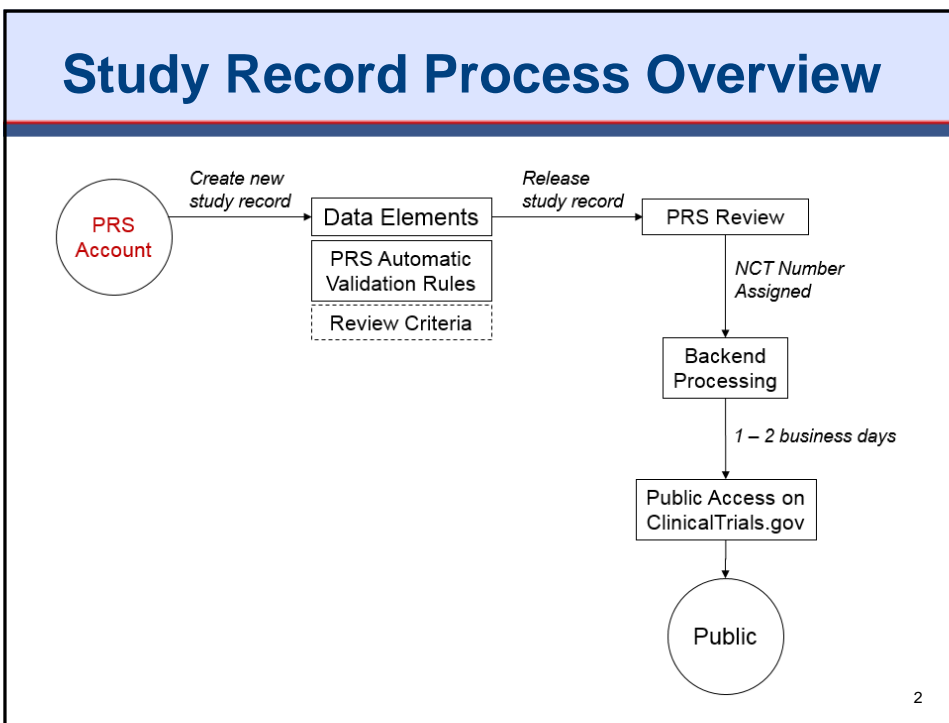


ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Protocol Registration and Results System (PRS) Overview

Results Database Train-the-Trainer Workshop
September 2015

 <http://ClinicalTrials.gov>



PRS Account: Roles and Responsibilities

3

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>

4

PRS Administrator

- Maintains PRS Account for organization
 - Creates/disables Users within account
 - Has access to all study records
 - Can grant Users access to any study record
 - 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

5

Home Page (Admin)

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

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-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 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: [PR](#) PRS Review [R](#) Results [DR](#) Delayed Results
[U](#) XML Upload [NP](#) No longer public

[Download](#)

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6

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

7

Home Page (User)

ClinicalTrials.gov PRS
Protocol Registration and Results System

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

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

Records ▾ Accounts ▾ Help ▾

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

Record List

Showing 1 record [Show/Hide Columns](#)

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...](#)

8

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)

9

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

Admin only
[Change Password](#)
[Update User Information](#)
[List TestOrg Administrator\(s\)](#)
[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	Clin	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		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-dmsid-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

10

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	

11

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:

Full Name:
Example: John J Smith, MD

Email Address:
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.

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12

PRS Account Management

13

Create a New 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	Clm	Entry	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 CompletedNever ReleasedMissing FDAAA InformationLate Results - per FDAAA
Open [none]	Test 1		Test 1 - Efficacy and Safety Study of DX-95 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 ErrorsReady for Review and ApprovalNever 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 6 ErrorsReady for Review and ApprovalNever Released
Open [none]	copy-of-riaid-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

14

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)

Search: williams [Show/Hide Columns]

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 Completed Never Released Missing FDAAA Information Late Results - per FDAAA
Open	[none]	Test 1	Entry	Completed	04/26/2012 15:35	Tony	<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	<ul style="list-style-type: none"> Record Has 8 Errors Ready for Review and Approval Never Released
Open	[none]	copy-of-enaid-dmid-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

15

Modify User Account (cont.)

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User: RWilliams Logout

Home > Users

User Account List - Modify

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	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	

16

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	

17

Enable/Disable 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 ▾

Record List

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

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

Search: williams [Show/Hide Columns]

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 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	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 	

18

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:

Transfer record ownership and disable Bergeris1 account?

