

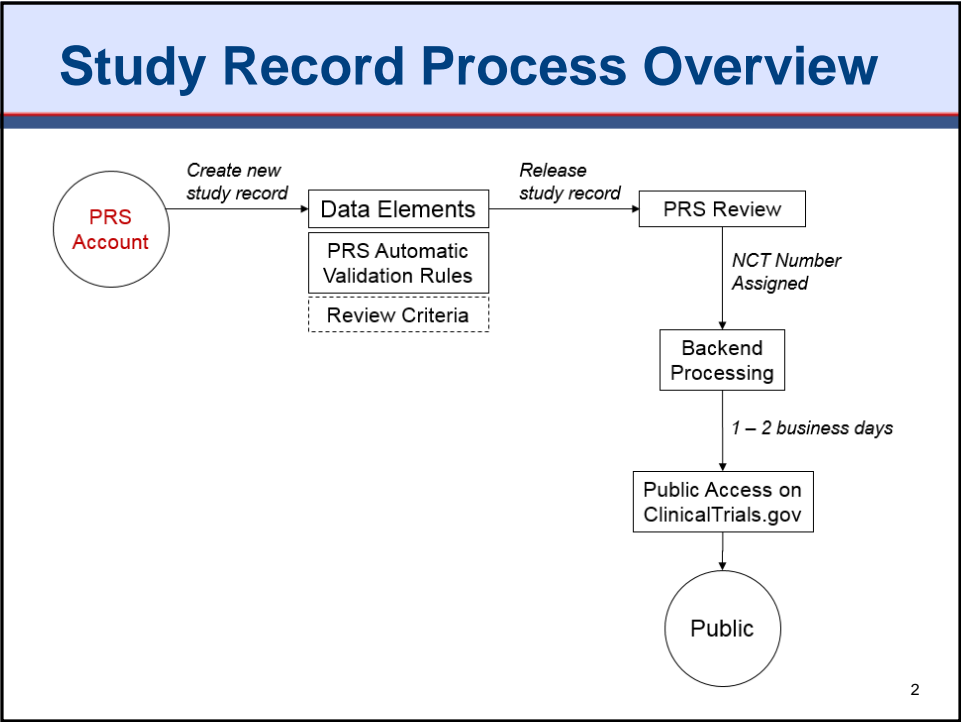
ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Protocol Registration and Results System (PRS) Overview

Results Database Train-the-Trainer Workshop
September 2015



<http://ClinicalTrials.gov>



PRS Account: Roles and Responsibilities

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PRS Roles and Terms

- **Administrator:** maintains PRS Account for organization (may be more than one)
- **User:** creates and edits records (unlimited number per PRS Account)
- **Record Owner:** primary contact for study record (may be Admin or User)
- **Responsible Party:** Sponsor* (Admin) or Principal Investigator (User)

* For Sponsor definition see: <https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>

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PRS Administrator

- Maintains PRS Account for organization
 - Creates/disables Users within account
 - Can grant Users access to any study record
 - Has access to all study records
 - Monitors records in account for “Problems”
 - Use Record List to identify records with Problems; work with Users to resolve Problems
 - Email is sent to Admin, generally every 6 months, notifying of Problems with records in their account at that time
 - Approves and Releases records when the Organization is the Sponsor and Responsible Party
 - Email is sent to Admin when a record is ready for Approval and Release

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Home Page (Admin)

ClinicalTrials.gov PRS

Protocol Registration and Results System

Org: TestOrg

User: RWilliams

Logout

Quick Links

New Record

Admin Quick Reference

Problem Resolution Guide

Records

Accounts

Help

Email: williamsre@mail.nih.gov

Update

Record List

Group: [ALL]

All Records (60)

Problem Records (60)

Custom Filter

Showing: 1-3 of 3 records

(filtered from 60 records)

All records per page

Search: [RW]

Show/Hide Columns

| Group | Protocol ID | ClinicalTrials.gov ID | Brief Title | Record Status | Last Update | Record Owner | Responsible Party | Problems |
|----------------------|-------------|--------------------------|--|-----------------|------------------|--------------|-------------------|--|
| Open | [none] | OBS-12345 | Observational Study of ClinicalTrials.gov Staff | In Progress | 09/07/2015 12:55 | RWilliams | | <ul style="list-style-type: none">• Entry Not Completed• Never Released• Missing FDAAA Information• Late Results - per FDAAA |
| Open | [none] | copy-of-niad-dmid-03-154 | Amphotericin Alone or in Combination With Fluconazole for AIDS-Associated Meningitis | Approved | 08/25/2015 16:24 | RWilliams | [Sponsor] | <ul style="list-style-type: none">• Record Has 2 Errors• Never Released• Missing FDAAA Information• Late Results - per FDAAA |
| Open | [none] | RJW-10571801 | Prospective Study to Compare a New Vascular Access Graft to Existing Grafts | Entry Completed | 06/09/2015 12:24 | RWilliams | [Sponsor] | <ul style="list-style-type: none">• Record Has 1 Error• Ready for Review and Approval• Never Released• Missing FDAAA Information• Late Results - per FDAAA |

Showing: 1-3 of 3 records

(filtered from 60 records)

All records per page

Page 1 of 3

KEY

PRS Review

Results

Delayed Results

XML Upload

No longer public

Download

6

3

PRS 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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Home Page (User)

ClinicalTrials.gov PRS

Protocol Registration and Results System

Org: PRSTrainingMaster User: RJW [Logout](#)

Email: [williamsre@mail.nih.gov](#) [Update](#)


Quick Links






[New Record](#)
[Quick Start Guide](#)
[Problem Resolution Guide](#)

Records ▾ Accounts ▾ Help ▾

Record List

Showing: 1 record

| Protocol ID ▾ | ClinicalTrials.gov ID ▾ | Brief Title ▾ | Record Status ▾ | Last Update ▾ | Responsible Party ▾ | Problems ▾ |
|--|-------------------------|--|-----------------|------------------|---------------------|---|
| Open  | TTTParalleIR | Parallel Study Design Example (With Results) | In Progress | 09/04/2015 16:55 | [Sponsor] | <ul style="list-style-type: none">• Entry Not Completed• Update Not Released |

KEY:  PRS Review  Results  Delayed Results
 XML Upload  No longer public

[Download...](#)

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PRS Record Owner

- Primary contact for study record
 - Initially assigned to person who created the study record; record ownership can be transferred (by Admin)
 - Can grant other Users access to the record
 - Receives email communications about record
 - Automatically signed up to receive email; can't opt out
 - Responsible Party will also receive emails (if not Record Owner)

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Verify Subscribed to PRS Emails Modify User Account/Password

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User: RWilliams Logout

Email: williamsre@mail.nih.gov [Update]

Quick Links

[New Record](#)
[Admin Quick Reference](#)
[Problem Resolution Guide](#)

Records Accounts Help

Change Password
Update User Information
List TestOrg Administrator(s)
Admin only:
New User Account
Modify User Account/Password
Enable/Disable User Account
Modify Organization Information
Manage Groups
List Email Addresses
Product Information

