocol ID	Brief Title	Overall Status	
NCT00000625	Published	ACTG 175	A Randomized, Double-Blind Phase II/III Trial of Monotherapy vs. Combination Therapy With Nucleoside Analogs in HIV-Infected Persons With CD4 Cells of 200-500/mm³	Completed	Phase
NCT00000626	Published	ACTG 149	Phase II Study of Filgrastim (G-CSF) Plus ABVD in the Treatment of HIV-Associated Hodgkin's Disease	Completed	Phase
NCT00000627	Published	ACTG 174	Pilot Study to Determine the Feasibility of Fluconazole for Induction Treatment and Suppression of Relapse of Histoplasmosis in Patients With the Acquired Immunodeficiency Syndrome	Completed	N/A

Listing of All Email Addresses

Administrative Functions

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Email Address List	
Main Menu	
Organization: Test Organization (TestOrg)	
Category	Email Address(es)
Official Representative	
Administrators	adb@testorg.com , pdq@testorg.com
Users	adb@testorg.com , pdq@testorg.com , dba@testorg.com , gdr@testorg.com , mba@testorg.com , ilm@testorg.com

Convenient way to **copy and paste** email addresses for all Administrators and/or Users in the PRS Account into mass email messages

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Identifying Problem Records

Administrative Functions

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- Record Owner Issues: e.g.,
 - # record(s) have Review Comments that need to be addressed.
 - # record(s) for recruiting studies have not been updated or verified within the past six months.
- US Public Law 110-85 (FDAAA) issues: e.g.,
 - # record(s) are missing one or more data elements required by FDAAA...
 - # record(s) appear to be overdue for results submission per FDAAA.

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Problems Report – FDAAA Issues

- For Informational Purposes Only
- Determination of whether a trial is subject to FDAAA must be made by the Responsible Party
- How do I get my trial off the report?
 - Provide all FDAAA required data elements
 - Verify accuracy of data for the following data elements:
 - Study Type, Intervention Type, Study Phase, IND/IDE Protocol?, Facility Location(s), Completion Dates – Primary and Study
 - If applicable, submit results, certification or extension request
 - **Note:** The PRS cannot detect if the trial includes an unapproved product.

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Identifying Problem Records (cont.)

Administrative Functions

Protocol Records

Problems: TestOrg Records

[Validate all records](#)

[Release all records](#)

[Check release status](#)

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- Administrator Issues: e.g.,
 - # record(s) are ready for review and approval.
 - # record(s) have never been released to ClinicalTrials.gov.

NOTE: A single record may be listed in multiple categories. Once a problem is resolved, the record will no longer be listed under that problem category.

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Downloading the Problem Report

Administrative Functions

Protocol Records
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[Release all records](#)
[Check release status](#)
[Change owner](#)
[Print](#)

Use
[C](#)
[M](#)
[E](#)

Or
[Main Menu](#) [All Records](#) [Selection Criteria](#) [Download](#)

Records checked for: TestOrg
Problem types checked: Record Owner, FDAAA, PRS Admin
Total number of records: 54
Problems detected: 100

[Admin Quick Reference](#)

File Download
Do you want to open or save this file?
 Name: prs_problem_report.csv
Type: Microsoft Office Excel Comma Separated Values File
From: prstest.nlm.nih.gov

While files from the Internet can be useful, some files can potentially harm your computer. If you do not trust the source, do not open or save this file. [What's the risk?](#)

ClinicalTrials.gov
Protocol Registration System

Problems: TestOrg Records

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Problem Report File

	A	B	C	D	E	F	G	H	I	J
1	Problem Type	Protocol ID	ClinicalTrials.gov ID	Brief Title	Overall Status	Last Verified	Record Status	Owner	Updater	Last Update
2	Not Completed	0-rp-demo-old	N/A	RP Demo Example: Re:Active, not recruiting	2009-03	In Progress	JG	JG		8/1/2011 8:33
3	Never Released	0-rp-demo-old	N/A	RP Demo Example: Re:Active, not recruiting	2009-03	In Progress	JG	JG		8/1/2011 8:33
4	Ready for Review and Approval	0-rp-demo-pi	N/A	RP Demo Example: Re:Not yet recruiting	2009-07	Completed	JG	QAab		9/29/2011 12:25
5	Never Released	0-rp-demo-pi	N/A	RP Demo Example: Re:Not yet recruiting	2009-07	Completed	JG	QAab		9/29/2011 12:25
6	Ready for Review and Approval	0-rp-demo-s	N/A	RP Demo Example: Re:Active, not recruiting		Completed	JG	JG		7/23/2011 11:14
7	Never Released	0-rp-demo-s	N/A	RP Demo Example: Re:Active, not recruiting		Completed	JG	JG		7/23/2011 11:14
8	Ready for Review and Approval	0-rp-demo-si	N/A	RP Demo Example: Re:Active, not recruiting		Completed	JG	JG		7/23/2011 11:13
9	Never Released	0-rp-demo-si	N/A	RP Demo Example: Re:Active, not recruiting		Completed	JG	JG		7/23/2011 11:13
10	Never Released	1	N/A	Donepezil and Vitamin Completed	2010-10	Approved	DBlacker	DBlacker		10/14/2010 22:22
11	Ready for Review and Approval	11110000	N/A	PARTICIPANT FLOW - 2 Not yet recruiting	2007-01	Completed	CampionC	CampionC		11/7/2011 12:30
12	Never Released	11110000	N/A	PARTICIPANT FLOW - 2 Not yet recruiting	2007-01	Completed	CampionC	CampionC		11/7/2011 12:30
13	Ready for Review and Approval	111999asdfsdfasd	N/A	PARTICIPANT FLOW - 1 Not yet recruiting	2011-06	Completed	CampionC	Tony		11/7/2011 13:56
14	Ready for Review and Approval	1234 1234	N/A	BASELINE MEASURE an Active, not recruiting		Completed	QAab	Tony		11/8/2011 12:40
15	Never Released	1234 1234	N/A	BASELINE MEASURE an Active, not recruiting		Completed	QAab	Tony		11/8/2011 12:40
16	Not Completed		123456	N/A	Test	None	In Progress	QAab	QAab	4/1/2009 12:46
17	Never Released		123456	N/A	Test	None	In Progress	QAab	QAab	4/1/2009 12:46
18	Not Completed		1234567	N/A	Test Interventional StI. Enrolling by invitation		In Progress	Tony	root	1/18/2011 9:42
19	Never Released		1234567	N/A	Test Interventional StI. Enrolling by invitation		In Progress	Tony	root	1/18/2011 9:42
20	Not Completed		124345	N/A	This is a Test for Verification Date		In Progress	QAab	QAab	6/1/2009 9:05
21	Never Released		124345	N/A	This is a Test for Verification Date		In Progress	QAab	QAab	6/1/2009 9:05
22	Never Released		124356	N/A	Jgfsghs Recruiting	2005-08	Approved	QAab	QAab	5/13/2009 7:11
23	Ready for Review and Approval	2007-1234	N/A	Study of Hypothetica II Recruiting	2007-11	Completed	QAab	QAab		11/7/2011 14:20

