ClinicalTrials.gov
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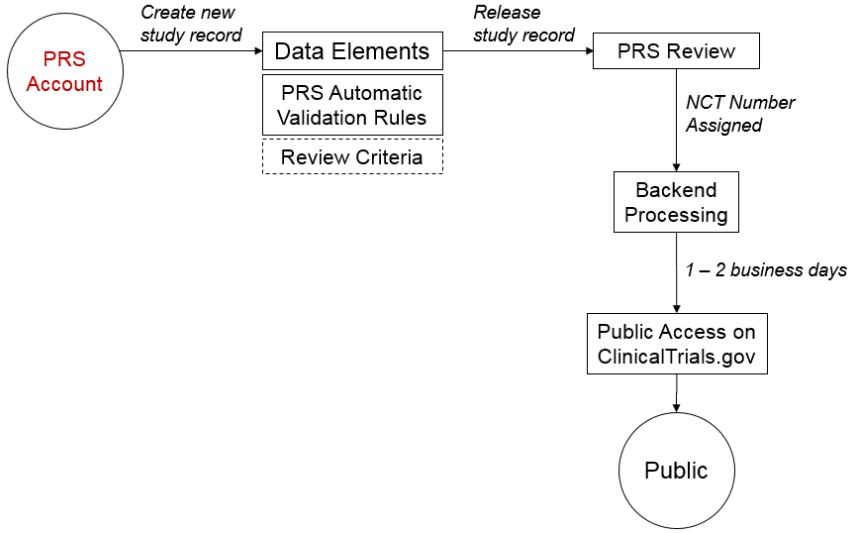
Protocol Registration and Results System (PRS) Overview

Results Database Train-the-Trainer Workshop
September 2015

http://ClinicalTrials.gov

Study Record Process Overview



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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)

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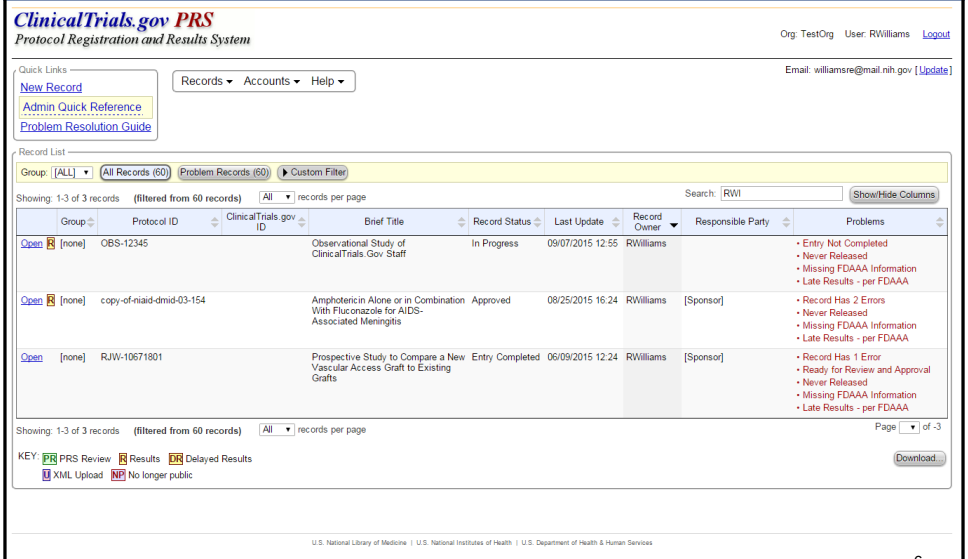
* For Sponsor definition see: https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf

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)



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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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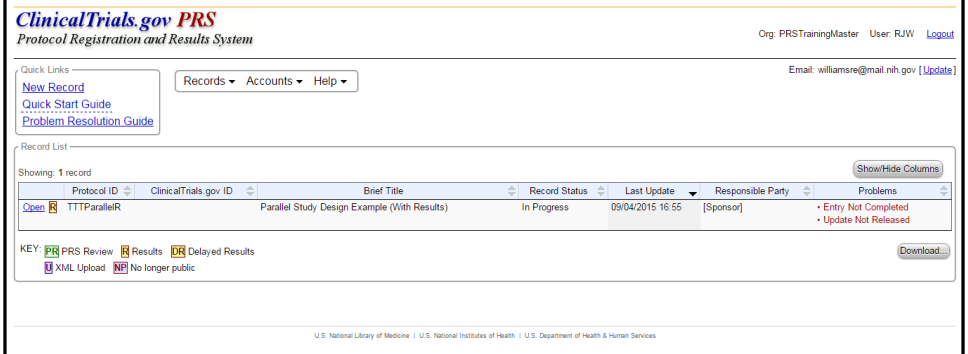
Home Page (User)



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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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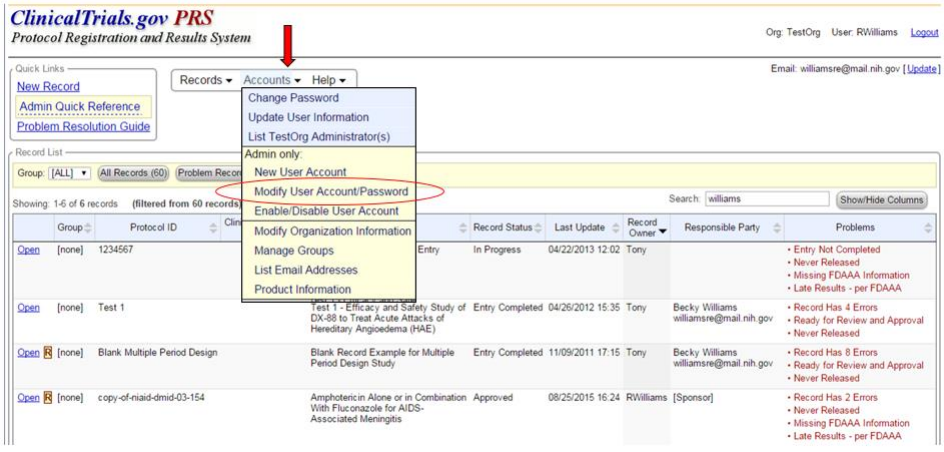
Verify Subscribed to PRS Emails
Modify User Account/Password



