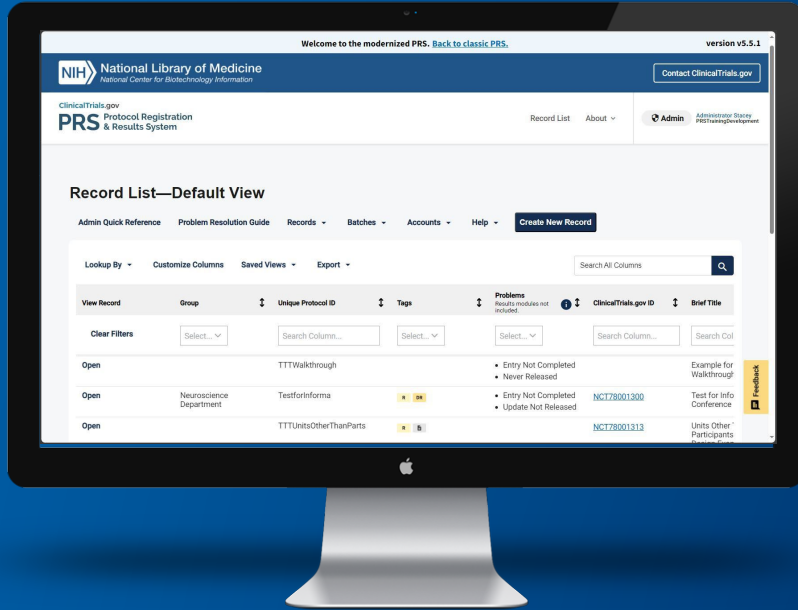




National Library of Medicine



Introduction to the Modernized Protocol Registration and Results System (PRS)

Webinar

October 8, 2024 | 1 p.m. ET

| Housekeeping Items



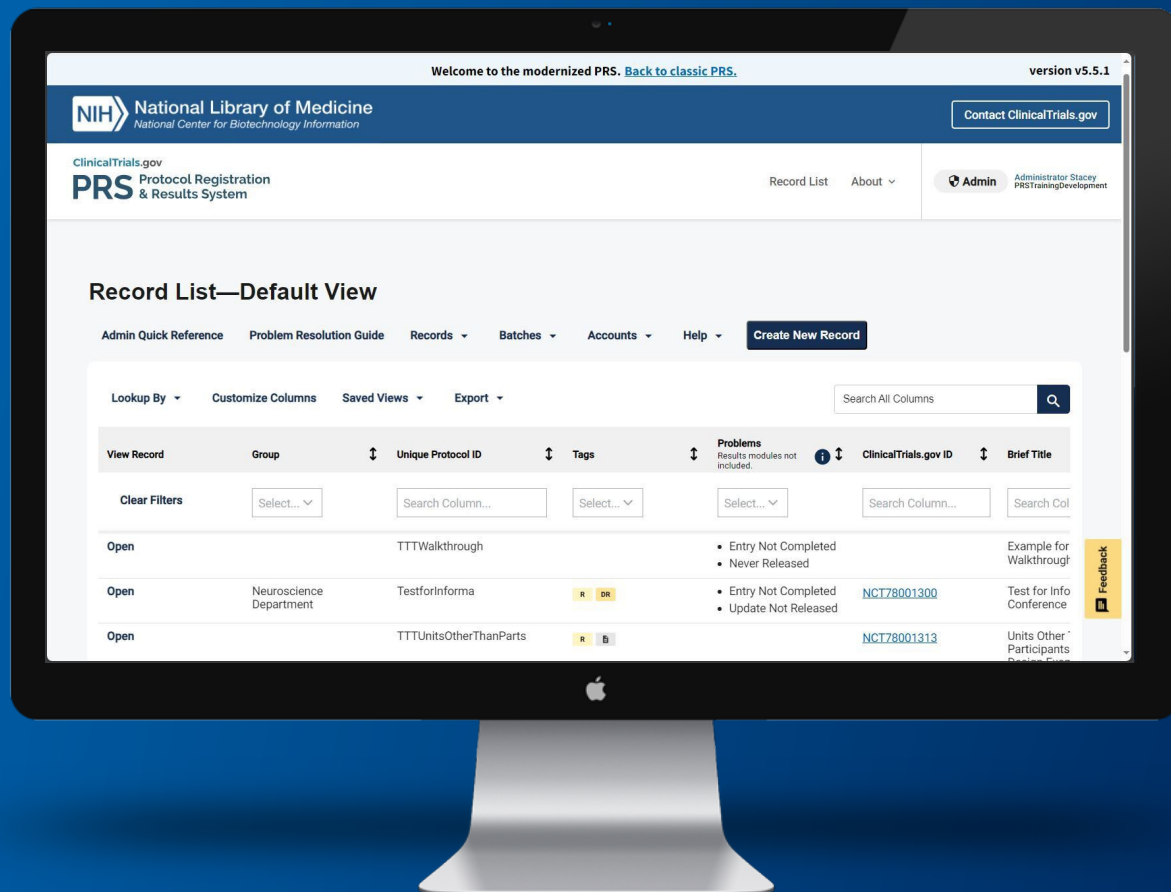
The webinar is being recorded, and the recording will be made available with the slides on our website within 30 days. Participants can download an Adobe PDF file of the slides from the chat during today's webinar.



All participants will be muted but will have the opportunity to interact via polls and the moderated question-and-answer (Q&A) session.



If you have technical issues during the webinar, please contact technical support via the chat box.



ClinicalTrials.gov Modernization Effort Update



Anna M. Fine
ClinicalTrials.gov Acting
Program Head

| Agenda

Time	Description	Presenter
1–1:45 p.m.	ClinicalTrials.gov Modernization Effort Update	Anna M. Fine
	Modernized PRS	Nachiket Dharker
	Navigating the Modernized PRS	Stacey Arnold
1:45–2 p.m.	Moderated Q&A	Anna M. Fine Stacey Arnold Nachiket Dharker

| Two Aims of ClinicalTrials.gov



ClinicalTrials.gov
PRS Protocol Registration
& Results System

- 1 Collect and disseminate** complete, accurate, and timely information about clinical studies that is submitted by study sponsors and principal investigators.



ClinicalTrials.gov

- 2 Facilitate information use** to help patients, clinicians, and researchers find studies of interest for participation or research.

ClinicalTrials.gov Modernization Vision and Goals

VISION

To ensure that **ClinicalTrials.gov** continues to be a trusted and premier public health resource that provides maximum value to the public and serves its mission well into the future

STRATEGIC GOALS



Improve the user experience.



Upgrade the technical infrastructure and processes to enhance sustainability.



Support the existing legal, regulatory, and policy framework.

Modernization Milestones



YEAR 1 (FY 2020)

Initial Engagement Activities

- Engaged stakeholders through a request for information, a public meeting, and webinars



YEARS 2–3 (FY 2021–22)

Development and Implementation

- Launched ClinicalTrials.gov Beta
- Launched PRS Beta



YEAR 4 (FY 2023)