Record List

Group: [ALL] All Records (60) Problem Record

Showing 1-6 of 6 records (filtered from 60 records)

| Group | Protocol ID | Record Status | Last Update | Record Owner | Responsible Party | Problems |
|-----------------------------|------------------------------|--|------------------|------------------|---|---|
| Open [none] | 1234567 | Entry | In Progress | 04/23/2013 12:02 | Tony | <ul style="list-style-type: none">• Entry Not Completed• Never Released• Missing FDAAA Information• Late Results - per FDAAA |
| Open [none] | Test 1 | Entry Completed | 04/26/2012 15:35 | Tony | Becky Williams williamsre@mail.nih.gov | <ul style="list-style-type: none">• Record Has 4 Errors• Ready for Review and Approval• Never Released |
| Open [none] | Blank Multiple Period Design | Entry Completed | 11/09/2011 17:15 | Tony | Becky Williams williamsre@mail.nih.gov | <ul style="list-style-type: none">• Record Has 8 Errors• Ready for Review and Approval• Never Released |
| Open [none] | copy-of-niaid-dmrd-03-154 | Amphotericin Alone or in Combination With Fluconazole for AIDS-Associated Meningitis | Approved | 08/25/2015 16:24 | RWilliams [Sponsor] | <ul style="list-style-type: none">• Record Has 2 Errors• Never Released• Missing FDAAA Information• Late Results - per FDAAA |

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Verify Subscribed to PRS Emails

Modify User Account

ClinicalTrials.gov PRS

Protocol Registration and Results System

Org: TestOrg User: RWilliams Logout

Home > Users

User Account List - Modify

Home Show Disabled Accounts New User

Organization: Test Organization (TestOrg)

Group: [ALL]

| | Username | Full Name | Access Level | Group | Email Address | Auto Email? | Announcements? | Other Info |
|---|-----------|----------------|---------------|-------|---------------|-------------|----------------|------------------------------|
| Modify Reset Password | | | Administrator | | | Y | N | |
| Modify Reset Password | | | Administrator | | | N | N | Test |
| Modify Reset Password | | | Administrator | | | Y | N | |
| Modify Reset Password | | | Administrator | | | N | N | |
| Modify Reset Password | | | Administrator | | | Y | N | |
| Modify Reset Password | | | Administrator | | | N | N | Professor of Medicine; Tufts |
| Modify Reset Password | | | Administrator | | | N | N | Test account |
| Modify Reset Password | RWilliams | Becky Williams | Administrator | | | N | N | |
| Modify Reset Password | | | Administrator | | | Y | Y | |
| Modify Reset Password | | | Normal | test2 | | Y | N | |
| Modify Reset Password | | | Normal | test | | Y | N | |
| Modify Reset Password | | | Normal | | | Y | N | |
| Modify Reset Password | | | Normal | | | Y | N | |
| Modify Reset Password | | | Normal | | | Y | N | |
| Modify Reset Password | | | Normal | | | Y | N | |

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Verify Subscribed to PRS Emails

ClinicalTrials.gov PRS

Protocol Registration and Results System

Org: TestOrg User: RWilliams

User Information

Group: [none]

Access Level: Administrator

Username: RWilliams

Full Name: Becky Williams

Example: John J Smith, MD

Email Address: williamsre@mail.nih.gov

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

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

☒ Send automatic (PRS-generated) email messages

☒ Subscribe to PRS Announcements (email)

Other User Information:

Include phone number.

Modify

Disable...

Cancel

PRS Account Management

Create a New User Account

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User: RWilliams Logout

Email: williamsr@mail.nih.gov [Update]

Quick Links

[New Record](#)
[Admin Quick Reference](#)
[Problem Resolution Guide](#)

Records Accounts Help

Change Password

Update User Information

List TestOrg Administrator(s)

Admin only

New User Account

Modify User Account/Password

Enable/Disable User Account

Modify Organization Information

Manage Groups

List Email Addresses

Product Information

Record List

Group: [ALL] All Records (50) Problem Record

Showing: 1-6 of 6 records (filtered from 60 records)

| Group | Protocol ID | Clinical ID | Record Status | Last Update | Record Owner | Responsible Party | Problems |
|----------------------|-------------|------------------------------|--|------------------|------------------|--|---|
| Open | [none] | 1234567 | Entry | In Progress | 04/22/2013 12:02 | Tony | <ul style="list-style-type: none">Entry Not CompletedNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |
| Open | [none] | Test 1 | Entry Completed | 04/26/2012 15:35 | Tony | Becky Williams williamsr@mail.nih.gov | <ul style="list-style-type: none">Record Has 4 ErrorsReady for Review and ApprovalNever Released |
| Open | [none] | Blank Multiple Period Design | Entry Completed | 11/09/2011 17:15 | Tony | Becky Williams williamsr@mail.nih.gov | <ul style="list-style-type: none">Record Has 6 ErrorsReady for Review and ApprovalNever Released |
| Open | [none] | copy-of-esiad-dmid-03-154 | Amphotericin Alone or in Combination With Fluconazole for AIDS-Associated Meningitis | Approved | 08/25/2015 16:24 | RWilliams [Sponsor] | <ul style="list-style-type: none">Record Has 2 ErrorsNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |

Modify User Account

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User: RWilliams Logout

Email: williamsre@mail.nih.gov [Update]

Quick Links —
New Record
Admin Quick Reference
Problem Resolution Guide

Records ▾ Accounts ▾ Help ▾

- Change Password
- Update User Information
- List TestOrg Administrator(s)
- Admin only
- New User Account
- Modify User Account/Password
- Enable/Disable User Account
- Modify Organization Information
- Manage Groups
- List Email Addresses
- Product Information

Record List

Group: [ALL] ▾ | All Records (60) Problem Record

Showing 1-6 of 6 records (filtered from 60 records)

| Group | Protocol ID | Clinical Study Title | Record Status | Last Update | Record Owner | Responsible Party | Problems |
|---------------|------------------------------|--|-----------------|------------------|------------------|---|--|
| [Open] [none] | 1234567 | | Entry | In Progress | 04/22/2013 12:02 | Tony | <ul style="list-style-type: none"> • Entry Not Completed • Never Released • Missing FDAAA Information • Late Results - per FDAAA |
| [Open] [none] | Test 1 | Test 1 -- Efficacy and Safety Study of DX-88 to Treat Acute Attacks of Hereditary Angioedema (HAE) | Entry Completed | 04/25/2012 15:35 | Tony | Becky Williams williamsre@mail.nih.gov | <ul style="list-style-type: none"> • Record Has 4 Errors • Ready for Review and Approval • Never Released |
| [Open] [none] | Blank Multiple Period Design | Blank Record Example for Multiple Period Design Study | Entry Completed | 11/09/2011 17:15 | Tony | Becky Williams williamsre@mail.nih.gov | <ul style="list-style-type: none"> • Record Has 8 Errors • Ready for Review and Approval • Never Released |
| [Open] [none] | copy-of-niaid-dmid-03-154 | Amphotericin Alone or in Combination With Fluconazole for AIDS-Associated Meningitis | Approved | 08/25/2015 16:24 | RWilliams | [Sponsor] | <ul style="list-style-type: none"> • Record Has 2 Errors • Never Released • Missing FDAAA Information • Late Results - per FDAAA |

Modify User Account (cont.)