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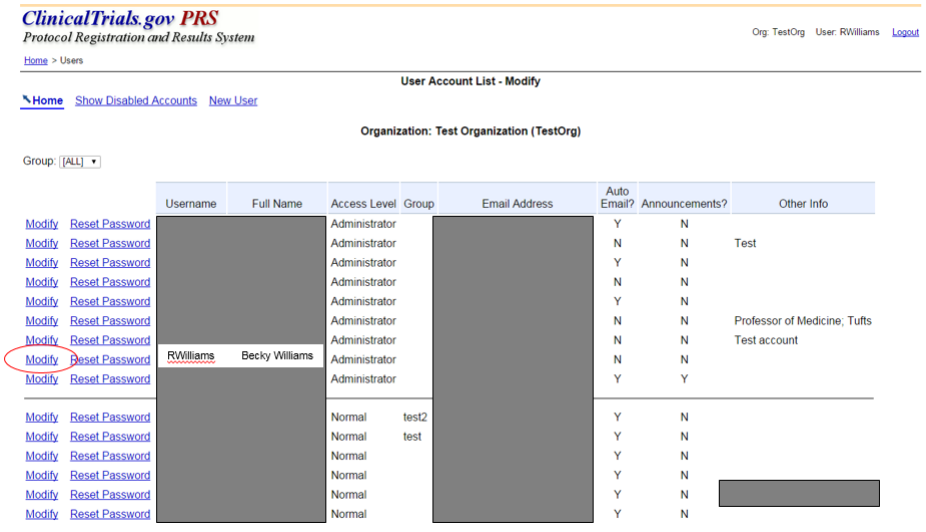
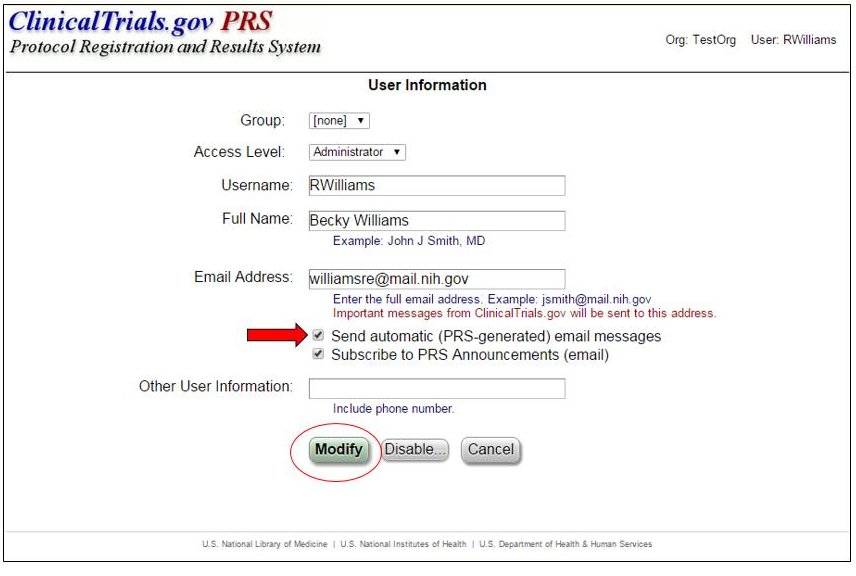
Verify Subscribed to PRS Emails
Modify User Account



11

Verify Subscribed to PRS Emails



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PRS Account Management

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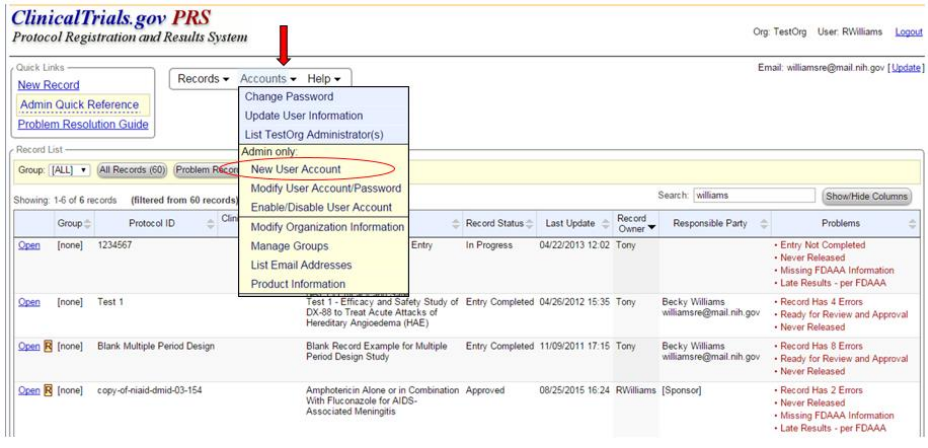
Create a New User Account



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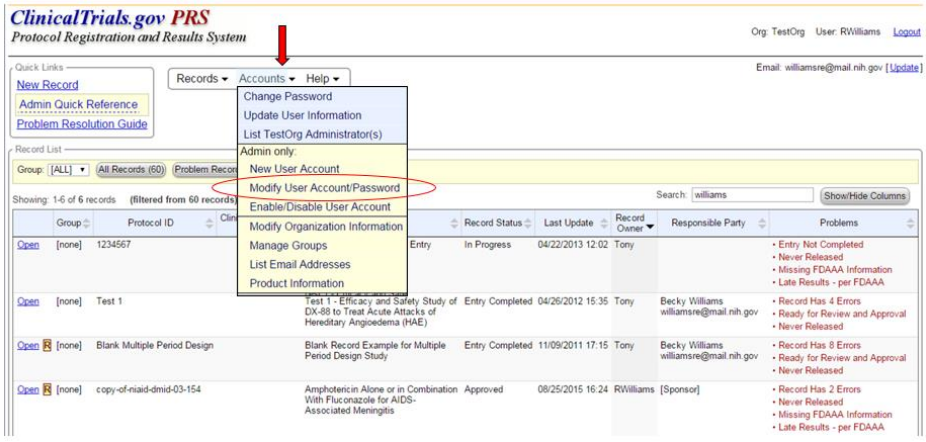
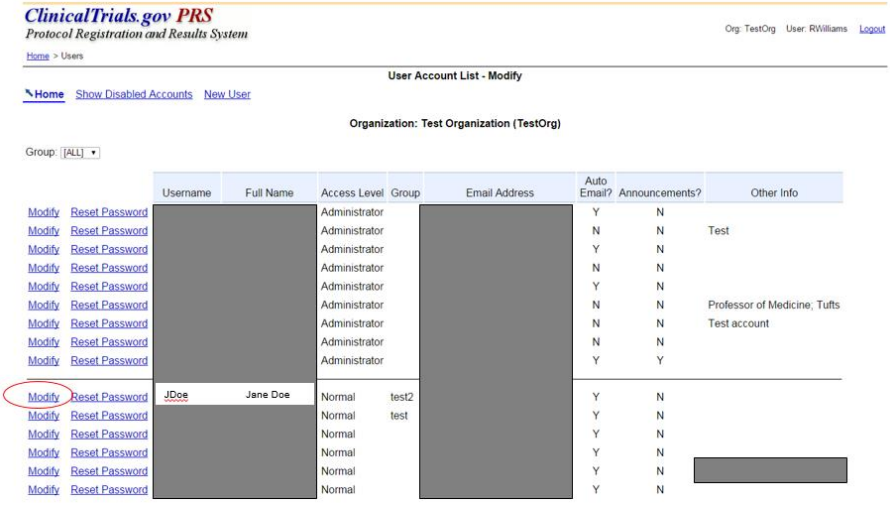
Modify User Account



15

Modify User Account (cont.)