Releases and Refinements

- Launched the modernized ClinicalTrials.gov website

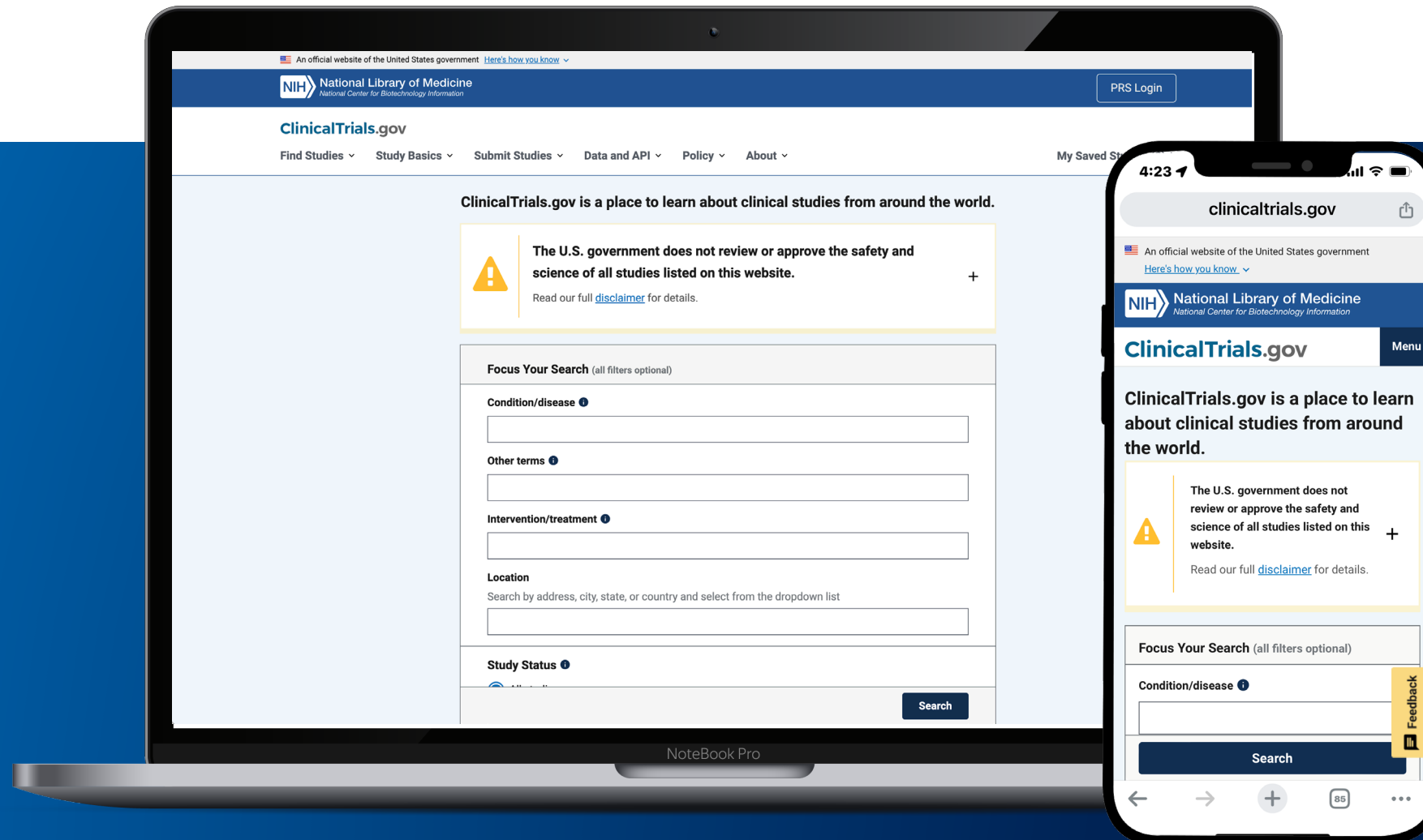


YEARS 5–6 (FY 2024–25)

Launches and Landings

- Retired the classic ClinicalTrials.gov website on June 25, 2024
- **Launched the modernized PRS on August 28, 2024**

Modernized ClinicalTrials.gov

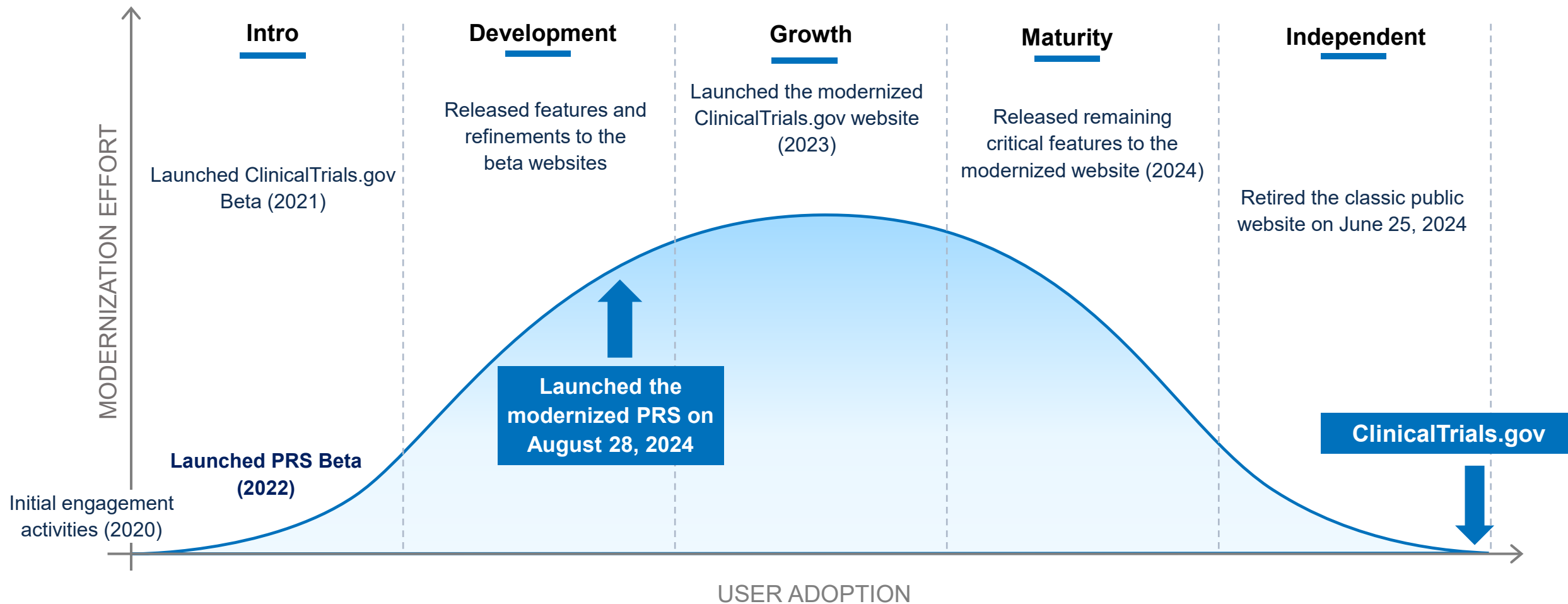


Modernized ClinicalTrials.gov Features

	Search Experience	Study Record Experience	Easy-to-Find and Easy-to-Use Content
AVAILABLE	- Enhanced search - Integrated search and search results - Data download (JSON, CSV, RIS) - Card view of search results - Modifiable table view of search results - Print view of search results - Ability to save studies of interest - Ability to save search/get search updates (RSS) - Application programming interface (API)	- Compiled study record data - On-page navigation - Print view of study registration - Study details view of study record - Researcher view of study record - Fast Healthcare Interoperability Resources (FHIR) API pilot - Integrated record history	- API documentation - Data about ClinicalTrials.gov - Support materials for searching - Streamlined information architecture - Compiled policy and regulatory content - About ClinicalTrials.gov page - Learn About Studies page - Access Data in FHIR page
FUTURE	- Rewritten ingest - Expert search capabilities - Ability to browse studies on a map - Ability to browse studies by topic	- Record history—view changes only - Next steps for patients	