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User RWilliams [Logout](#)

[Home](#) > Users

User Account List - Modify

[Home](#) [Show Disabled Accounts](#) [New User](#)

Organization: Test Organization (TestOrg)

Group: [ALL ▼]

| Username | Full Name | Access Level | Group | Email Address | Auto Email? | Announcements? | Other Info |
|---|---------------|---------------|-------|---------------|-------------|----------------|--|
| Modify Reset Password | | Administrator | | | Y | N | Test |
| Modify Reset Password | | Administrator | | | N | N | |
| Modify Reset Password | | Administrator | | | Y | N | |
| Modify Reset Password | | Administrator | | | N | N | |
| Modify Reset Password | | Administrator | | | Y | N | Professor of Medicine; Tufts Test account |
| Modify Reset Password | | Administrator | | | N | N | |
| Modify Reset Password | | Administrator | | | N | N | |
| Modify Reset Password | | Administrator | | | N | Y | |
| Modify Reset Password | JDoe Jane Doe | Normal | test2 | Y | N | | |
| Modify Reset Password | Normal | test | Y | N | | | |
| Modify Reset Password | Normal | | Y | N | | | |
| Modify Reset Password | Normal | | Y | N | | | |
| Modify Reset Password | Normal | | Y | N | | | |
| Modify Reset Password | Normal | | Y | N | | | |

Reset User Password

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User: RWilliams Logout

Home > Users

User Account List - Modify

Home Show Disabled Accounts New User

Organization: Test Organization (TestOrg)

Group: [ALL]

| | Username | Full Name | Access Level | Group | Email Address | Auto Email? | Announcements? | Other Info |
|-----------------------|----------|-----------|---------------|-------|---------------|-------------|----------------|------------------------------|
| Modify Reset Password | | | Administrator | | | Y | N | |
| Modify Reset Password | | | Administrator | | | N | N | Test |
| Modify Reset Password | | | Administrator | | | Y | N | |
| Modify Reset Password | | | Administrator | | | N | N | |
| Modify Reset Password | | | Administrator | | | Y | N | |
| Modify Reset Password | | | Administrator | | | N | N | Professor of Medicine, Tufts |
| Modify Reset Password | | | Administrator | | | N | N | Test account |
| Modify Reset Password | | | Administrator | | | N | N | |
| Modify Reset Password | | | Administrator | | | Y | Y | |
| Modify Reset Password | JDoe | Jane Doe | Normal | test2 | | Y | N | |
| Modify Reset Password | | | Normal | test | | Y | N | |
| Modify Reset Password | | | Normal | | | Y | N | |
| Modify Reset Password | | | Normal | | | Y | N | |
| Modify Reset Password | | | Normal | | | Y | N | |
| Modify Reset Password | | | Normal | | | Y | N | |

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Enable/Disable User Account

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User: RWilliams Logout

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Update User Information
List TestOrg Administrator(s)
Admin only
New User Account
Modify User Account/Password
Enable/Disable User Account
Modify Organization Information
Manage Groups
List Email Addresses
Product Information

Record List
Group: [ALL] All Records (60) Problem Records

Showing 1-6 of 6 records (filtered from 60 records)

| Group | Protocol ID | Record Status | Last Update | Record Owner | Responsible Party | Problems |
|-------------|------------------------------|--|------------------|------------------|---|---|
| Open [none] | 1234567 | Entry | In Progress | 04/22/2013 12:02 | Tony | <ul style="list-style-type: none">Entry Not CompletedNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |
| Open [none] | Test 1 | Entry Completed | 04/26/2012 15:35 | Tony | Becky Williams williamsre@mail.nih.gov | <ul style="list-style-type: none">Record Has 4 ErrorsReady for Review and ApprovalNever Released |
| Open [none] | Blank Multiple Period Design | Entry Completed | 11/09/2011 17:15 | Tony | Becky Williams williamsre@mail.nih.gov | <ul style="list-style-type: none">Record Has 8 ErrorsReady for Review and ApprovalNever Released |
| Open [none] | copy-of-niad-dmrd-03-154 | Amphotericin Alone or in Combination With Fluconazole for AIDS-Associated Meningitis | Approved | 08/25/2015 16:24 | RWilliams [Sponsor] | <ul style="list-style-type: none">Record Has 2 ErrorsNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |

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Disable User Account

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User: RWilliams Logout

Disable User

| User Name | Access Level | Full Name |
|-----------|--------------|-----------|
| Bergeris1 | Normal | bergeris |

2 record(s) are currently owned by Bergeris1.

➔ Change owner to: Becky Williams [rwilliams]

Transfer record ownership and disable Bergeris1 account?

Disable

Cancel

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

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Changing Record Ownership

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User: RWilliams Logout

Home > Record Summary

ID: OBS-12345 Observational Study of ClinicalTrials.Gov Staff [NCT ID not yet assigned]

Record Summary

Home Help

Record Status

In Progress ➔ Entry Completed ➔ Approved ➔ Released ➔ PRS Review ➔ Public

Next Step: Finish Results section [Entry Complete]

Record Owner: RWilliams

Last Updated: 09/07/2015 12:55 by RWilliams

Initial Release: [Not yet released]

Results Expected: December 2013

Access List: [1] Edit

Upload: Allowed Edit

PRS Review: [Not yet released]

Public Site: [Not yet registered]

Spelling Preview Draft Receipt (PDF RTF) Download XML Delete... Admin Only: Copy Protocol Change Owner

Open Protocol Section

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: OBS-12345

Brief Title: Observational Study of ClinicalTrials.Gov Staff

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List Email Addresses

ClinicalTrials.gov PRS

Protocol Registration and Results System

Org: TestOrg

User: RWilliams

Logout

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Change Password

Update User Information

List TestOrg Administrator(s)

Admin only

New User Account

Modify User Account/Password

Enable/Disable User Account

Modify Organization Information

Manage Groups

List Email Addresses

Product Information

Record List

Group: [ALL] All Records (60) Problem Record

Showing 1-6 of 6 records (filtered from 60 records)

| Group | Protocol ID | Group | Record Status | Last Update | Record Owner | Responsible Party | Problems |
|-------|-------------|------------------------------|-----------------|------------------|------------------|---|---|
| Open | [none] | 1234567 | Entry | In Progress | 04/22/2013 12:02 | Tony | <ul style="list-style-type: none">Entry Not CompletedNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |
| Open | [none] | Test 1 | Entry Completed | 04/26/2012 15:35 | Tony | Becky Williams williamsre@mail.nih.gov | <ul style="list-style-type: none">Record Has 4 ErrorsReady for Review and ApprovalNever Released |
| Open | [none] | Blank Multiple Period Design | Entry Completed | 11/09/2011 17:15 | Tony | Becky Williams williamsre@mail.nih.gov | <ul style="list-style-type: none">Record Has 6 ErrorsReady for Review and ApprovalNever Released |
| Open | [none] | copy-of-niaid-dmrd-03-154 | Approved | 08/25/2015 16:24 | RWilliams | [Sponsor] | <ul style="list-style-type: none">Record Has 2 ErrorsNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |

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PRS Account Email Address List

ClinicalTrials.gov PRS

Protocol Registration and Results System

Org: TestOrg

User: RWilliams

Logout

Home

Email Address List

Organization: Test Organization (TestOrg)

| Category | Email Address(es) |
|--|---|
| Official Representative Administrators | adb@testorg.com |
| Users | adb@testorg.com , pdg@testorg.com , dba@testorg.com , gdr@testorg.com , mba@testorg.com , ilm@testorg.com |

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

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

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Help on PRS Functions

ClinicalTrials.gov PRS
Protocol Registration and Results System

Quick Links
[New Record](#)
[Admin Quick Reference](#)
[Problem Resolution Guide](#)

Records ▾ Accounts ▾ Help ▾

Quick Start Guide
 What's New July 21, 2015
 Protocol Data Entry
 Results Data Entry
 Problem Resolution Guide
PRS User's Guide
 Admin only
 Admin Quick Reference

Record List

Group: [ALL] ▾ All Records (60) Problem Records (60) ▾

Showing 1 of 3 records (filtered from 60 records) All ▾

| Group | Protocol ID | ClinicalTrials.gov ID |
|-------|-------------|-----------------------|
| | | |

ClinicalTrials.gov PRS
Protocol Registration and Results System

User's Guide
June 2015

| Section |
|---|
| Overview |
| Procedures for Protocol |
| Procedures for Results |
| Procedures for Administrators |
| XML File Transfer |

Overview

The ClinicalTrials.gov Protocol Registration and Results System (PRS) is a web-based tool developed for submitting clinical trials information to ClinicalTrials.gov. This document provides step-by-step instructions for entering, modifying and releasing protocol/results records using the PRS. Records submitted through the PRS (<https://register.clinicaltrials.gov>) are available to the public at ClinicalTrials.gov (<https://clinicaltrials.gov>). Information on account application, registering studies and submitting results, frequently asked questions and support materials is available on the [Submit Studies](#) page of the ClinicalTrials.gov website.