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19

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	Access List Edit
Last Updated: 09/07/2015 12:55 by RWilliams	Upload: Allowed Edit
Initial Release: [Not yet released]	PRS Review: [Not yet released]
Results Expected: December 2013	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

20

List Email Addresses

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

Admin only:

- Change Password
- Update User Information
- List TestOrg Administrator(s)
- 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	Class	Record Status	Last Update	Record Owner	Responsible Party	Problems
[none]	1234567	Entry	In Progress	04/22/2013 12:02	Tony		<ul style="list-style-type: none"> Entry Not Completed Never Released Missing FDA/AA Information Late Results - per FDA/AA
[none]	Test 1	Test 1 - Efficacy and Safety Study of DX-88 to Treat Acute Attacks of Hereditary Angioedema (HAE)	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
[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 6 Errors Ready for Review and Approval Never Released
[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 FDA/AA Information Late Results - per FDA/AA

21

PRS Account Email Address List

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User: RWilliams Logout

Email Address List

[Home](#)

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

22

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) Cut
Showing 1-3 of 3 records (filtered from 60 records) All

ClinicalTrials.gov ID		Group	Protoc ID

ClinicalTrials.gov PRS
Protocol Registration and Results System

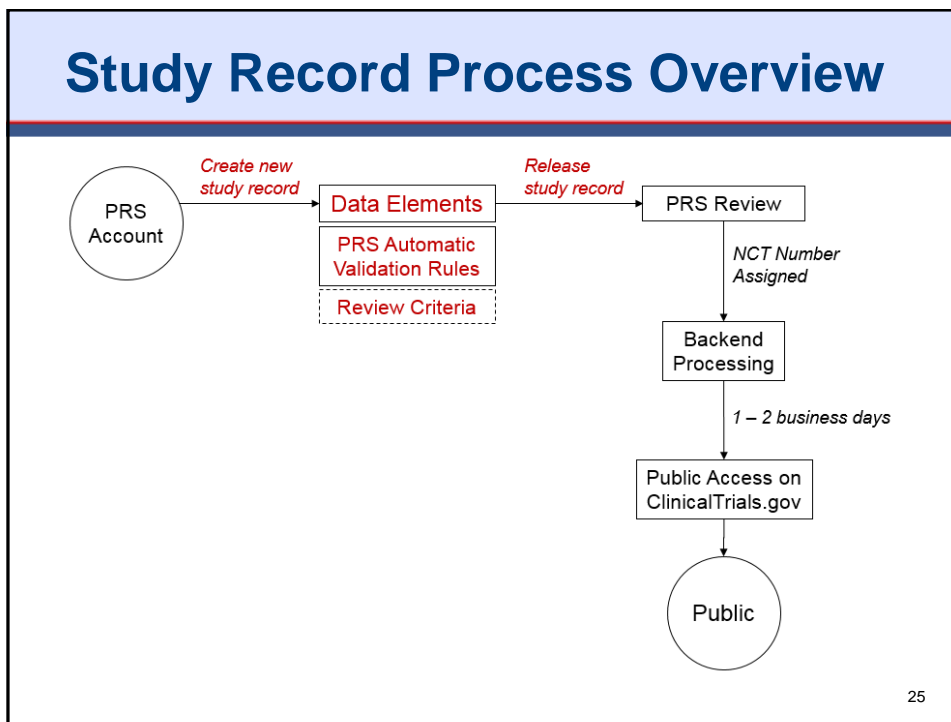
User's Guide
June 2015

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.

23

PRS: Study Record Basics



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])

26

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

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

27

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

28

Data Element Definitions in PRS During data entry (cont.)

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 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 ClinicalTrials.gov
† = FDAAA Required to comply
(†) = (FDAAA) May be required to

U.S. National Library of Medicine

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

29

Data Element Definitions in PRS Help Menu

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**

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) [Cut]

Showing 1-6 of 6 records (filtered from 60 records) All [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-dmid-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

30

Data Element Definitions in PRS Help Menu (cont.)

The screenshot shows the ClinicalTrials.gov PRS interface. On the left, the 'Help' dropdown menu is open, with 'Protocol Data Entry' highlighted. A red arrow points to this menu item. On the right, the 'Help: Protocol Data Entry' page is displayed, featuring a red box around 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 bulleted links to various guides and regulations. A 'Close' button is visible at the bottom of the help window.

31

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

32

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](#)

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

33

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)

34

PRS Validation Rules (cont.)