Updated 9.30.24

Modernization Lifecycle





Nachiket Dharker

PRS Product Owner

Modernized PRS

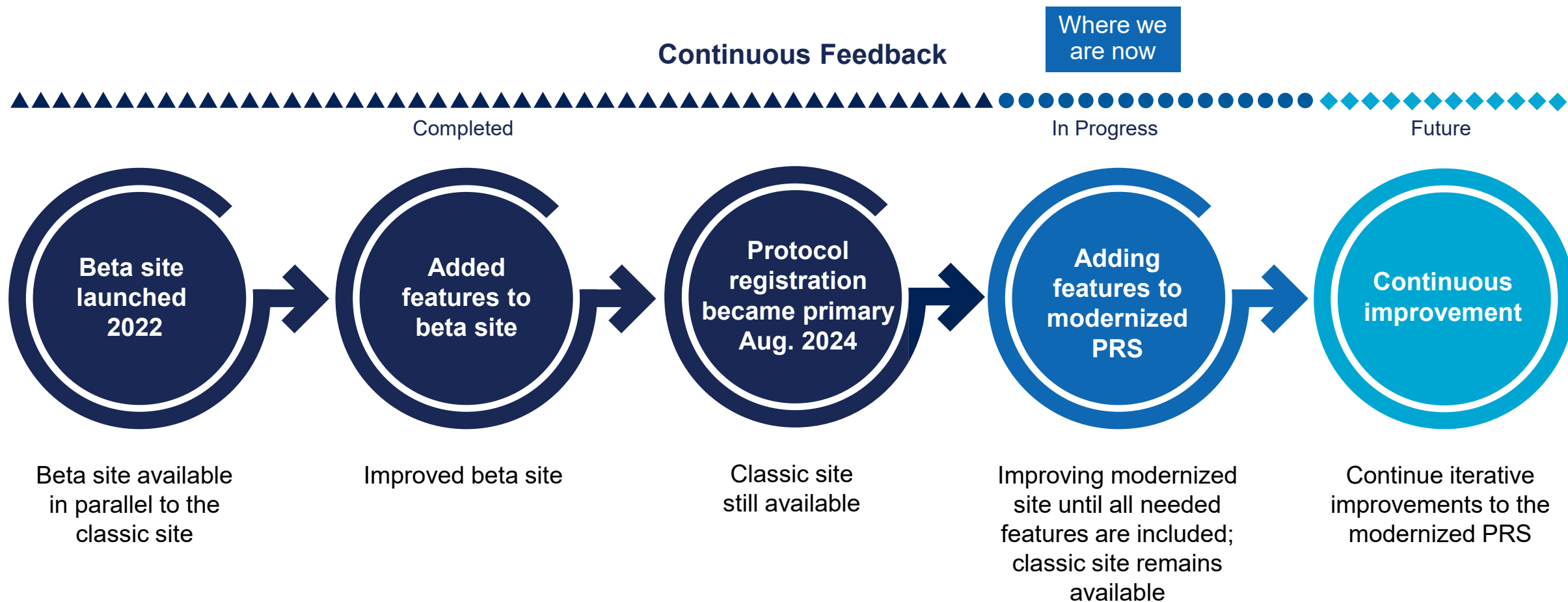
Poll Question #1

Have you used the modernized PRS to update or manage your records or submit a study since August 28, 2024?

- A. Yes
- B. No



How Users See PRS Changes



Updated 9.30.24

PRS Beta: 2022



PRS Beta Home Page

Record List

10 per page Viewing 1 - 10 | 36 records Clear Filters Customize Columns Search All Columns

View Record	Unique Protocol ID	Tags	NCT Number	Secondary IDs	Brief Title	Record Status	Last Update	Record Owner	Responsible Party	Problems
Open	TTTCrossover				Crossover Study Design Example	In Progress	2022-03-14 14:03	Stacey Arnold	[Sponsor]	- Entry Not Completed - Never Release
Open	TTTParallel	PR			Parallel Study Design Example	Released	2022-03-10 14:03	Stacey Arnold	[Sponsor]	
Open	TTTUnitsOtherThanPar	R			Units Other Than Participants Study Design Example (With Results)	In Progress	2021-11-09 15:11	Stacey Arnold	[Sponsor]	- Entry Not Completed - Never Release
Open	TTTClusterRandomized	R			Cluster Randomized Study Design Example (With Results)	In Progress	2021-11-09 15:11	Stacey Arnold	[Sponsor]	- Entry Not Completed - Never Release
Open	Test for User				Test Access List for Record Owner	In Progress	2021-07-22 09:07	Stacey Arnold	[Sponsor]	- Entry Not Completed - Never Release

36 total

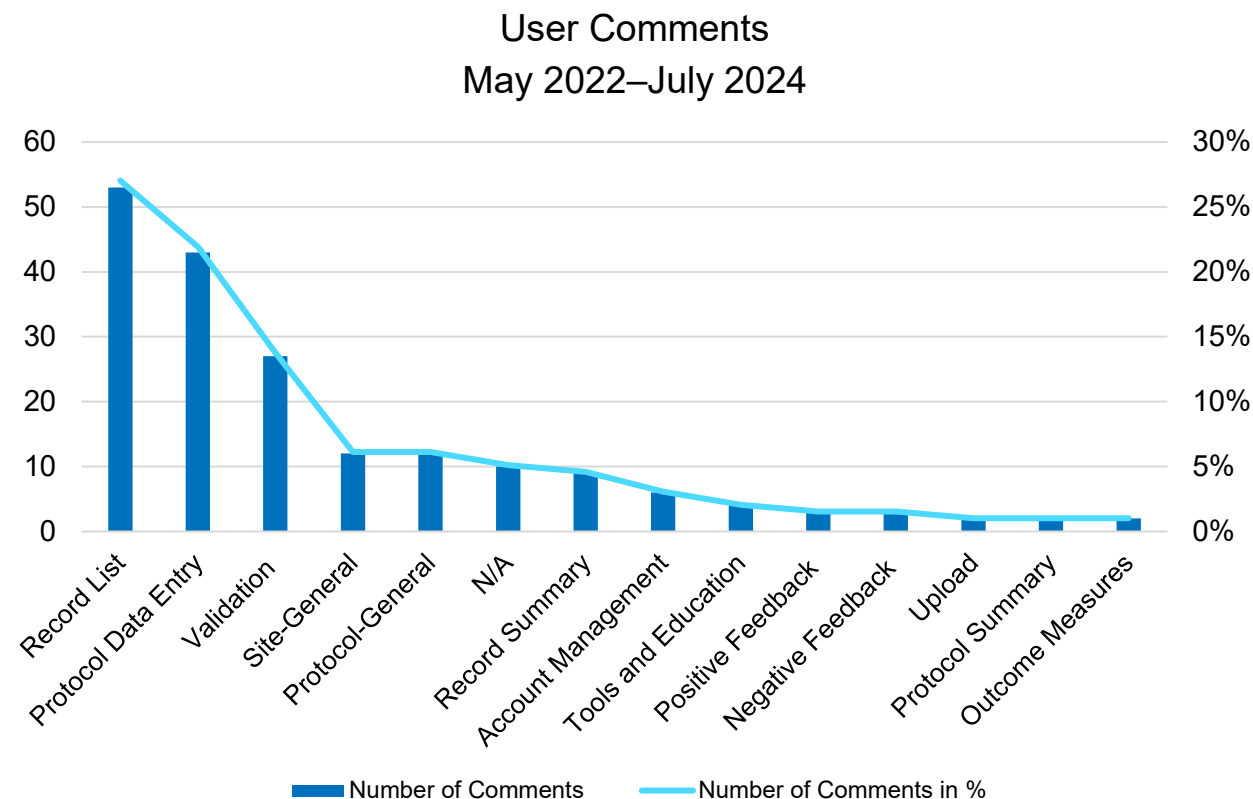
Tag Key: R Results CR Delayed Results PR PRS Review NP No Longer Public S Study Documents XML PRS Review Comments

About PRS Beta

Give Feedback

Summary of Cumulative User Comments

- 27% of the comments were about the Record List.
- 22% of the comments were about the protocol data-entry modules.
- 14% of the comments were on the system validation rules.
- 6% of the comments were related to issues with site performance and bugs.
- 6% of the comments were about the protocol, in general.
- 5% of the comments were about the record summary information.
- 3% of the comments were related to the creation or maintenance of accounts.
- 2% of the comments were about training and instructional material.
- 4% of the comments were positive and negative feedback.
- 6% of the comments were classified as “Other” and were related to uploading data and documents, the protocol summary, and outcome measures.
- 5% of the comments tagged as “N/A” were non-contextual feedback.



Note: Each comment submitted by a user could have multiple labels (outcomes) assigned to it. Therefore, some comments are double counted. For this period, we had 189 comments and 197 outcomes.