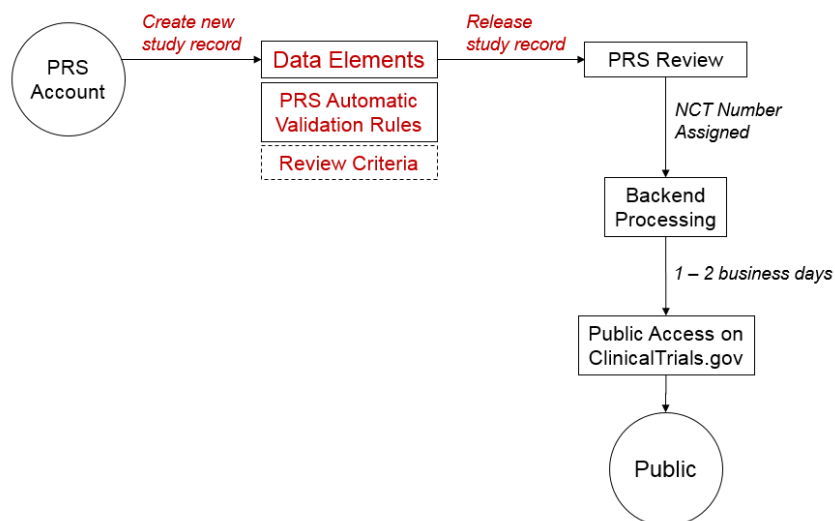
PRS users enter information about their clinical trials, ensuring that the information is correct, readily understood by members of the public, and updated in a timely manner.

Administrators are responsible for the process by which clinical trial information is released to ClinicalTrials.gov on behalf of their organization. This process includes creating accounts for PRS users and editing and approving clinical trial records prior to initial release and after record updates. They serve as points of contact for the ClinicalTrials.gov team and resolve questions associated with the information that is provided.

The ClinicalTrials.gov team maintains the PRS and the ClinicalTrials.gov site and may make minor corrections to records.

PRS: Study Record Basics

Study Record Process Overview



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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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Data Elements

- Data elements: pull-down menus or free text
 - Required*
 - Optional (Note: some are needed for FDAAA)
 - Indicated as **FDAAA required** and **(FDAAA) may be required**
 - Conditionally required[*]
 - If provide optional item, all related information must be entered
- ClinicalTrials.gov > Submit Studies > Support Materials:
<https://clinicaltrials.gov/ct2/manage-recs/resources>
 - Protocol Data Element Definitions (DRAFT)
 - “Basic Results” Data Element Definitions (DRAFT)
 - Simple Results Templates & Data Preparation Checklists
 - Overview of tabular format and additional explanation of data needed

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Data Element Definitions in PRS During data entry

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: PRSTrainingMaster User: RJW

Home > Record Summary > Protocol Section > Study Status

ID: TTTParallelR Parallel Study Design Example (With Results) [NCT ID not yet assigned]

Edit Study Status

Help Definitions

* ‡ Record Verification Date: December Year: 2011

* ‡ Overall Recruitment Status: Completed
Tip: Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.

‡ Study Start Date: March Year: 2010

* ‡ Primary Completion Date: August Year: 2011 Type: Actual
Final data collection date for primary outcome measure.

Study Completion Date: August Year: 2011 Type: Actual
Final data collection date for study.

Save Cancel

* Required by ClinicalTrials.gov
‡ = FDAAA Required to comply with US FDA Amendments Act
(‡) = (FDAAA) May be required to comply with US FDA Amendments Act

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

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Data Element Definitions in PRS

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: PRSTrainingMaster User: RJW

Home > Record Summary > Protocol Section > Study Status

ID: TTTTParallelR Parallel Study Design Example (With Results) [NCT ID not yet assigned]

Edit Study Status

*** † Record Verification Date:** December † Yes

*** † Overall Recruitment Status:** Completed
Tip: Before select

† Study Start Date: March † Yes

*** † Primary Completion Date:** August † Yes
Final data collect

Study Completion Date: August † Yes
Final data collect

Save Cancel

* Required by Clinica
† = FDAAA Required to comply
(†) = (FDAAA) May be required to

U.S. National Library of Medicine

Help Definitions

ClinicalTrials.gov Data Element Definitions (DRAFT) - Google Chrome

https://prstest.nlm.nih.gov/prs/html/definitions.html#status

2. Study Status

Record Verification Date * FDAAA
Definition: Date the protocol information was last verified. Verification date is shown along with organization name on ClinicalTrials.gov to indicate to the public whether the information is being kept current, particularly recruiting status and contact information. **Update verification date when reviewing the record for accuracy and completeness, even if no other changes are made.**

Overall Recruitment Status * FDAAA *[Required when Study Type is "Interventional" or "Observational".]*
Definition: Overall accrual activity for the protocol. Select one.

- Not yet recruiting: participants are not yet being recruited
- Recruiting: participants are currently being recruited
- Enrolling by invitation: participants are being (or will be) selected from a predetermined population
- Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled
- Completed: the study has concluded normally: participants are no longer being examined or treated (i.e., last patient's last visit has occurred)
- Suspended: recruiting or enrolling participants has halted prematurely but potentially will resume
- Terminated: recruiting or enrolling participants has halted prematurely and will not resume: participants are no longer being examined or treated
- Withdrawn: study halted prematurely: prior to enrollment of first participant

Data Element Definitions in PRS

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User: RWilliams [Logout](#)

Email: williamsre@mail.nih.gov [\[Update\]](#)

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- Admin Quick Reference

Record List

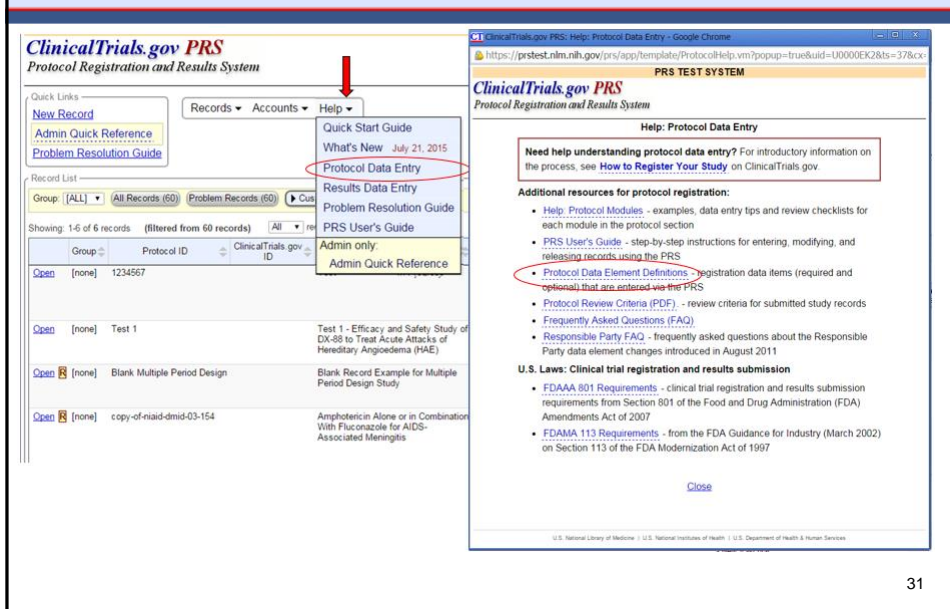
Group: **[ALL]** ▾ [All Records \(60\)](#) [Problem Records \(60\)](#) [\[Close\]](#)