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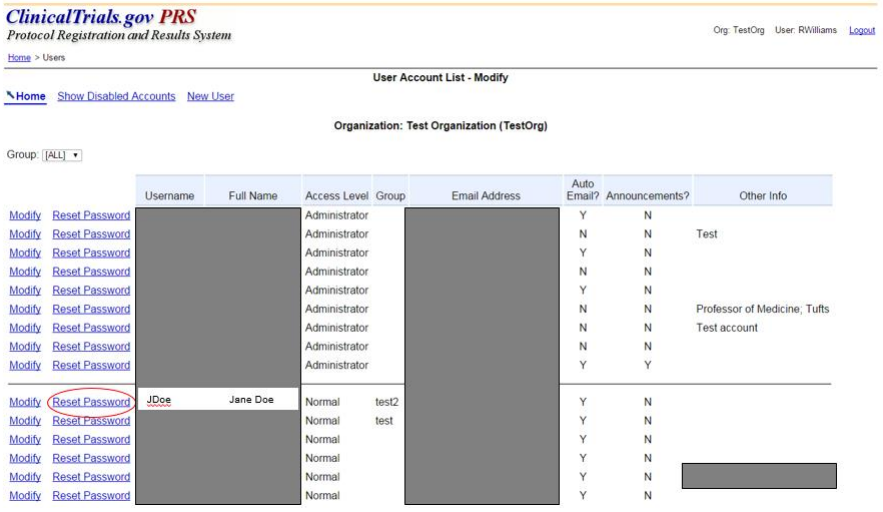
Reset User Password



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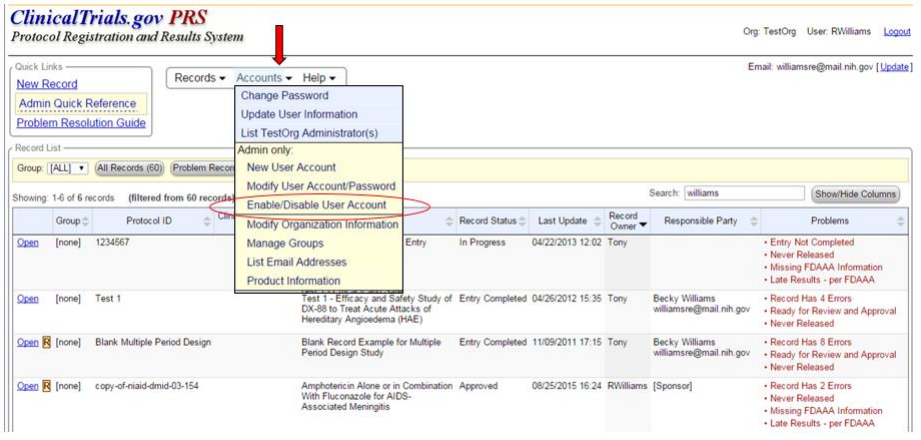
Enable/Disable User Account



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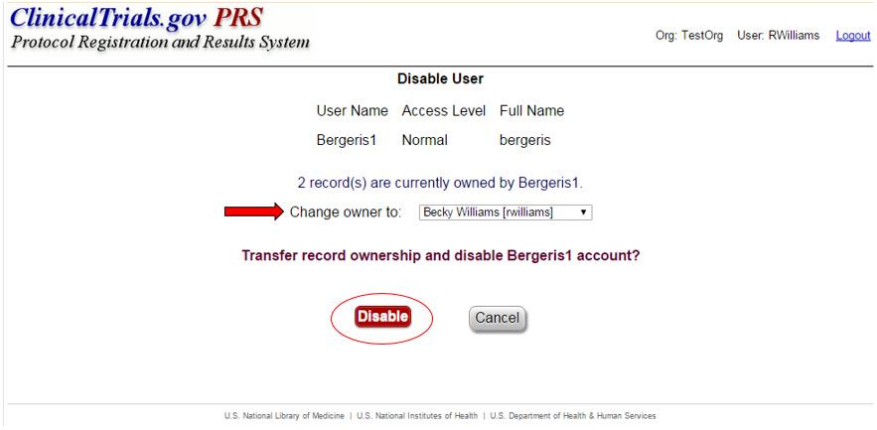
Disable User Account



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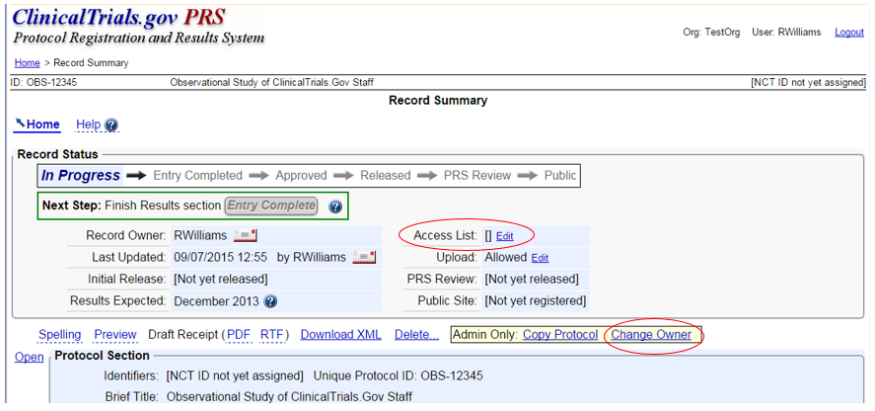
Changing Record Ownership