(PRS Beta responses submitted via the **Feedback** button before becoming primary)

Protocol Data Entry: User Requests for Improved Navigation



“It would be beneficial to have all information in one place or put it under easily accessible tabs as opposed to having to go back to a previous screen.”



“When inputting information. . . there is a fair amount of toggling between screens. . . It would be beneficial to have all information in one place.”

“The UI is difficult to navigate. It is not easy to shift through the different pages of the application.”



“Improved navigation and user-friendly features are needed to facilitate registration and results reporting.”



“It may be easier to navigate if each section was tabulated, so a user could click back and forth between sections with one click versus multiple clicks.”



Protocol Data Entry: Navigation in the Classic PRS (1)

Protocol Section	
Record Summary Preview Edit All Help Definitions	
Edit	Study Identification Unique Protocol ID: ParallelStudy_ForDemoND Brief Title: A 24-Week Placebo-Controlled Trial of Remuverol in Adults With Condition A Official Title: Example Parallel Study_A 24-Week Placebo-Controlled Trial of Remuverol in Adults With Condition A Secondary IDs:
Edit	Study Status Record Verification: September 2017 Overall Status: Completed Study Start: February 1, 2010 [Actual] Primary Completion: August 1, 2011 [Actual] Study Completion: August 1, 2011 [Actual]
Edit	Sponsor/Collaborators Sponsor: National Library of Medicine (NLM)  WARNING: Sponsor should be Protocol Registration System Quality Assurance. Include other organizations register@clinicaltrials.gov. Responsible Party: Sponsor Collaborators:

Protocol Data Entry: Navigation in the Classic PRS (2)

Protocol Section

[Record Summary](#) [Preview](#) [Edit All](#) [Help](#) [Definitions](#)

[Edit](#) **Study Identification**

Unique Protocol ID: [Help](#) [Definitions](#)

* Organization's Unique Protocol ID:

* Brief Title:

[*] Acronym: (if any)

If specified, will be included at end of Brief Title in parentheses.

* § Official Title:

[*] Secondary IDs: (if any)

[Edit](#) **Study Status**

Record Verification:

Overall Status:

Study Completion:

Primary Completion:

Study Completion:

[Edit](#) **Sponsor/Collaborator**

Sponsor:

Responsible Party:

Collaborators:

Save **Cancel**

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Protocol Data Entry: Navigation in the Classic PRS (3)

Protocol Section	
Record Summary Preview Edit All Help Definitions	
Edit	Study Identification Unique Protocol ID: ParallelStudy_ForDemoND Brief Title: A 24-Week Placebo-Controlled Trial of Remuverol in Adults With Condition A Official Title: Example Parallel Study_A 24-Week Placebo-Controlled Trial of Remuverol in Adults With Condition A Secondary IDs:
Edit	Study Status Record Verification: September 2017 Overall Status: Completed Study Start: February 1, 2010 [Actual] Primary Completion: August 1, 2011 [Actual] Study Completion: August 1, 2011 [Actual]
Edit	Sponsor/Collaborators Sponsor: National Library of Medicine (NLM)  WARNING: Sponsor should be Protocol Registration System Quality Assurance. Include other organizations register@clinicaltrials.gov. Responsible Party: Sponsor Collaborators:

Protocol Data Entry: Navigation in the Classic PRS (4)

Record Summary

Preview

Edit All

Edit

Study Identification

Unique Protocol ID: Parallel

Brief Title: A 24-W

Official Title: Examp

Secondary IDs:

Edit

Study Status

Record Verification: Septem

Overall Status: Comple

Study Start: Februa

Primary Completion: August

Study Completion: August

Edit

Sponsor/Collaborators

Sponsor: National

⚠️ WARN

register

Responsible Party: Sponsor

Collaborators:

Protocol Section

Edit Study Status

Help

Definitions

* Record Verification Date:

Month: Year:

* Overall Recruitment Status:

Before selecting Suspended, Terminated or Withdrawn see the [Overall Recruitment Status definition](#).

Tip: Day is not required for Anticipated dates.

* § Study Start Date:

Month: Day: Year: Type:

Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).

* Primary Completion Date:

Month: Day: Year: Type:

Final data collection date for primary outcome measure.

* § Study Completion Date:

Month: Day: Year: Type:

Final data collection date for study.

Save

Cancel

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Further User Research to Finalize Protocol Data-Entry Navigation

Question about the order of protocol modules:

Here is a list of the 13 parts of the Protocol Section on the PRS, in random order. Drag and drop the below items in the order that would best suit your workflow.



“This is more or less the order already—it follows the flow of information as we assess each record on a regular basis.”



“It would be helpful to have contacts/locations towards the top since they are likely to change through the study. Fields that are rarely updated (e.g. Conditions, Oversight) could be further down.”

Question about the grouping of the protocol modules:

Are there any of the 13 parts of the Protocol Section that you would like to see grouped together, as opposed to having their own section?



“One reason for grouping sections together would be so there is less clicking back and forth.”



“Separation promotes readability. I like everything separated. Provides me with a quick read this way.”

Protocol Data Entry: Navigation in the Modernized PRS (1)

Edit Mode
Disabled



Protocol Summary

Study Identification

Study Status

Sponsors and Collaborators

Oversight

Study Description

Conditions

Study Design

Arms and Interventions

Outcome Measures

Eligibility

Contacts and Locations

IPD Sharing Statement

References

Protocol Summary

Study Identification

Organization's Unique Protocol ID

Test_Parallel_1

Brief Title

Parallel Study Design Example_1

Acronym

ABC

Study Type

Interventional

Official Title

Parallel Study Design Example_1

Secondary IDs

 Edit Study Identification

Protocol Data Entry: Navigation in the Modernized PRS (2)

Edit Mode
Disabled

Protocol Summary

Study Identification

Study Status

Sponsors and Collaborators

Oversight

Study Description

Conditions

Study Design

Arms and Interventions

Outcome Measures

Eligibility

Contacts and Locations

IPD Sharing Statement

References

Study Identification

Use this module to enter information that uniquely identifies this study.

* Required
* **S** Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Organization's Unique Protocol ID * **i**

Test_Parallel_1

15 characters left

Brief Title * **i**

Write a short, easy-to-understand version of the official study title using title case.

Parallel Study Design Example_1

269 characters left

Acronym [*] **i**

Required if one exists. It will be included in parentheses at the end of the Brief Title.

ABC

11 characters left

Protocol Data Entry: Navigation in the Modernized PRS (3)

Edit Mode
Disabled

Protocol Summary

Study Identification

Study Status

Sponsors and Collaborators

Oversight

Study Description

Conditions

Study Design

Groups and Interventions

Outcome Measures

Eligibility

Contacts and Locations

IPD Sharing Statement

References

Study Status

Use this module to enter the start and completion dates for the study, as well as the study's recruitment status.

* Required
* **S** Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Record Verification Date * **i**

Month *
Dec

Year *
2023

Overall Recruitment Status * **i**

If you select "Suspended," "Terminated," or "Withdrawn," an explanation of why the study was stopped is required.

Not yet recruiting

Addressing User Feedback: Record Access (1)

Classic PRS

Record Access List

Select one or more users from the list below to allow those users to access this record. A user granted access to a record in this manner can perform all of the same actions on the record as if he were the record owner, with the exception of modifying the Record Access List.

Record Owner: AdminStacey

Current Access List:

Allow access to:

- ☐ Chris Souhrada (csouhradaUser)
- ☐ Investigator Peter (PIPeter)
- ☐ Investigator Venka (PIVenka)

Save **Cancel**

Feedback before Modernization Began

- Allow users to type in a name or username instead of having to look through a long list of users
- Allow users to sort or filter the record access list

Addressing User Feedback: Record Access (2)

Modernized PRS—1st Iteration

Close X

Record Access

By default, a record is only accessible to the Record Owner and the Administrators for an organization. To give access to additional users, select one or more from the User List below.