35

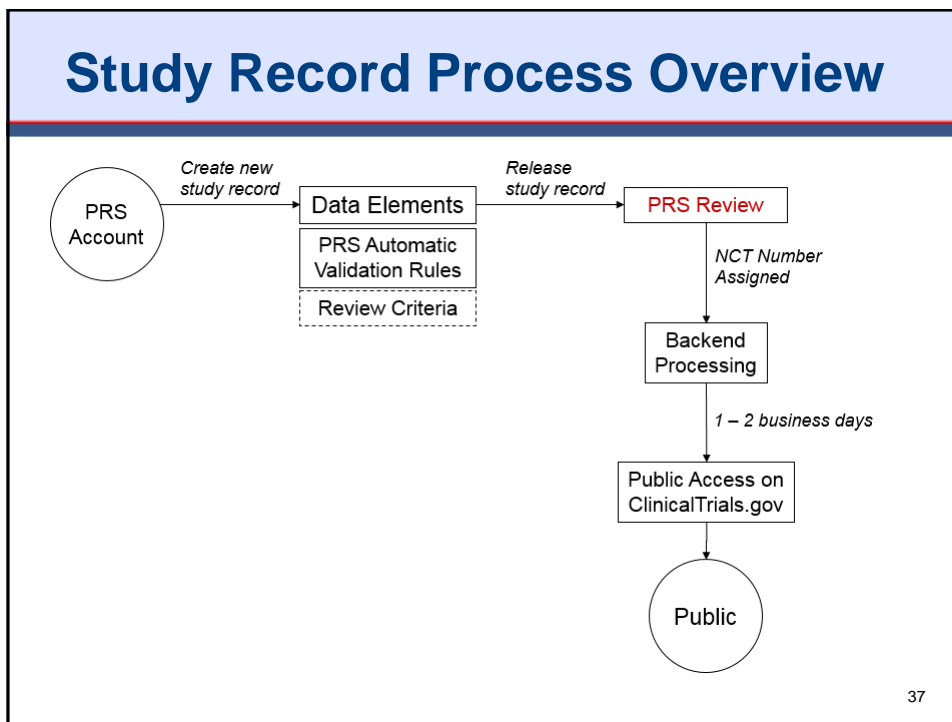
Record Status

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

	In Progress	→	Entry Completed	→	Approved	→	Released	→	PRS Review	→	Public
R O L E	Record is being edited or has PRS Review Comments		Record editing is complete; ready for approval & release		Record reviewed and verified		Record submitted to PRS for review		Record locked; in queue or being reviewed		Record passed PRS Review for posting on ClinicalTrials.gov*
	Admin or User		Admin or User		Admin or User (if Resp Party)		Resp Party (PI or Admin)		PRS Reviewer		PRS Reviewer
	<div style="border: 1px solid black; width: 50%; margin: 0 auto; padding: 5px;">Record did not pass PRS Review</div>										

* 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

36



- ## Review Criteria
- Entered protocol and results information must be consistent with review criteria applied by PRS Reviewers (ClinicalTrials.gov staff)
 - Overview of review criteria
 - Logic and internal consistency
 - Apparent validity
 - Meaningful entries
 - Formatting
 - ClinicalTrials.gov Review Criteria (DRAFT)
 - Protocol: <https://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf>
 - Results: <https://prsinfo.clinicaltrials.gov/ResultsDetailedReviewItems.pdf>
- 38

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

39

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

40

Find Records with PRS Review Comments

ClinicalTrials.gov PRS
Protocol Registration and Results System

Org: TestOrg User: RWilliams Logout

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

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

Records Accounts Help

Record List

Group: [ALL] All Records (60) Problem Records (60) Custom Filter Custom filter applied

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

Record Status:
 In Progress
 Entry Completed
 Approved
 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
 PRS Review Comments
 Missing FDAAA Information
 Late Results - per FDAAA
 Never Released
 Update Not Released
 Not Recently Updated
 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

41

Accessing Review Comments

Record Summary

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

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

Next Step: Read Review Comments

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.

42

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**

43

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.

44

PRS 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.

45

PRS 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

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.

46

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.