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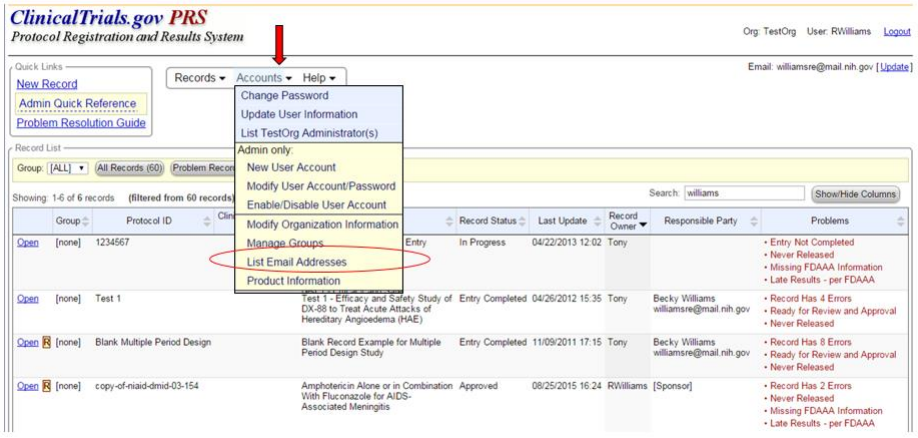
List Email Addresses



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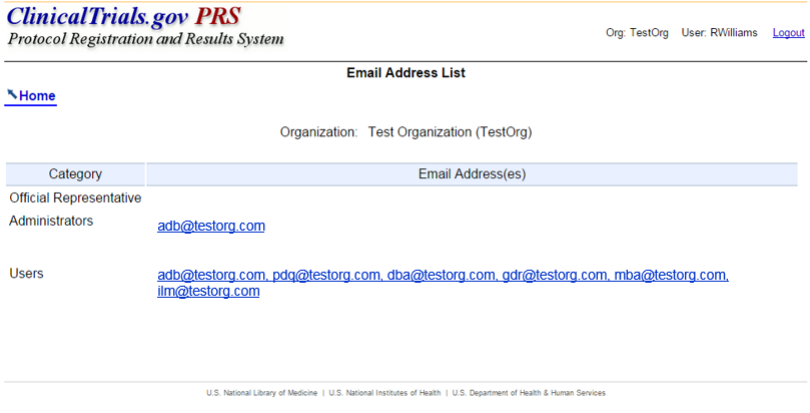
PRS Account Email Address List



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

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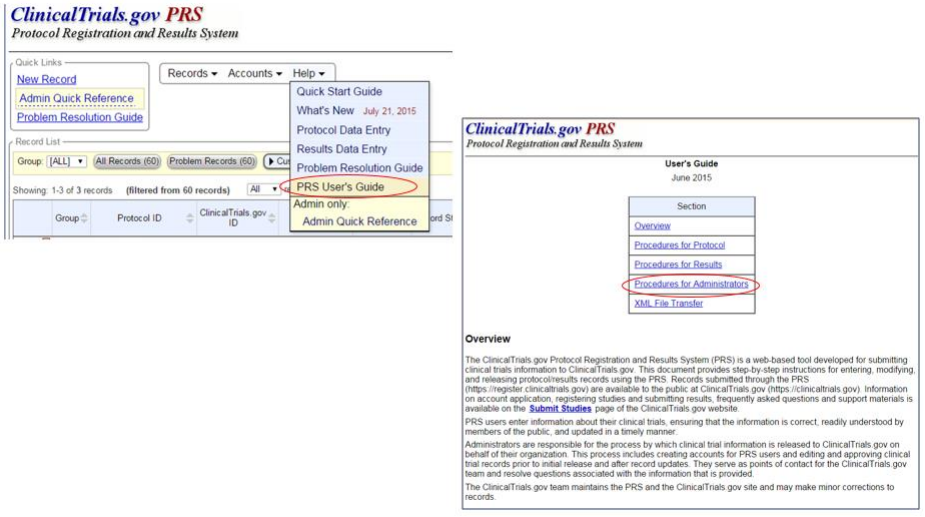
Help on PRS Functions



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PRS: Study Record Basics

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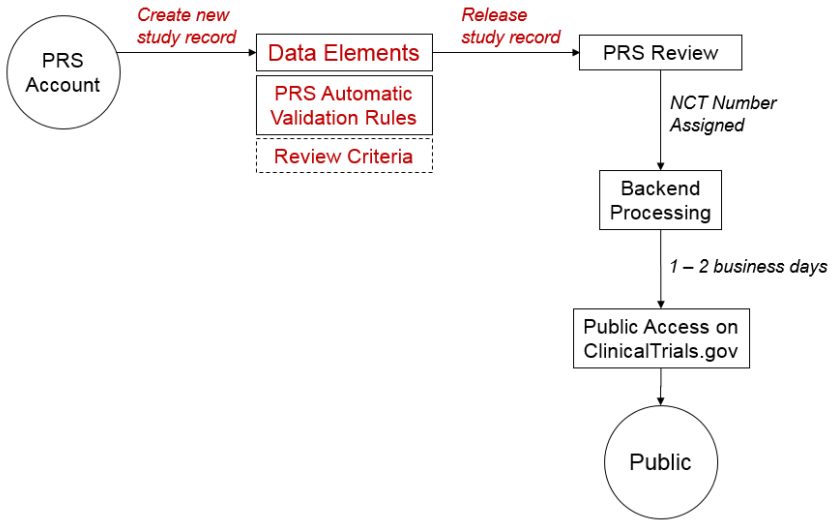
Study Record Process Overview



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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])

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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

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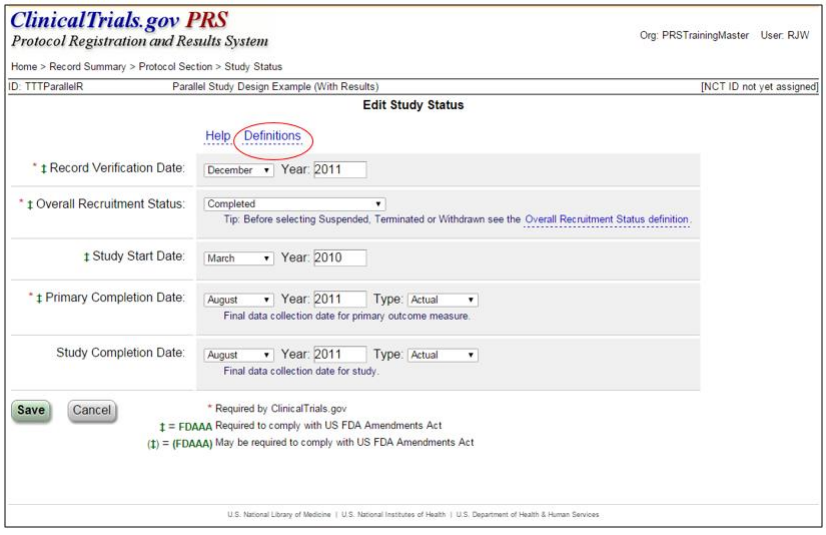
Data Element Definitions in PRS
During data entry