☒ Email all users with access

No Access (106) **Access List (1)**

☐	Username	Name	Contact
	Search Column...	Search Column...	
☒	adevereuxt2	Austin Devereux T2	☒ Email
☐	adevereuxt3	Austin Devereux T3	☒ Email
☐	adevereuxt4	austin devereux t4	☒ Email
☐	ADTEST1234	AustinTestAcct2	☒ Email
☐	AFine	Anna Fine	☒ Email
☐	ambergeris	annice bergeris	☒ Email
☐	AustinSuperPRSDev	Austin Devereux	☒ Email
☐	benprstestsuper	benprstestsuper	☒ Email

Feedback after the 1st Iteration

- It would greatly alleviate the administrative burden for a PRS Administrator to have an option to autogenerate an email to not just the Record Owner, but to some or all users in the Access List.
- The access list for a study does not clearly identify who currently has access to the study.
- Only five users show at a time under the record access drop-down.

Addressing User Feedback: Record Access (3)

Modernized PRS—Current Version

Record Access

By default, a record is only accessible to the Record Owner and the Administrators for an organization. To give access to additional users, select one or more from the User List below.

Email all users with access

No Access (106)

Access List (1)

☐	Username	Name	Contact
	Search Column...	Search Column...	
☒	adevereuxt2	Austin Devereux T2	Email
☐	adevereuxt3	Austin Devereux T3	Email
☐	adevereuxt4	austin devereux t4	Email
☐	ADTEST1234	AustinTestAcct2	Email
☐	AFine	Anna Fine	Email
☐	ambergeris	annice bergeris	Email
☐	AustinSuperPRSTest	Austin Devereux	Email
☐	benprstestsuper	benprstestsuper	Email

Save

Cancel

No Access (106)

Access List (1)

☐	Username	Name	Contact
	Search Column...	Search Column...	
☒	adevereuxt2	Austin Devereux T2	Email
☐	adevereuxt3	Austin Devereux T3	Email
☐	adevereuxt4	austin devereux t4	Email

Modernized PRS Features

	Record and Account Management Experience	Data Submission and Review Experience	Technology Modernization
AVAILABLE	Intuitive Record List Search, filter, and sort functionality Customizable columns and views	Protocol registration submission Protocol registration QA/QC functionality Record summary and actions Easy navigation Improved error handling Just-in-time help	Migration to National Center for Biotechnology Information (NCBI) secure platform Helpful pop-up content
IN PROGRESS	Secure log-in Account creation and modification Management of groups and permissions Password management Notifications Dashboards	Fix issues in Protocol Registration Results data entry (Participant Flow, Baseline Characteristics, Outcome Measures, Adverse Events) Other results modules Study document upload Results validations Fix issues and address critical feedback in Results Adverse Events upload Results QA/QC functionality Delayed results XML upload	Optimized database design Move to cloud Improved system architecture Optimized database performance and data integrity

| Thank You for the Feedback

4 Weeks

 Feedback

200+

Comments



250+

Emails

ClinicalTrials.gov staff responded via email to 340+ and plans for releases and fixes.

These figures represent comments/emails received during the 4 weeks following the August 28, 2024, release.

Sample of Feedback

- Discrepancy between modernized PRS vs. classic PRS
- Study Identification—Unique Protocol ID already in use
- Individual Participant Data (IPD)—URL error
- Investigator Name—Account has been disabled
- Special characters conversion in free-text fields
- Arms and Interventions cross-reference issue
- Oversight—Status and false warnings
- Study dates-related errors
- Record List scrolling

Modernized PRS: Release

- The Unique Protocol ID will no longer trigger an error unless it is duplicated in an active record within the user's organization.
- Deleting or renaming an arm or group in the modernized PRS will no longer create cross-referencing errors in the classic PRS.
- Work continues to make errors shown for study dates consistent with how these errors are handled in the classic system.
- No error will be generated when the URL field for an IPD Sharing Statement has not been filled in.
- Active user accounts will no longer produce an error in the Responsible Party field indicating that the account has been disabled.
- Users can more easily be added to the Record Access List using several different methods.
- Fields with special characters (‘, &, ") are displayed correctly.

The screenshot shows the 'Release Notes' page for the ClinicalTrials.gov PRS (Protocol Registration & Results System). The page is dated 'October 02, 2024'. It contains a summary of updates and improvements. The 'Improvements' section lists changes to the Record Summary and Protocol Section. The 'Completed or Coming Soon' section lists new links, videos, and bug fixes. The bug fixes include: Unique Protocol ID duplication, deleting/renaming arms/groups, study date consistency, URL field errors, disabled accounts, Record Access List additions, and Record List group names.

ClinicalTrials.gov
PRS Protocol Registration & Results System

Record List About ▾

[Back](#)

Release Notes

October 02, 2024

With this release to the Modernized PRS, several important bug fixes were made in response to user feedback and improvements were made to the record access list. In addition, two new demonstration videos were posted on [Fast Forward from ClinicalTrials.gov](#) that show how to use some of the features in the Modernized PRS. These videos can be accessed through the About menu in the Modernized PRS.

Improvements

- Record Summary:
 - Enhancements to and remodeling of the record access list.
 - Redesigned the search feature so users can search by name or username.
 - Column headers have been relabeled as "No Access" and "Access List" to clearly indicate which users have access to the record. Each user appears in a single column and can be moved to the other column as needed.
- Protocol Section:
 - Outcome measures in the Outcome Measures module are now numbered.

Completed or Coming Soon

- Links Accessible from About Menu:
 - Additional Fast Forward videos
- Bug Fixes to the Protocol Section and Record List:
 - The Unique Protocol ID will no longer trigger an error unless it is duplicated in an active record within the user's organization.
 - Deleting or renaming an arm or group in the Modernized PRS will no longer create cross-referencing errors in the Classic PRS.
 - Continuing work on making errors shown for study dates consistent with how these errors are handled in the classic system.
 - No error will be generated when the URL field for an IPD Sharing Statement has not been filled in.
 - Active user accounts will no longer produce an error in the Responsible Party field indicating that the account has been disabled.
 - Users can be more easily added to the Record Access List using several different methods.
 - On the Record List, the group column now displays the user's group name in the correct format.