47

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

48

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

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

49

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

50

PRS Home Page & Record List

51

Home Page (Admin)

ClinicalTrials.gov PRS
Protocol Registration and Results System

Menu Bar

Org: TestOrg User: RWilliams Logout

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 (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		<ul style="list-style-type: none">Entry Not CompletedNever ReleasedMissing FDAAA InformationLate Results - per FDAAA
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 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](#)

52

PRS Record List Features

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

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	Group
Open	[none]	OBS-12345	Observational Study of ClinicalTrials Gov Staff	In Progress	09/07/2015 12:55	RWilliams		<input checked="" type="checkbox"/> Protocol ID <input checked="" type="checkbox"/> ClinicalTrials.gov ID <input checked="" type="checkbox"/> Brief Title <input type="checkbox"/> Overall Status <input type="checkbox"/> Verification Date <input type="checkbox"/> Primary Completion Date <input checked="" type="checkbox"/> Record Status <input type="checkbox"/> Results Status <input type="checkbox"/> Delayed Results Status <input checked="" type="checkbox"/> Last Update <input type="checkbox"/> Last Updated by <input checked="" type="checkbox"/> Record Owner <input checked="" type="checkbox"/> Responsible Party <input type="checkbox"/> Central Contacts <input type="checkbox"/> Study Officials
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]	
Open	[none]	RJW-10671801	Prospective Study to Compare a New Vascular Access Graft to Existing Grafts	Entry Completed	05/09/2015 12:24	RWilliams	[Sponsor]	

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

KEY: [PR](#) PRS Review [R](#) Results [DR](#) Delayed Results
[U](#) XML Upload [NP](#) No longer public

53

PRS Record List Features (cont.)

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

Record List: Group: [ALL] | All Records (60) | Problem Records (60) | Custom Filter | Custom filter applied | [Clear Filter](#)

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	Created	05/27/2015 09:55	RWilliams	[Sponsor]	PR Review Comments

⋮

54

PRS Record List Download

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

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-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
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 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: [PR](#) PRS Review | [R](#) Results | [DR](#) Delayed Results | [U](#) XML Upload | [NF](#) No longer public

Download

Download Record List
- Displayed columns and records
- .csv file (compatible with Excel)

55

Problem Records

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

Record List

Group: [ALL] | All Records (60) | **Problem Records (60)** | Custom 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

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

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	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

56

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

57

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.

58

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>

59

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]

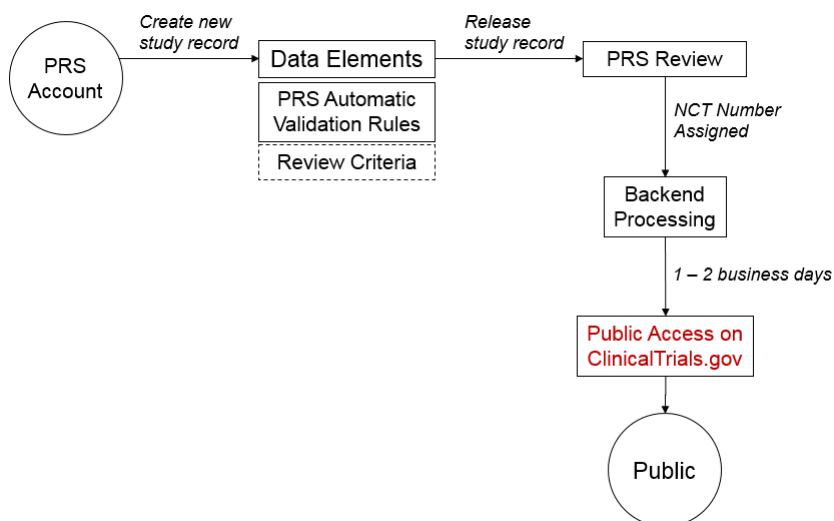
60

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

61

Study Record Process Overview



62

Study record on ClinicalTrials.gov

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

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 Text Size ▾

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

[Disclaimer](#) [How to Read a Study Record](#)

63

Example of items added during processing

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

[Disclaimer](#) [How to Read a Study Record](#)

Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [systemic lupus erythematosus](#)

[MedlinePlus](#) related topics: [Lupus](#)

[Drug Information](#) available for: [Tofacitinib](#) [Tofacitinib citrate](#)

[U.S. FDA Resources](#)

64

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](#)

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

Group	Protocol ID	Brief Title	Record Status	Last Update	Record Owner	Responsible Party	Problems
Open	[none] OBS-12345	Original Study of ...	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-niaid-dmid-	...in Alone or in ...	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	...ve Study to Compare ...	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

65

Questions?

Email register@clinicaltrials.gov at any time!

66