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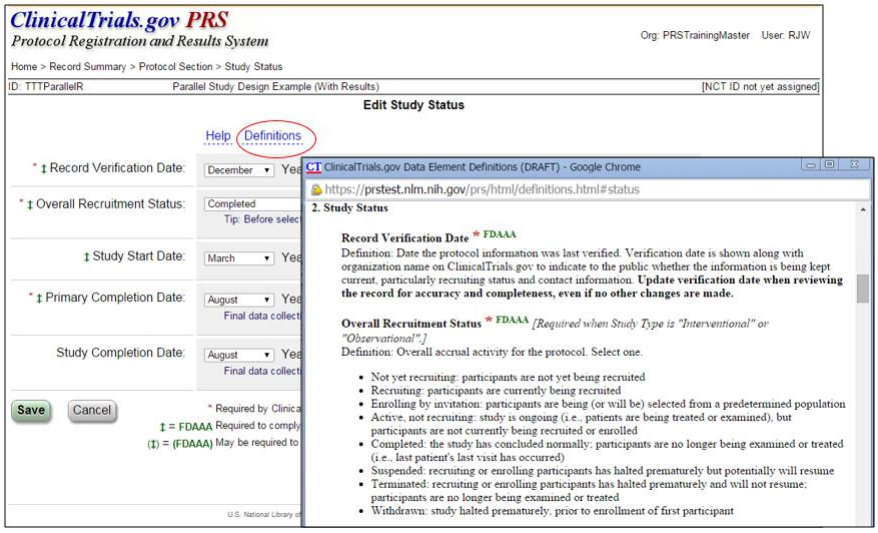
Data Element Definitions in PRS
During data entry (cont.)



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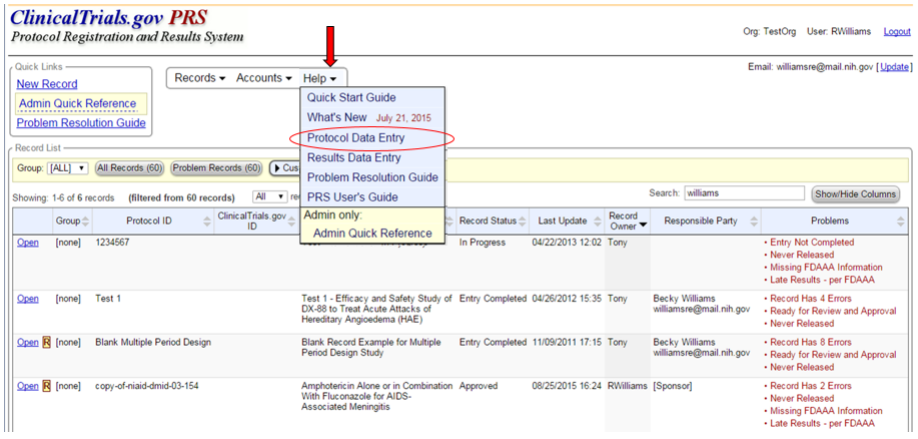
Data Element Definitions in PRS
Help Menu



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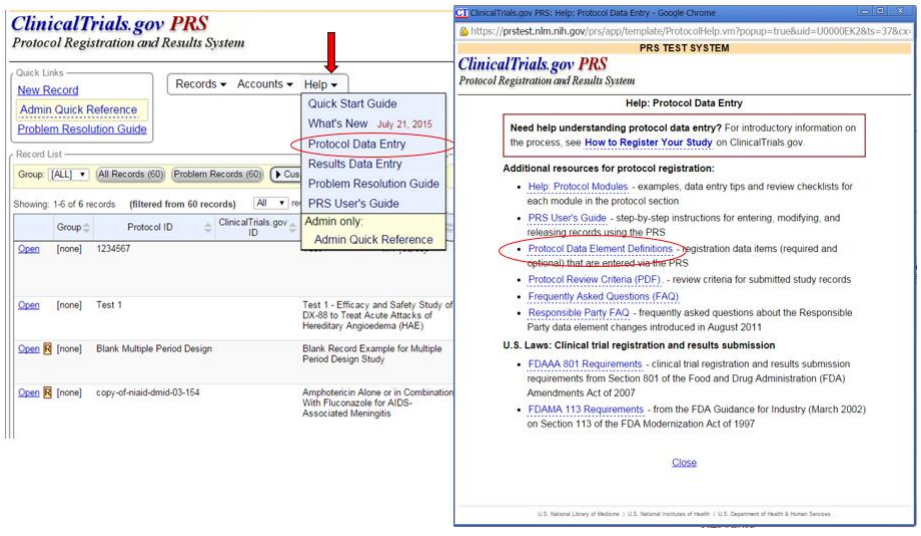
Data Element Definitions in PRS

Help Menu (cont.)



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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

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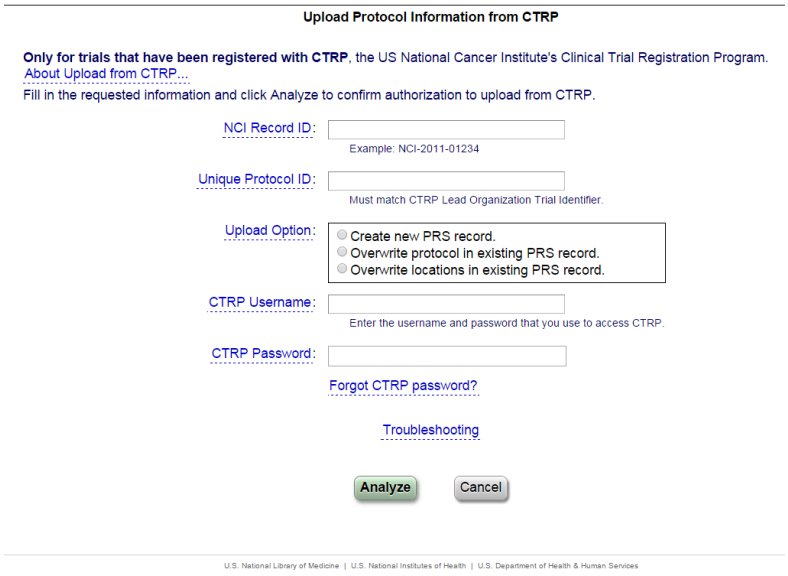
Upload from NCI CTRP