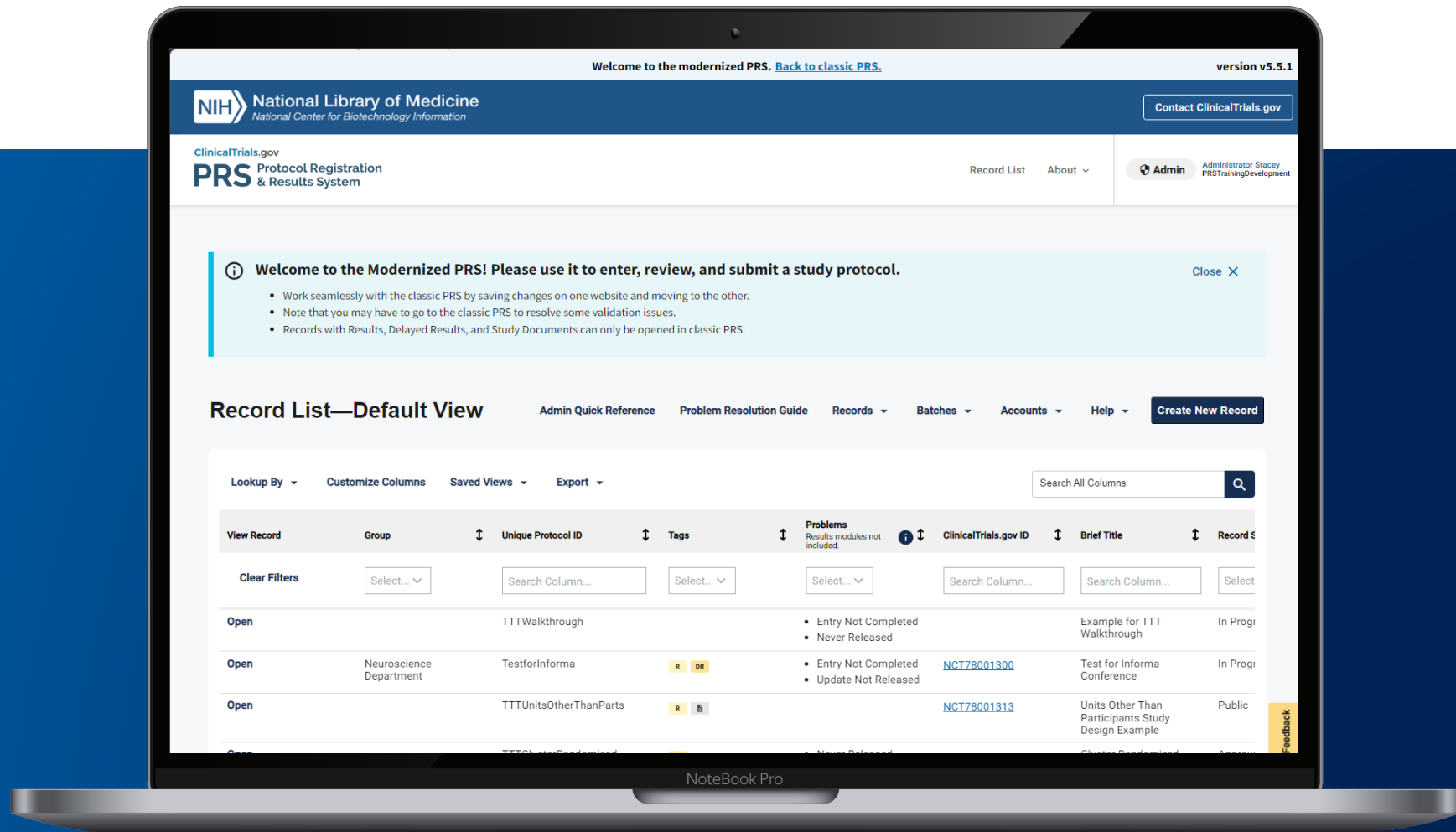
register.clinicaltrials.gov/prs/beta/public/release-notes-prod



Stacey Arnold
PRS Subject Matter Expert

Navigating the Modernized PRS

Landing Page: Record List



Record List: Customizing Columns

New Features of the Modernized PRS

- Ability to reorder columns

Record List—Default View Admin Quick Reference Problem Resolution Guide Records ▾ Batches ▾ Accounts ▾ Help ▾ [Create New Record](#)

Lookup By ▾ **Customize Columns** Saved Views ▾ Export ▾

View Record	Group	Unique Protocol ID	Tags	Problems Results modules not included.	ClinicalTrials.gov ID	Brief Title	Record S
Clear Filters	Select... ▾	Search Column...	Select... ▾	Select... ▾	Search Column...	Search Column...	Select
Open		TTTWalkthrough		- Entry Not Completed - Never Released		Example for TTT Walkthrough	In Progi
Open	Neuroscience Department	Testforinforma	R DR	- Entry Not Completed - Update Not Released	NCT78001300	Test for Informa Conference	In Progi
Open		TTTUnitsOtherThanParts	R B		NCT78001313	Units Other Than Participants Study Design Example	Public
Open		TTTClusterRandomized	DR	Never Released		Cluster Randomized Study Design Example	Approvi
Open		Record Progress Message Test 2	DR		NCT78001001	Smoke Test Record for Checking Expected Results Dates	Public
Open		Multiple_Period_SA_OnlineTTT	R		NCT78001287	Multiple Period Study Design Example (with Results)	Public
Open	Neuroscience Department	Record Progress Message Test	R B		NCT78000754	Taking a Record Through Record Progress Steps	Public
Open		Test_Demo_Parallel	DR	Update Not Released	NCT78001014	Test_Demo_Parallel (Remuverol Disc Herniation Study)	Approvi
Open	Neuroscience Department	TTTDose_EscalationR	R	- Entry Not Completed - Never Released		Dose Escalation Study Design Example (with Results)	In Progi
Open		TTTClusterRandomizedR	R	- Entry Not Completed - Never Released		Cluster Randomized Study Design Example (With Results)	In Progi

10 per page ▾ Viewing 1 - 10 | 46 records 1 2 3 4 5 Next >

Feedback

Record List: Customizing Columns (cont.)

Customize Column Display

Select or deselect columns to view in the record list table. Click and drag the labels or use the arrows to reorder the columns in the table.

☐ Select All Selected Columns: (10)

☒ 01 Group <i>i</i> ↓	☐ 23 Last Public Release <i>i</i> ↑ ↓
☐ 02 Unique Protocol ID <i>i</i> ↑ ↓	☐ 24 Last Modifier <i>i</i> ↑ ↓
☒ 03 Tags <i>i</i> ↑ ↓	☐ 25 Record Verification Date <i>i</i> ↑ ↓
☐ 04 Problems <i>i</i> ↑ ↓	☐ 26 Study Start Date <i>i</i> ↑ ↓
☐ 05 ClinicalTrials.gov ID <i>i</i> ↑ ↓	☐ 27 Intervention Types <i>i</i> ↑ ↓
☐ 06 Secondary ID <i>i</i> ↑ ↓	☐ 28 IND/IDE <i>i</i> ↑ ↓
☒ 07 Brief Title <i>i</i> ↑ ↓	☐ 29 Locations in U.S.? <i>i</i> ↑ ↓
☐ 08 FDAAA <i>i</i> ↑ ↓	☐ 30 Primary Completion Date <i>i</i> ↑ ↓
☐ 09 Overall Recruitment Status <i>i</i> ↑ ↓	☐ 31 Study Completion Date <i>i</i> ↑ ↓
☐ 10 Update Expected <i>i</i> ↑ ↓	☒ 32 Record Status <i>i</i> ↑ ↓

[Cancel](#) [Save](#)

Drag and drop with mouse

Move with up/down arrows

Click for information

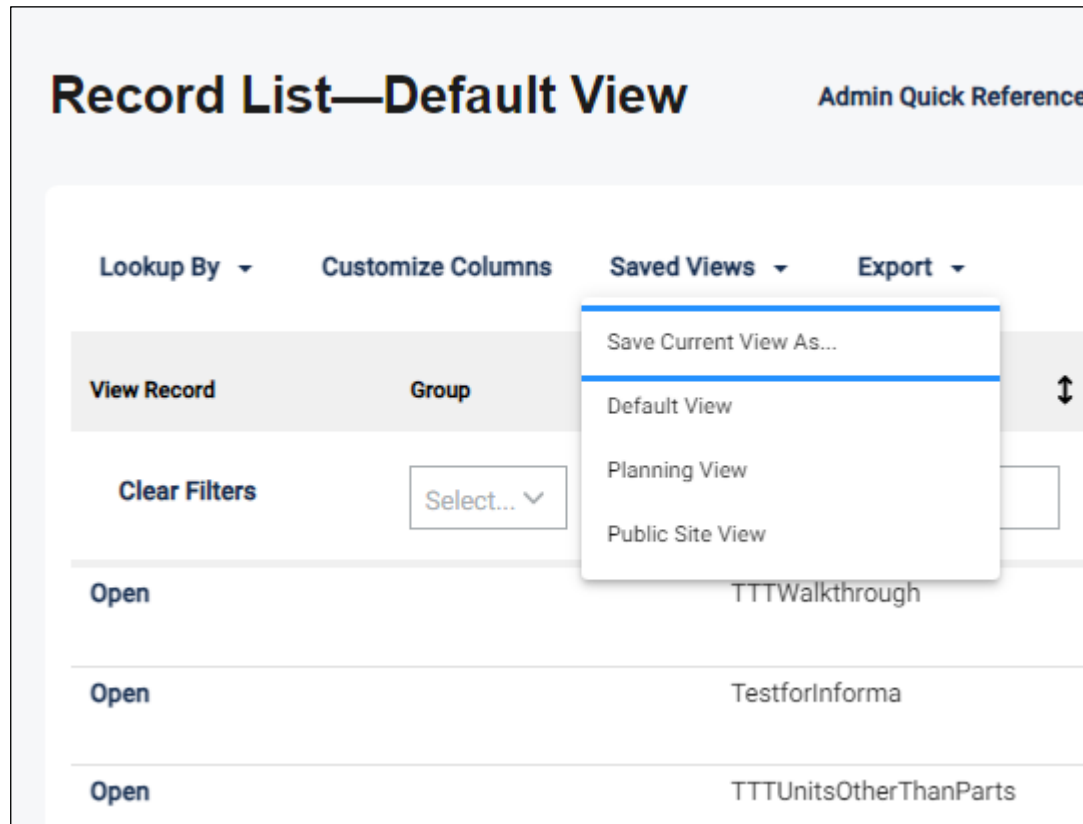
Deselect columns

Select columns

New Features of the Modernized PRS

- Ability to reorder columns

Record List: Saving Views



New Features of the Modernized PRS

- Ability to reorder columns
- Ability to save views and access all views from a single location