Showing 1-6 of 6 records (filtered from 60 records) **All** ▾

Search: [Show/Hide Columns](#)

| Group | Protocol ID | ClinicalTrials.gov ID | Record Status | Last Update | Record Owner | Responsible Party | Problems |
|----------------------|-------------|--|-----------------|------------------|---------------------|--|--|
| Open | [none] | 1234567 | In Progress | 04/22/2013 12:02 | Tony | | <ul style="list-style-type: none"> • Entry Not Completed • Never Released • Missing FDAAA Information • Late Results - per FDAAA |
| Open | [none] | Test 1 | Entry Completed | 04/26/2012 15:35 | Tony | Becky Williams williamsre@mail.nih.gov | <ul style="list-style-type: none"> • Record Has 4 Errors • Ready for Review and Approval • Never Released |
| Open | [none] | Blank Multiple Period Design | Entry Completed | 11/09/2011 17:15 | Tony | Becky Williams williamsre@mail.nih.gov | <ul style="list-style-type: none"> • Record Has 8 Errors • Ready for Review and Approval • Never Released |
| Open | [none] | copy-of-niaid-dmisd-03-154 | Approved | 08/25/2015 16:24 | RWilliams [Sponsor] | | <ul style="list-style-type: none"> • Record Has 2 Errors • Never Released • Missing FDAAA Information • Late Results - per FDAAA |
| | | Amphotericin Alone or in Combination With Fluconazole for AIDS-Associated Meningitis | | | | | |

Data Element Definitions in PRS Help Menu (cont.)



The screenshot shows the ClinicalTrials.gov PRS (Protocol Registration and Results System) interface. On the left, the 'Help' dropdown menu is open, and 'Protocol Data Entry' is highlighted with a red circle. A red arrow points to this menu item. On the right, the 'Help: Protocol Data Entry' page is displayed, featuring a red box with the text: 'Need help understanding protocol data entry? For introductory information on the process, see [How to Register Your Study](#) on ClinicalTrials.gov'. Below this, there are sections for 'Additional resources for protocol registration:' and 'U.S. Laws: Clinical trial registration and results submission', both containing links to various guides and regulations. The page number '31' is visible in the bottom right corner.

Trials Registered with NCI's CTRP

- Not automatically registered with ClinicalTrials.gov
- Upload Protocol Information from CTRP to PRS (access from PRS Main Menu > XML Upload)
- Information needed:
 - NCI Record ID
 - Unique Protocol ID
 - CTRP Username and Password
- Recommended Uses:
 - Create a new study record
 - Update locations in an existing study record

Upload from NCI CTRP

Upload Protocol Information from CTRP

Only for trials that have been registered with CTRP, the US National Cancer Institute's Clinical Trial Registration Program.
[About Upload from CTRP...](#)
Fill in the requested information and click Analyze to confirm authorization to upload from CTRP.

NCI Record ID:

Example: NCI-2011-01234

Unique Protocol ID:

Must match CTRP Lead Organization Trial Identifier.

Upload Option:

☐ Create new PRS record.

☐ Overwrite protocol in existing PRS record.

☐ Overwrite locations in existing PRS record.

CTRP Username:

Enter the username and password that you use to access CTRP.

CTRP Password:

[Forgot CTRP password?](#)

[Troubleshooting](#)

Analyze





Cancel

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

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PRS Validation Rules

- A record must have no Errors in order for it to be submitted for posting on ClinicalTrials.gov

| Type | Explanation |
|---|---|
|  ERROR | Problems that must be addressed (e.g., missing required* content, internal inconsistency) |
|  WARNING | Items that are FDAAA <u>required</u> or (FDAAA) <u>may be required</u> (e.g., Study Start Date data element) |
|  ALERT | Problems that need to be addressed |
|  NOTE | <u>Potential</u> problems that should be reviewed and corrected, if possible (if not possible, then may ignore) |

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PRS Validation Rules (cont.)

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: PRSTrainingMaster User: RJW [Logout](#)

[Home](#) > Record Summary

ID: TTTParallelR Parallel Study Design Example (With Results) [NCT ID not yet assigned]

Record Summary

[Home](#) [Help](#)

Record Status

In Progress → Entry Completed → Approved → Released → PRS Review → Public

Next Step: Confirm data entry complete **Entry Complete**

Record Owner: abergeris [Edit](#) Upload: [Allowed](#) [Edit](#)

Last Updated: 07/12/2013 13:34 by QA16 PRS Review: [Review History](#)

Initial Release: 06/20/2013 Public Site: [Not yet registered]

Initial Results Release: 06/20/2013

Last Release: 06/20/2013 [Receipt \(PDF\)](#)

Results Expected: August 2012 [?](#)

[Spelling](#) [Preview](#) [Draft Receipt \(PDF\)](#) [RTF](#) [Download XML](#) [Delete...](#)

Open Protocol Section

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: TTTParallelR

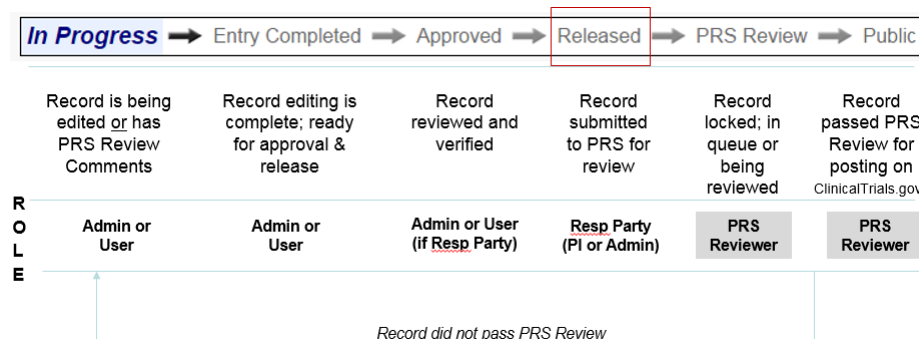
Brief Title: Parallel Study Design Example (With Results)

Module Status:

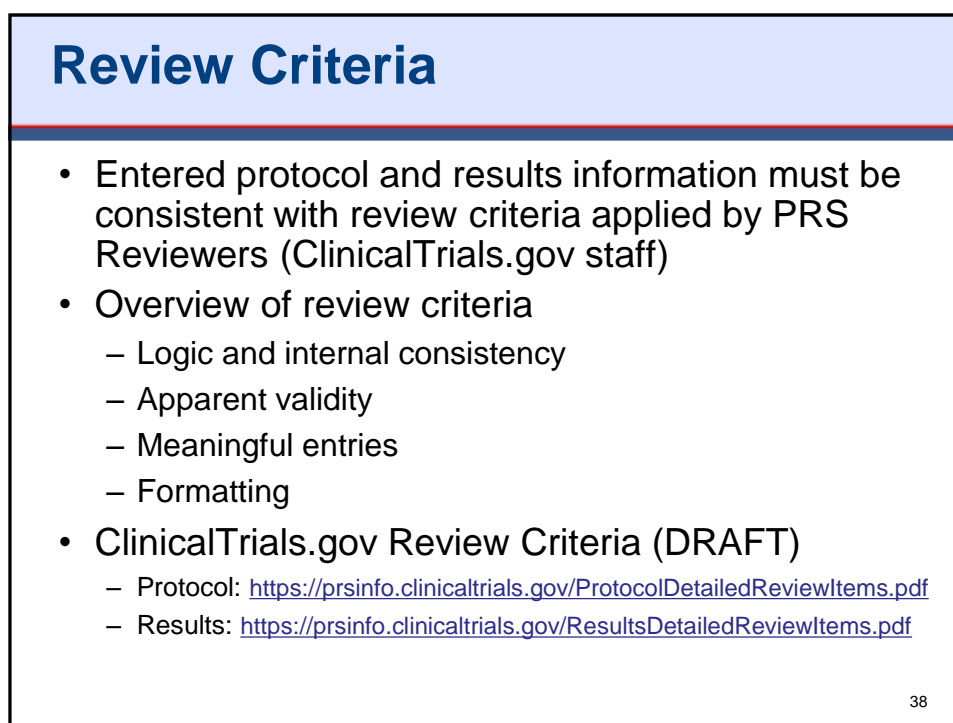
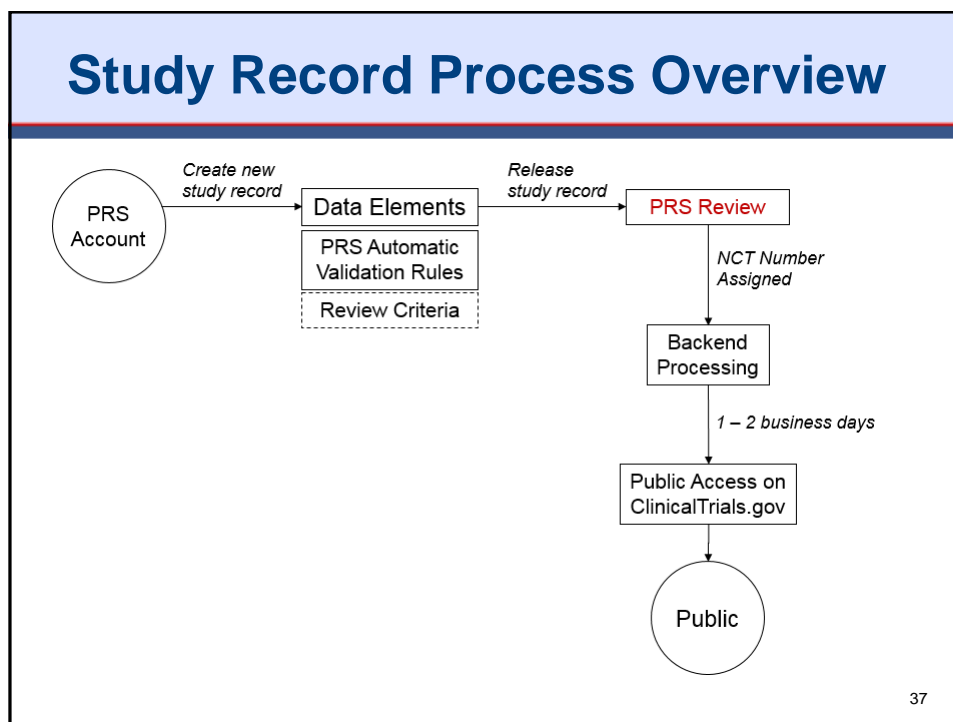
- Study Identification: ✓
- Study Status: ✓
- Sponsor/Collaborators: 1 Warning
- Oversight: 2 Notes
- Study Description: ✓
- Conditions: 1 Note
- Study Design: ✓
- Arms and Interventions: 2 Notes
- Eligibility: ✓
- Contacts/Locations: 5 Notes
- References:

Record Status

Summarizes where the PRS version of the record is in the overall process of getting posted on ClinicalTrials.gov



* If new record, NCT # assigned; may be 1–2 days for new or updated record to appear on ClinicalTrials.gov due to internal processing procedures



Review Comments

- When record “Reset”, the Responsible Party and Record Owner (if different) will receive an email
- Comments can be accessed within each record with the Review Comments link

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Review Comments (cont.)

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

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Find Records with PRS Review Comments

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User: RWilliams Logon

Email: williamsre@mail.nih.gov [Update]

Quick Links
[New Record](#)
[Admin Quick Reference](#)
[Problem Resolution Guide](#)

Records ▾ Accounts ▾ Help ▾

Record List

Group: [ALL ▾] All Records (50) Problem Records (50) Custom Filter Custom filter applied Clear Filter

Overall Status
☐ Not yet recruiting
☐ Recruiting
☐ Active, not recruiting
☐ Enrolling by invitation
☐ Completed
☐ Suspended
☐ Terminated
☐ Withdrawn

Record Status
☐ In Progress
☐ Entry Completed
☐ Approved
☐ Released
☐ PRS Review
☐ Public
☐ No Longer Public (e.g., duplicates)

Results Status
☐ No Results
☐ Created
☐ Released
☐ Posted

Delayed Results Status
☐ No Delayed Results
☐ Created
☐ Released
☐ Processed

Problems
☒ No Problems
☐ Missing FDAAA Information
☐ Late Results - per FDAAA
☐ Never Released
☐ Update Not Released
☐ Record Has Errors
☐ Ready for Review and Approval

Showing: 1-3 of 3 records (filtered from 60 records) All ▾ records per page Search: RWilliams Show/Hide Columns

| Group | Protocol ID | ClinicalTrials.gov ID | Brief Title | Overall Status | Primary Completion Date | Record Status | Results Status | Last Update | Record Owner | Responsible Party | Problems |
|----------------------|-------------|-----------------------|---|----------------|-------------------------|---------------|----------------|------------------|--------------|-------------------|-----------------------|
| Open | [none] | OBS-12345 | Observational Study of ClinicalTrials Gov Staff | Recruiting | 02/2016 | In Progress | | 05/27/2015 09:55 | RWilliams | [Sponsor] | • PRS Review Comments |

Accessing Review Comments

Record Summary

[Home](#) [Help](#)

Record Status: **In Progress** → Entry Completed → Approved → Released → PRS Review → Public

Next Step: Read **Review Comments** Entry Complete

| | |
|--|--|
| Record Owner: DZarin | Access List: Edit |
| Last Updated: 06/09/2015 12:09 by root | Upload: Allowed Edit |
| Initial Release: 06/09/2015 | PRS Review: Record Reset Review Comments Review History |
| Last Release: 06/09/2015 Receipt (PDF) | Public Site: [Registration in process]* |
| Results Expected: February 2010 | |

* Records usually appear on ClinicalTrials.gov within 2 business days of PRS Review.

PRs Review Comments

ClinicalTrials.gov PRS

Protocol Registration and Results System

PRs Review Comments - Jun-10-2015 09:31

Number of Comments: 1 (see below)

Comment Resolution Status: Not updated

▼ Hide All

Show Only Sections With Comments

Observational Study of ClinicalTrials.gov Staff

Completed

| | |
|--|---|
| Sponsor: | National Library of Medicine |
| Collaborators: | ICF International, Inc. Thoughtful Solutions, Inc. |
| Information Provided by (Responsible Party): | National Library of Medicine |
| ClinicalTrials.gov Identifier: | NCT12345678 |

Study Release Date: Jun-09-2015 12:09:18.1

► General Comments

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Review Comments Example

Data Provider Perspective

► Participant Flow

Period Title: Overall Study

| | |
|-----------------------|------------------------------|
| Arm/Group Title | All ClinicalTrials.gov Staff |
| STARTED | 30 |
| COMPLETED | 28 |
| Not Completed | 2 |
| Withdrawal by Subject | 2 |

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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PRSR

Review Comments

Previous Comments not Addressed

General Comments

Comments [1] :

This record cannot be posted/updated on ClinicalTrials.gov because previous PRS Review Comments have not been fully addressed. To address those comments:

1. Select the Review History link on the Record Summary page.

2. Select the comments recorded on MM-DD-YYYY and review all comments.

3. Make the necessary changes to the Protocol/Results Section (accessed via the corresponding Open link on the Record Summary page).