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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 required or (FDAAA) may be required (e.g., Study Start Date data element)
ALERT	Problems that need to be addressed
NOTE	Potential problems that should be reviewed and corrected, if possible (if not possible, then may ignore)

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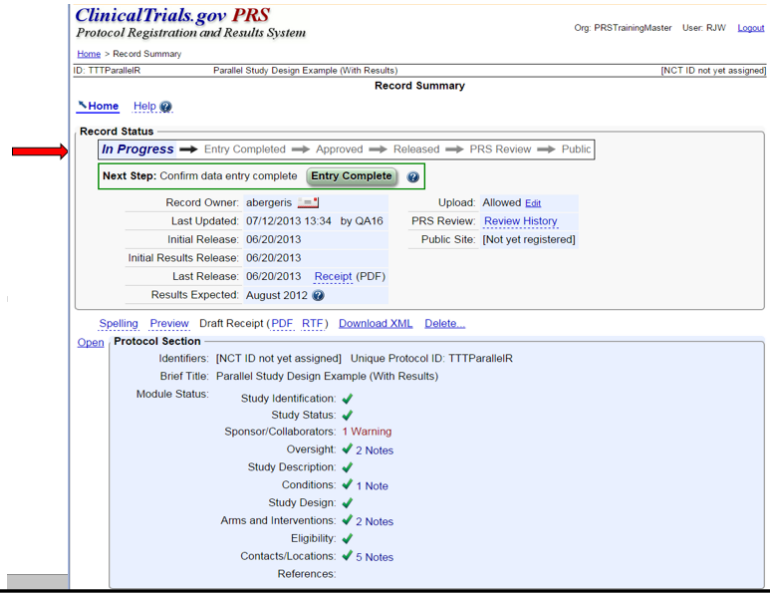
PRS Validation Rules (cont.)



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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
	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*
ROLE	Admin or User	Admin or User	Admin or User (if Resp Party)	Resp Party (PI or Admin)	PRS Reviewer	PRS Reviewer

Record did not pass PRS Review

* 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

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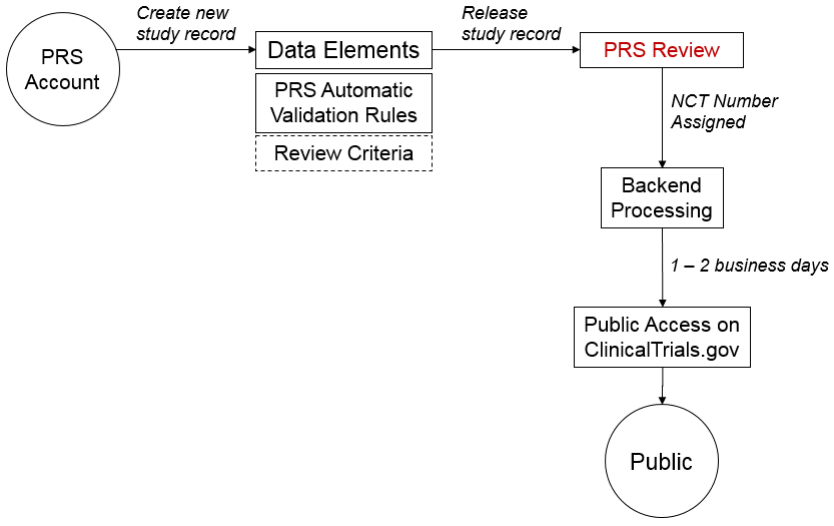
Study Record Process Overview



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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

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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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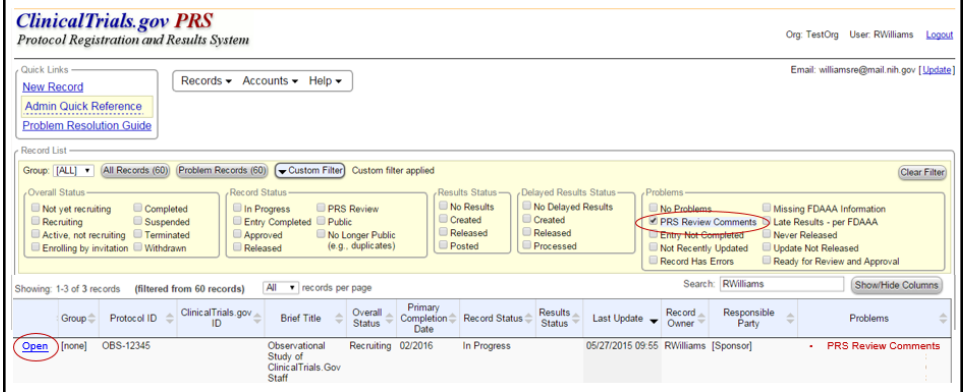
Find Records with PRS Review Comments



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Accessing Review Comments

Record Summary

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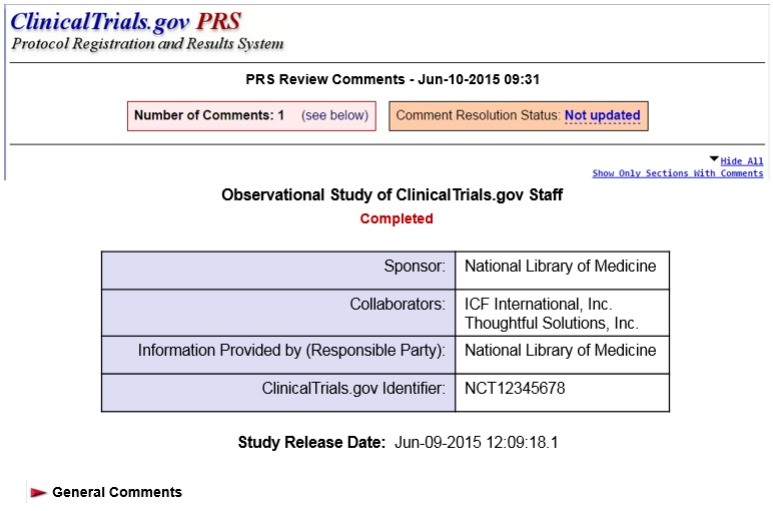
PRS Review Comments



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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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.