Record List: Filtering Columns

Record List—Default View Admin Quick Reference

Lookup By ▾ Customize Columns Saved Views ▾ Export ▾

View Record	Group	↕	Unique Protocol ID	↕	Tags	↕	Problems Results modules not included.	i ↕	ClinicalTrials.gov ID	↕
-------------	-------	---	--------------------	---	------	---	---	-----	-----------------------	---

Clear Filters

Select... ▾

Search Column...

Select... ▾

Select... ▾

Search Column...

New Features of the Modernized PRS

- Ability to reorder columns
- Ability to save views and access all views from a single location
- Ability to filter data in all columns

Record List: Sending Emails

Search All Columns 🔍					
Brief Title	↕	Record Owner	↕	Responsible Party	↕
Search Column...		Select... ▾		Select... ▾	
Example for TTT Walkthrough		Administrator Stacey AdminStacey Email Record Owner for TTTWalkthrough		AdminStacey	
Test for Informa Conference		Administrator Michael AdminMichael		Sponsor	
Units Other Than Participants Study Design Example		Administrator Stacey AdminStacey		Sponsor	

New Features of the Modernized PRS

- Ability to reorder columns
- Ability to save views and access all views from a single location
- Ability to filter data in all columns
- Ability to click on names to send emails without having to open a record

About the Modernized PRS

Welcome to the modernized PRS. [Back to classic PRS.](#)

version v5.5.1

 **National Library of Medicine**
National Center for Biotechnology Information

Contact ClinicalTrials.gov

ClinicalTrials.gov
PRS Protocol Registration
& Results System

Record List About ^

Admin Administrator Stacey
PRSTrainingDevelopment

 **Welcome to the Modernized PRS! Please use it to enter, review, and submit a study protocol.**

- Work seamlessly with the classic PRS by saving changes on one website and moving to the other.
- Note that you may have to go to the classic PRS to resolve some validation issues.
- Records with Results, Delayed Results, and Study Documents can only be opened in classic PRS.

About the Modernized PRS 

How to Videos: PRS Fast 

Release Notes (PRS TEST)

Close X

Record List—Default View

Admin Quick Reference Problem Resolution Guide Records ▾ Batches ▾ Accounts ▾ Help ▾ **Create New Record**

Lookup By ▾ Customize Columns Saved Views ▾ Export ▾

Search All Columns 

View Record	Group	↕	Unique Protocol ID	↕	Tags	↕	Problems Results modules not included.	 ↕	ClinicalTrials.gov ID	↕	Brief Title	↕	Record S
Clear Filters	Select... ▾		Search Column...		Select... ▾		Select... ▾		Search Column...		Search Column...		Select
Open			TTTWalkthrough				• Entry Not Completed • Never Released				Example for TTT Walkthrough		In Progi

About the Modernized PRS (cont.)

Welcome to the modernized PRS.

NIH National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov
PRS Protocol Registration
& Results System

Welcome to the Modernized PRS! Please use it to enter, review, and submit

- Work seamlessly with the classic PRS by saving changes on one website and moving to the other.
- Note that you may have to go to the classic PRS to resolve some validation issues.
- Records with Results, Delayed Results, and Study Documents can only be opened in classic PRS.

Record List—Default View Admin Quick Reference Problem Resolution

Lookup By ▾ Customize Columns Saved Views ▾ Export ▾

View Record	Group	↕	Unique Protocol ID	↕	Tags
Clear Filters	Select... ▾		Search Column...		Select... ▾
Open	TTTWalkthrough				

About the Modernized PRS

Menu

- [About PRS Modernization](#)
- [Working in the Modernized PRS](#)
- [Record List Views](#)
 - [Customizing the View — Selecting Records per Page and Navigating Pages](#)
 - [Customizing the View — Selecting and Ordering Columns](#)
 - [Customizing the View — Filtering](#)
 - [Saving Custom Views](#)
 - [Accessing the Planning View and Public Site View](#)
 - [Using Other Features on the Record List Page](#)
- Accessing User Account Information
- Adjusting Column Widths
- Contacting ClinicalTrials.gov
- Emailing PRS Users
- Exporting Records
- Help Links and Other Menus
- Returning to the Classic PRS Home Page
- Sorting Columns
- Understanding the Tag Column
- [Help: Using Links to Send Email Messages](#)

Fast Forward Videos

Welcome to the modernized PRS. [Back to classic PRS.](#)

version v5.5.1

 **National Library of Medicine**
National Center for Biotechnology Information

Contact ClinicalTrials.gov

ClinicalTrials.gov
PRS Protocol Registration
& Results System

Record List About ^

Admin Administrator Stacey
PRSTrainingDevelopment

 **Welcome to the Modernized PRS! Please use it to enter, review, and submit a study protocol.**

- Work seamlessly with the classic PRS by saving changes on one website and moving to the other.
- Note that you may have to go to the classic PRS to resolve some validation issues.
- Records with Results, Delayed Results, and Study Documents can only be opened in classic PRS.

About the Modernized PRS 

How to Videos: PRS Fast Forward

Release Notes (PRS TEST)

Close X

Record List—Default View

Admin Quick Reference Problem Resolution Guide Records ▾ Batches ▾ Accounts ▾ Help ▾ **Create New Record**

Lookup By ▾ Customize Columns Saved Views ▾ Export ▾

Search All Columns 

View Record	Group	↕ Unique Protocol ID	↕ Tags	↕ Problems Results modules not included. 	↕ ClinicalTrials.gov ID	↕ Brief Title	↕ Record S
Clear Filters	Select... ▾	Search Column...	Select... ▾	Select... ▾	Search Column...	Search Column...	Select
Open		TTTWalkthrough		• Entry Not Completed • Never Released		Example for TTT Walkthrough	In Progr

Fast Forward Videos (cont.)

Welcome

NIH National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov
PRS Protocol Registration & Results System

Welcome to the Modernized PRS! Please use it to enter

- Work seamlessly with the classic PRS by saving changes on one website and
- Note that you may have to go to the classic PRS to resolve some validation
- Records with Results, Delayed Results, and Study Documents can only be

Record List—Default View Admin Quick Reference

Lookup By ▾ Customize Columns Saved Views ▾ Export ▾

View Record Group ↕ Unique Protocol ID

Clear Filters Select... ▾ Search Column...

Open TTTWalkthrough

ClinicalTrials.gov Demonstration Videos

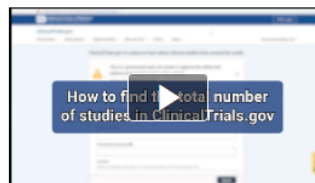
In 2019, NLM began a multi-year effort to modernize the ClinicalTrials.gov public website and the related clinical trial information submission and management portal, the Protocol Registration and Results System (PRS). One of the strategic goals of this effort is to improve the user experience.

Fast Forward from ClinicalTrials.gov is a series of short videos provided to educate users on the modernized websites. They address common questions directly from users on how to accomplish tasks on the modernized public website and PRS. Your feedback is welcome as we develop more videos.