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PRS Email Communication

Event	To: and cc:	Description
Record status changed by User ["completed" or reset to "completed" or "in-progress" status]	To: Responsible Party	Record may be waiting for "next action"
Record "released"	To: Responsible Party	Confirmation - record released to ClinicalTrials.gov for processing
Record "reset"	To: Record Owner cc: Responsible Party Last updater	Changes must be made - record (or updates) not published on ClinicalTrials.gov
Record "published"	To: Record Owner cc: Responsible Party Last updater	Notification - record will be published on ClinicalTrials.gov

Responsible Party = **Administrator(s)** if Sponsor; **User** if Sponsor-Investigator or Designated Principal Investigator

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PRS Email Communication (cont.)

Event	To: and cc:	Description
Problem Notification – Record Owners	To: Record Owner Administrator(s) Responsible Party	<ul style="list-style-type: none"> • QA Comments • Record was updated but not marked "Completed" • Recruiting (or not yet recruiting) studies have not been updated or verified within the past six months • Ongoing, non-recruiting studies have not been updated or verified within the past year.

Responsible Party = **Administrator(s)** if Sponsor; **User** if Sponsor-Investigator or Designated Principal Investigator

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PRS Email Communication (cont.)

Event	To: and cc:	Description
Problem Notification – Administrators and Responsible Party	To: Administrator(s) Responsible Party	<ul style="list-style-type: none"> Records ready for review and approval (and release) Records that have never been released to ClinicalTrials.gov Records that have been updated and need to be re-released to ClinicalTrials.gov

Responsible Party = **Administrator(s)** if Sponsor; **User** if Sponsor-Investigator or Designated Principal Investigator

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PRS Email Communication (cont.)

Event	To: and cc:	Description
Problem Notification – All (FDAAA Issues)	To: Record Owner Administrator(s) Responsible Party	<ul style="list-style-type: none"> Missing one or more data elements required by FDAAA, such as: Responsible Party, Study Start Date, Primary Completion Date and Primary Outcome Measure Appear to be overdue for registration of results per FDAAA

Responsible Party = **Administrator(s)** if Sponsor; **User** if Sponsor-Investigator or Designated Principal Investigator

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Seeking Help on PRS Functions

Standard Functions

Protocol Records
[Create](#)
[Modify](#)
[View](#)
[QA Review Comm](#)
[Problems: Tony Re](#)
[Undelete](#)

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

Help
[Quick Start Guide](#)
[Frequently Asked Q](#)
[Responsible Party E](#)
[What's New Sep 12, 2](#)
[User's Guide](#)
[Protocol Data Element](#)
[Results Data Element](#)
[Protocol Review Criteria](#)
[Results Review Criteria](#)
[FDAMA 113 Requirements](#)
[Simple Results Forms](#)

[XML Upload](#)

PRS User's Guide

August 2011

Section	Audience
Overview	All PRS Users
Procedures for Protocol	All PRS Users
Procedures for Results	All PRS Users
Procedures for Administrators	PRS Administrators
XML File Transfer	All PRS Users

Procedures for Administrators

[Admins-A. Create User Accounts](#)
[Admins-B. View and Select Organization Records](#)
[Admins-C. Review, Perform Quality Check, and Approve Completed ClinicalTrials.gov Record](#)
[Admins-D. Release Record to ClinicalTrials.gov](#)
[Admins-E. Release a Batch of Records to ClinicalTrials.gov](#)
[Admins-F. Change Ownership of Record](#)
[Admins-G. Updating Records](#)
[Admins-H. Edit User Information](#)
[Admins-I. Reset Existing User Password](#)
[Admins-J. Disable/Enable User Account](#)
[Admins-K. Review Organization Account](#)
[Admins-L. Create a Group](#)
[Admins-M. Modify Group](#)
[Admins-N. Contact PRS System Administrator](#)

Admins-A. Create User Accounts

- Click [Create] under User Accounts/Administrative Functions on the **Main Menu**
- Complete the fields on the **User Registration** screen:
 - Access Level: "Normal" for Users (or "Administrator" for Administrators)
 - Enter User Login Name: (e.g., last name, first initial)
 - Full User Name:(e.g., full first name followed by last name)

Login to PRSTest

- <https://prstest.nlm.nih.gov>
- Organization: PRSTraining [same for all]
- Username: User## [on folder]
- Password: User!password [same for all]

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Thank you!

Questions?