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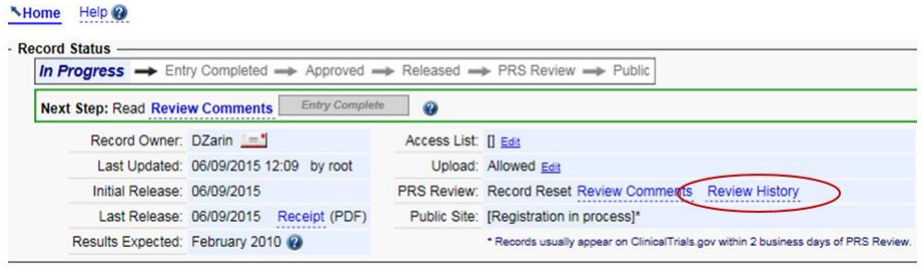
PRS Review History



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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

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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

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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

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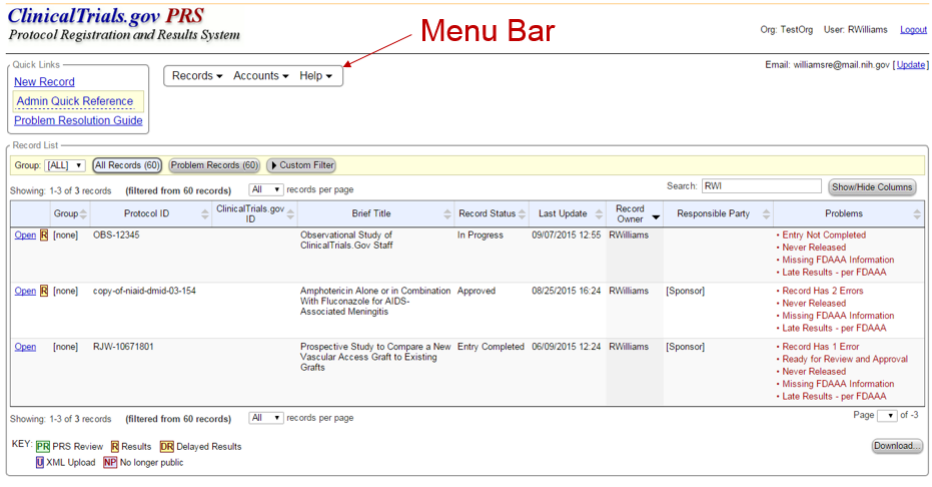
Home Page (Admin)



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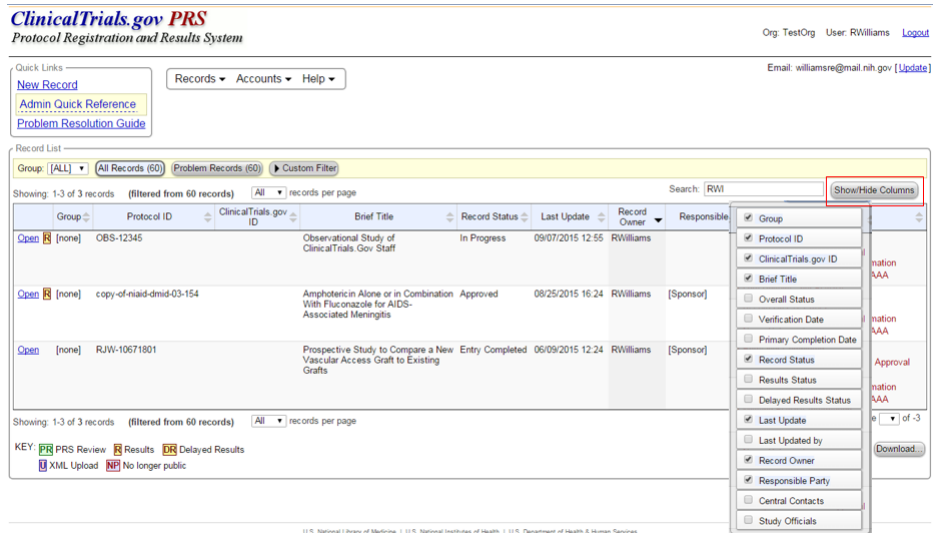
PRS Record List Features



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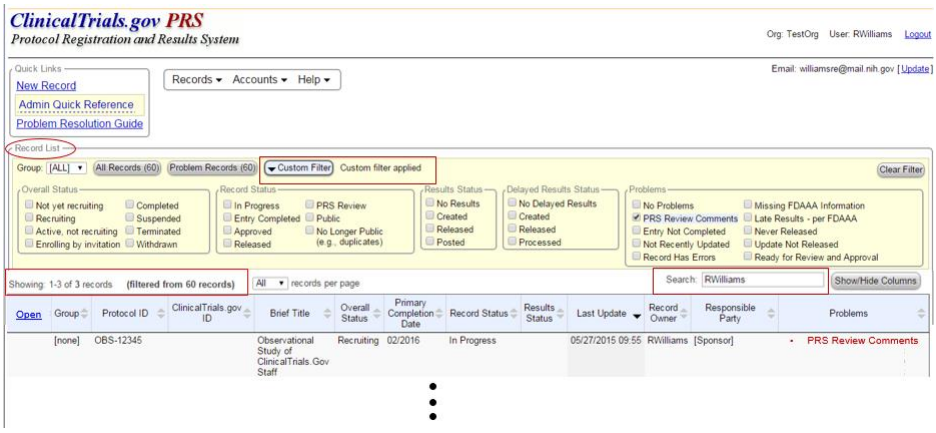
PRS Record List Features (cont.)



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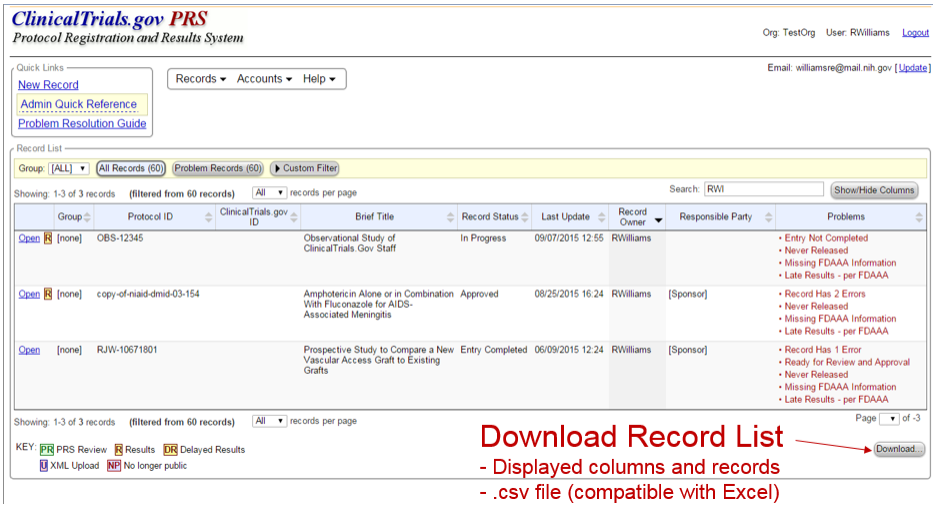
PRS Record List Download