4. Follow the instructions in the Next Step box on the Record Summary page to Release the updated record for PRS Review and posting/update on ClinicalTrials.gov.

Tip: If you have questions or require assistance in addressing the PRS Review Comments, contact register@clinicaltrials.gov.

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PRSR

Review History

Home

Help

Record Status

In Progress

Entry Completed

Approved

Released

PRS Review

Public

Next Step: Read Review Comments

Entry Complete

Record Owner: DZarin

Last Updated: 06/09/2015 12:09 by root

Initial Release: 06/09/2015

Last Release: 06/09/2015 Receipt (PDF)

Results Expected: February 2010

Access List: []

Upload: Allowed

PRS Review: Record Reset Review Comments Review History

Public Site: [Registration in process]*

* Records usually appear on ClinicalTrials.gov within 2 business days of PRS Review.

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PRS Review History

ClinicalTrials.gov *PRS*
Protocol Registration and Results System

ID: NLM- 123

Observational Study of ClinicalTrials.gov Staff

[NCT ID not yet assigned]

PRS Review History

| Event | User/Reviewer | Date/Time | |
|---------|------------------------|------------------|--|
| Reset | QA17 | 06/10/2015 09:31 | Review Comments (1) |
| Release | DZarin | 06/09/2015 12:09 | |
| Reset | QA17 | 06/08/2015 14:02 | Review Comments (3) Viewed by DZarin 1 time(s) – last access: Tue Jun 9 10:36:11 EDT 2015 |
| Release | DZarin | 06/07/2015 16:01 | |

The date the record was reviewed and determined acceptable for posting on ClinicalTrials.gov will appear as Event “Published” with Date/Time.

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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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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 (NCT Number)
 - **Email:** Sent to the Resp. Party 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 and bottom of the record
- A study is not “registered” until it receives an NCT Number
 - Initial Release Date will be reported on public site
- Some studies will be “reset” without public posting
- Check your PRS Account and the public site to ensure that a study is properly registered

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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 Home Page & Record List

Home Page (Admin)

ClinicalTrials.gov PRS
Protocol Registration and Results System

Quick Links

New Record

Admin Quick Reference

Problem Resolution Guide

Records

Accounts

Help

Org: TestOrg User: RWilliams Logout

Email: williamsre@mail.nih.gov [Update]

Record List

Group: [ALL]

All Records (60)

Problem Records (60)

Custom Filter

Showing: 1-3 of 3 records (filtered from 60 records) All records per page Search: RWI Show/Hide Columns

| | Group | Protocol ID | ClinicalTrials.gov ID | Brief Title | Record Status | Last Update | Record Owner | Responsible Party | Problems |
|------|--------|--------------------------|-----------------------|--|-----------------|------------------|--------------|-------------------|--|
| Open | [none] | OBS-12345 | | Observational Study of ClinicalTrials.gov Staff | In Progress | 09/07/2015 12:55 | RWilliams | [Sponsor] | <ul style="list-style-type: none">Entry Not CompletedNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |
| Open | [none] | copy-of-maid-dmid-03-154 | | Amphotericin Alone or in Combination With Fluconazole for AIDS-Associated Meningitis | Approved | 08/25/2015 16:24 | RWilliams | [Sponsor] | <ul style="list-style-type: none">Record Has 2 ErrorsNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |
| Open | [none] | RJW-10671801 | | Prospective Study to Compare a New Vascular Access Graft to Existing Grafts | Entry Completed | 06/09/2015 12:24 | RWilliams | [Sponsor] | <ul style="list-style-type: none">Record Has 1 ErrorReady for Review and ApprovalNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |

Showing: 1-3 of 3 records (filtered from 60 records) All records per page Page 1 of 3

KEY: PR PRS Review R Results DR Delayed Results

XML Upload NF No longer public

Download

PRS Record List Download

ClinicalTrials.gov PRS

Protocol Registration and Results System

Org: TestOrg

User: RWilliams

Logout

Quick Links

New Record

Admin Quick Reference

Problem Resolution Guide

Records

Accounts

Help

Email: williamsre@mail.nih.gov [\[Update\]](#)

Record List

Group: [ALL]

All Records (60)

Problem Records (60)

Custom Filter

Showing: 1-3 of 3 records

(filtered from 60 records)

All

records per page

Search:

Show/Hide Columns

| Group | Protocol ID | ClinicalTrials.gov ID | Brief Title | Record Status | Last Update | Record Owner | Responsible Party | Problems |
|----------------------|-------------|---------------------------|--|-----------------|------------------|--------------|-------------------|--|
| Open | [none] | OBS-12345 | Observational Study of ClinicalTrials.gov Staff | In Progress | 09/07/2015 12:55 | RWilliams | | <ul style="list-style-type: none">Entry Not CompletedNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |
| Open | [none] | copy-of-niaid-dmrd-03-154 | Amphotericin Alone or in Combination With Fluconazole for AIDS-Associated Meningitis | Approved | 08/25/2015 16:24 | RWilliams | [Sponsor] | <ul style="list-style-type: none">Record Has 2 ErrorsNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |
| Open | [none] | RJW-10671801 | Prospective Study to Compare a New Vascular Access Graft to Existing Grafts | Entry Completed | 06/09/2015 12:24 | RWilliams | [Sponsor] | <ul style="list-style-type: none">Record Has 1 ErrorReady for Review and ApprovalNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |

Showing: 1-3 of 3 records

(filtered from 60 records)

All

records per page

Page 1 of 3

KEY:

PRS Review

Results

Delayed Results

XML Upload

No longer public

Download

Download Record List

- Displayed columns and records

- .csv file (compatible with Excel)

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Problem Records

ClinicalTrials.gov PRS

Protocol Registration and Results System

Org: TestOrg

User: RWilliams

Logout

Quick Links

New Record

Admin Quick Reference

Problem Resolution Guide

Records

Accounts

Help

Email: williamsre@mail.nih.gov [\[Update\]](#)

Record List

Group: [ALL]

All Records (60)

Problem Records (60)

Custom Filter

Showing: 1-3 of 3 records

(filtered from 60 records)

All

records per page

Search:

Show/Hide Columns

| Group | Protocol ID | ClinicalTrials.gov ID | Brief Title | Record Status | Last Update | Record Owner | Responsible Party | Problems |
|----------------------|-------------|-----------------------|---|---------------|------------------|--------------|-------------------|---|
| Open | [none] | OBS-12345 | Observational Study of ClinicalTrials.gov Staff | In Progress | 09/07/2015 12:55 | RWilliams | | <ul style="list-style-type: none">Entry Not CompletedNever ReleasedMissing FDAAA InformationLate Results - per FDAAA |

Overall Status

☐ Not yet recruiting

☐ Recruiting

☐ Active, not recruiting

☐ Enrolling by invitation

☐ Withdrawn

☐ Completed

☐ Suspended

☐ Terminated

☐ In Progress

☐ Entry Completed

☐ Approved

☐ Released

☐ PRS Review

☐ Public

☐ No Longer Public (e.g., duplicates)

☐ No Results

☐ Created

☐ Released

☐ Posted

☐ No Delayed Results

☐ Created

☐ Released

☐ Processed

☐ No Problems

☐ PRS Review Comments

☐ Entry Not Completed

☐ Not Recently Updated

☐ Record Has Errors

☐ Missing FDAAA Information

☐ Late Results - per FDAAA

☐ Never Released

☐ Update Not Released

☐ Ready for Review and Approval

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Identifying Problem Records

- Data Entry (Record Owner) Issues: e.g.,
 - PRS Review Comments that need to be addressed
 - Record(s) for recruiting studies that have not been updated or verified within the past six months.
- FDAAA 801 issues: e.g.,
 - Record(s) are missing one or more data elements required by FDAAA...
 - Record(s) appear to be overdue for results submission
- Administrator Issues: e.g.,
 - Record ready for Review and Approval
 - Update Not Released

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Problem Records – 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 relevant, submit results, certification or extension request
 - Note: PRS can't detect if trial includes an unapproved product.

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What is an ACT?

- **“Applicable Clinical Trials”* (ACTs) subject to FDAAA are:**
 - Interventional studies of drugs, biologics, & devices
 - Not phase 1 (drugs/biologics), not small feasibility (devices)
 - US FDA jurisdiction (e.g., IND/IDE or US site)
 - ACTs initiated after 9/27/07 or if initiated on or before 9/27/07, “ongoing” as of 12/26/07

* <http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>

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FDAAA Issues Records

- ClinicalTrials.gov Protocol Data Elements
 - **Study Type** [Interventional] AND
 - **Intervention Type** [Drug, Biologic, Device, Radiation or Genetic] AND
 - **Study Phase** [Not Phase 0 or Phase 1] AND
 - **Facility Location(s)** [At least 1 US location or locations not specified] OR **IND/IDE Protocol?** [Yes] AND
 - **Primary Completion Date** (PCD) [on or after January 2008 or not specified] OR **Study Completion Date** [on or after January 2008 if PCD not specified] AND
 - **Overall Recruitment Status** [not Withdrawn]

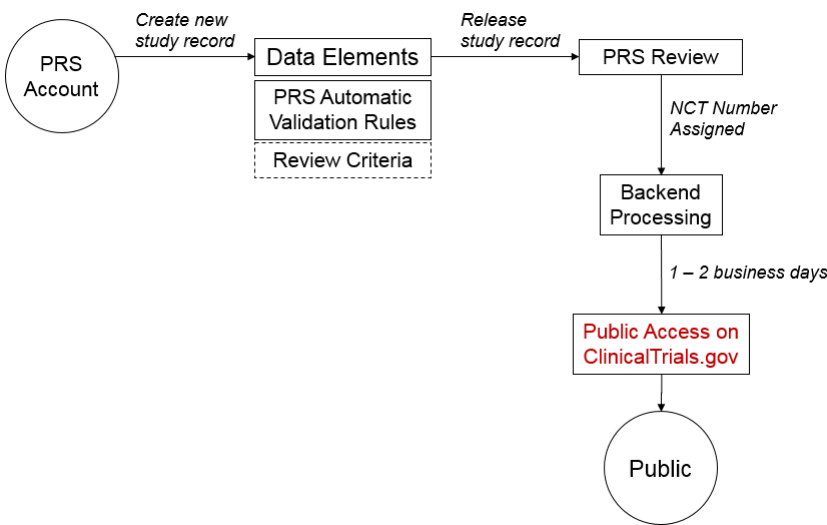
60

How to Avoid FDAAA Issues

- Provide all FDAAA data elements (i.e., address all Warnings)
- Ensure data elements used to identify records with potential FDAAA Issues are properly specified
- Use Primary Completion Date to identify studies that may be due for results within the next year
 - Notify Responsible Party at regular intervals


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Study Record Process Overview



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Study record on ClinicalTrials.gov



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

Example: "Heart attack" AND "Los Angeles"

Search for studies:

Advanced Search | Help | Studies by Topic | Glossary

[Find Studies](#)
[About Clinical Studies](#)
[Submit Studies](#)
[Resources](#)
[About This Site](#)

Home > Find Studies > Search Results > Study Record Detail

Trial record 1 of 1 for: NCT02535689

[Previous Study](#) | [Return to List](#) | [Next Study](#)

Safety of Tofacitinib, an Oral Janus Kinase Inhibitor, in Systemic Lupus Erythematosus

This study is currently recruiting participants. (see [Contacts and Locations](#))

Verified August 2015 by National Institutes of Health Clinical Center (CC)

Sponsor:
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Information provided by (Responsible Party):
National Institutes of Health Clinical Center (CC) (National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS))

ClinicalTrials.gov Identifier:
NCT02535689

First received: August 28, 2015
Last updated: NA
Last verified: August 2015
History: No changes posted

[Full Text View](#)
[Tabular View](#)
[No Study Results Posted](#)
[Disclaimer](#)
[How to Read a Study Record](#)

Example of items added during processing

| Safety of Tofacitinib, an Oral Janus Kinase Inhibitor, in Systemic Lupus Erythematosus | |
|---|--|
| <p>This study is currently recruiting participants. (see Contacts and Locations)</p> <p><i>Verified August 2015 by National Institutes of Health Clinical Center (CC)</i></p> <p>Sponsor: National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)</p> <p>Information provided by (Responsible Party): National Institutes of Health Clinical Center (CC) (National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS))</p> | <p>ClinicalTrials.gov Identifier: NCT02535689</p> <p>First received: August 28, 2015 Last updated: NA Last verified: August 2015 History: No changes posted</p> |
| <p> Full Text View Tabular View No Study Results Posted Disclaimer How to Read a Study Record </p> | |
| <p>Resource links provided by NLM:</p> <p>Genetics Home Reference related topics: systemic lupus erythematosus</p> <p>MedlinePlus related topics: Lupus</p> <p>Drug Information available for: Tofacitinib Tofacitinib citrate</p> <p>U.S. FDA Resources</p> | |

Public Site Report

Improvements coming end of Sept 2015

ClinicalTrials.gov PRS

Protocol Registration and Results System

Org: TestOrg

User: RWilliams

Logout

Email: williamsre@mail.nih.gov [Update]

Quick Links

[New Record](#)

[Admin Quick Reference](#)

[Problem Resolution Guide](#)

Record List

Group: [ALL] (All Records (60))

Showing: 1-3 of 3 records (filtered from 60 records)

Group

Protocol ID

Open

none

OBS-12345

Group

Protocol ID

Open

none

copy-of-niaid-dmrd-

Group

Protocol ID

Open

none

RJW-10671801

Records

Accounts

Help

New Record

Problems: RWilliams Records

PRS Review Comments

Upload Record (XML)

Upload from NCI CTRP

Admin only:

Problems: TestOrg Records

Public Site Report

Undelete Record

Batch Record Upload (XML)

Check Batch Upload Status

Batch Record Release

Check Batch Release Status

Batch Record Download (XML)

Public Site Report

- Report of records/versions posted on ClinicalTrials.gov

Search: RWilliams

Show/Hide Columns

| Brief Title | Record Status | Last Update | Record Owner | Responsible Party | Problems |
|---|-----------------|------------------|--------------|-------------------|--|
| Original Study of Gov Staff | In Progress | 09/07/2015 12:55 | RWilliams | | <ul style="list-style-type: none">• Entry Not Completed• Never Released• Missing FDAAA Information• Late Results - per FDAAA |
| ...in Alone or inon With Fluconazole ...Associated Meningitis | Approved | 08/25/2015 16:24 | RWilliams | [Sponsor] | <ul style="list-style-type: none">• Record Has 2 Errors• Never Released• Missing FDAAA Information• Late Results - per FDAAA |
| ...ve Study to Comparea New Vascular Access Graft ...to Existing Grafts | Entry Completed | 06/09/2015 12:24 | RWilliams | [Sponsor] | <ul style="list-style-type: none">• Record Has 1 Error• Ready for Review and Approval• Never Released• Missing FDAAA Information• Late Results - per FDAAA |

Showing: 1-3 of 3 records (filtered from 60 records) All records per page

Page 1 of 3

Download

KEY: PRS Review Results Delayed Results

XML Upload No longer public

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Questions?

Email register@clinicaltrials.gov at any time!

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