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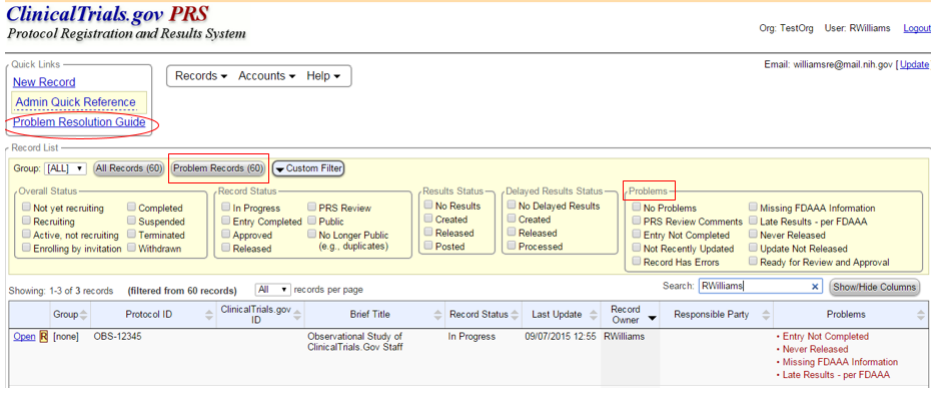
Problem Records



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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

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

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]

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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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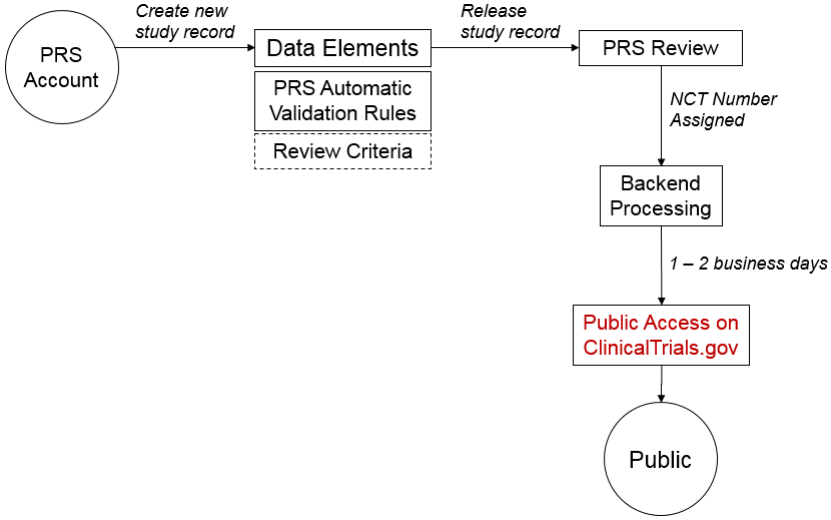
Study Record Process Overview



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Study record on ClinicalTrials.gov

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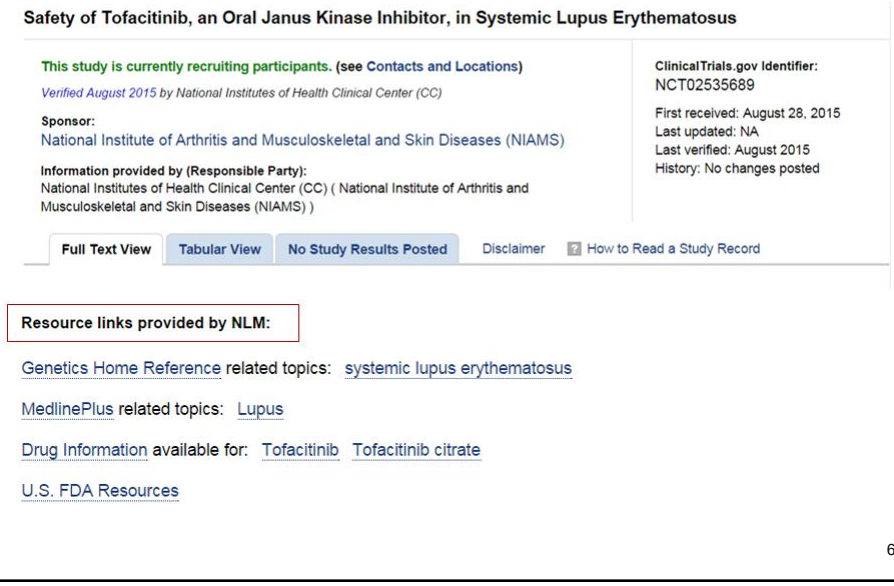
Example of items added during processing



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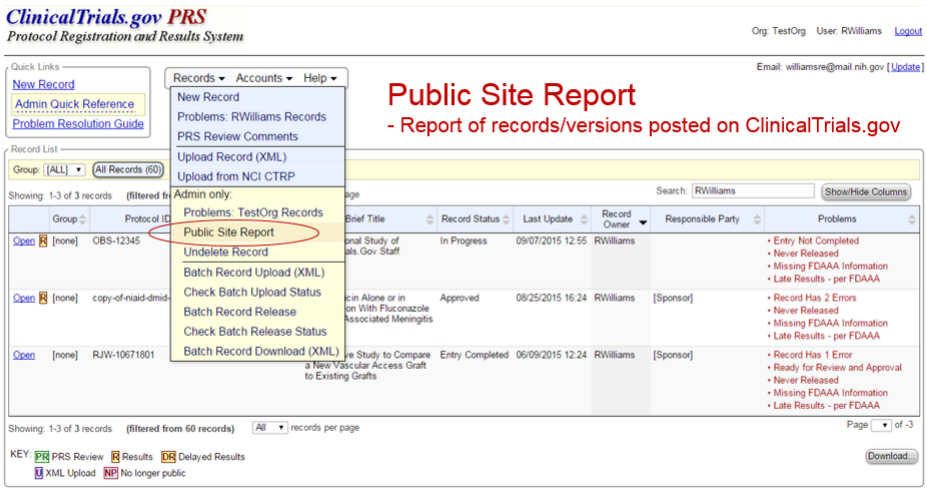
Public Site Report
Improvements coming end of Sept 2015



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Questions?

Email register@clinicaltrials.gov at any time!

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