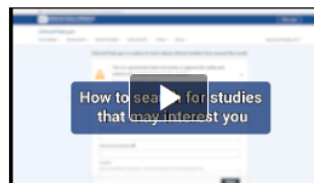
Videos on ClinicalTrials.gov

These brief videos show users how to perform common tasks on the ClinicalTrials.gov website.

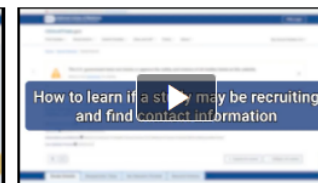
How to Find the Total Number of Studies in ClinicalTrials.gov (00:49)



How to Search for Studies That May Interest You (02:47)



How to Learn if a Study May Be Recruiting and Find Contact Information (02:33)

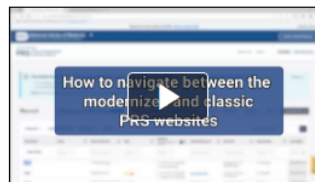


Keyboard controls: Space bar - toggle play/pause; Right and Left Arrow - seek the video forward and back; Up and Down Arrow - increase and decrease the volume; M key - toggle mute/unmute; F key - toggle fullscreen off and on.

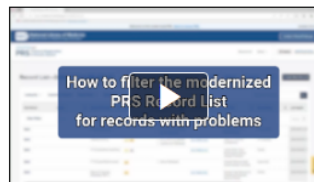
Videos on the PRS

These brief videos show users how to perform common tasks on the PRS.

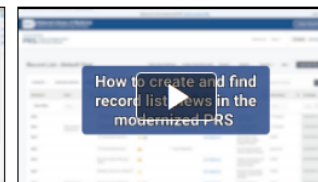
How to Navigate Between the Modernized and Classic PRS Websites (02:47)



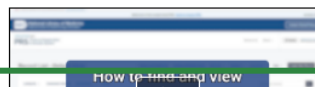
How to Filter the Modernized PRS Record List for Records with Problems (02:03)



How to Create and Find Record List Views in the Modernized PRS (03:21)



How to Find and View ClinicalTrials.gov Quality Control Review Comments in the Modernized PRS (02:05)



| Fast Forward from ClinicalTrials.gov

Series of videos that include tips for using the modernized PRS:

- How to Navigate Between the Modernized and Classic PRS Websites
- How to Filter the Modernized PRS Record List for Records with Problems
- How to Create and Find Record List Views in the Modernized PRS
- How to Find and View ClinicalTrials.gov Quality Control Review Comments in the Modernized PRS



[Demo Videos](#)

Action Expected and Records with Problems (1)

Record List
Planning View

Action Expected ▾ **All Records**

Look up By ▾ Customize Columns Saved Views ▾ Export ▾

View Record **Group**

Clear Filters

Open	TestforInforma
Open	TTTUnitsOtherThanParts
Open	Record Progress Message Test 2

Record List
Planning View

Action Expected ▾ **All Records**

☒ All Actions
☒ Update Expected
☒ Corrections Expected
☒ Results Expected
☒ All Results Expected

Saved Views ▾ Export ▾

Unique Protocol ID

Open	TestforInforma
Open	TTTUnitsOtherThanParts
Open	Record Progress Message Test 2

Action Expected and Records with Problems (2)

Record List—Default View

Adm

Lookup By

Customize Columns

Saved Views

Export

View Record

Group

Unique Protocol ID

Tags

Problems
Results modules not included.

Clear Filters

Select...

Search Column...

Select...

Select...

Open		TTTWalkthrough		- Entry Not Completed - Never Released
Open	Neuroscience Department	TestforInforma	R DR	- Entry Not Completed - Update Not Released
Open		TTTUnitsOtherThanParts	R	
Open		TTTClusterRandomized	DR	Never Released
Open		Record Progress Message Test 2	DR	
Open		Multiple_Period_SA_OnlineTTT	R	

Record List—Default View

Adm

Lookup By

Customize Columns

Saved Views

Export

View Record

Group

Unique Protocol ID

Tags

Problems
Results modules not included.

Clear Filters

Select...

Search Column...

Problems

☐ Records with Any Problems

☐ Records with No Problems

☐ Pending PRS Review Comments

☐ Entry Not Completed

☐ Not Recently Updated

☐ Record Has Errors

☐ Missing FDAAA Information

Apply

Reset

Open		TTTWalkthrough		
Open	Neuroscience Department	TestforInforma		
Open		TTTUnitsOtherThanParts		
Open		TTTClusterRandomized		
Open		Record Progress Message Test 2		
Open		Multiple_Period_SA_OnlineTTT	R	

Problems

☒ Records with Any Problems

☐ Records with No Problems

☒ Pending PRS Review Comments

☒ Entry Not Completed

☒ Not Recently Updated

☒ Record Has Errors

☒ Missing FDAAA Information

Apply

Reset

Help Drawer

The image shows a screenshot of the ClinicalTrials.gov PRS (Protocol Registration & Results System) 'Create New Record' page. A 'Help Drawer' is open on the right side of the page. The drawer contains two sections: 'Additional Information' and 'Data Element Definition'. The 'Additional Information' section explains the Unique Protocol ID and lists two bullet points: 'Can be the study's ethics committee approval number, grant number, institutional review board number, or any similar unique identifier' and 'Can be used for only one record in the organization's PRS account'. The 'Data Element Definition' section defines the 'Unique Protocol Identification Number' as 'Any unique identifier assigned to the protocol by the sponsor', with a limit of 30 characters and a link to the DED. The main page shows a 'Review these tips before creating a record.' section with three numbered tips. A hand icon points to the 'Organization's Unique Protocol ID' field, which has a character count of '30 characters allowed'.

Welcome to the modernized PRS. [Back to classic](#)

NIH National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov
PRS Protocol Registration & Results System

Create New Record

Review these tips before creating a record. [Cancel record](#)

1. Use the PRS account of the study sponsor.
 - a. Verify that the study sponsor (the initiator of the trial) has a PRS account and that you are using the correct account.
 - b. For help, see:
[How to Apply for a PRS Account](#)
2. Only the [responsible party](#) can register the study.
 - a. You can create the record even if you are not the responsible party, but only the responsible party will be notified when the necessary information has been entered.
 - b. For help, see:
[How do I determine who is the responsible party for a study?](#)
3. The study should be registered only once.
 - a. A study with multiple collaborators or sites should only be registered by the study's responsible party.
 - b. All study sites should be listed in a single study record.

* Required
* **S** Required if Study Start Date is on or after January 18, 2017
* **C** Conditionally required

Organization's Unique Protocol ID *

30 characters allowed

Organization's Unique Protocol ID *

Enter the unique string of characters used by the sponsor to identify this study record.

Additional Information

The Unique Protocol ID:

- Can be the study's ethics committee approval number, grant number, institutional review board number, or any similar unique identifier
- Can be used for only one record in the organization's PRS account

Data Element Definition

Unique Protocol Identification Number *

Definition: Any unique identifier assigned to the protocol by the sponsor.

Limit: 30 characters.

[Link to DED](#)

Feedback

New Help Drawer

- Includes the following for each data element:
 - Brief guidance
 - Additional information
 - Data element definition
- Pop-out feature is easy to see while entering data anywhere on the page.
- Drawer is consistent with the modernized ClinicalTrials.gov glossary design.

Side Panel Navigation

The screenshot displays the ClinicalTrials.gov Protocol Registration & Results System (PRS) interface. At the top, a blue header bar contains the NIH logo, the text "National Library of Medicine National Center for Biotechnology Information", and a "Contact ClinicalTrials.gov" button. Below this, a navigation bar includes "Record List", "About", and an "Admin" button with a dropdown menu. The main content area is divided into four tabs: "Record Summary", "Protocol" (which is highlighted with a blue border), "Study Documents", and "Results". On the left side of the "Protocol" tab, there is a side panel with a green border. This panel contains an "Edit Mode" toggle (currently disabled) and a list of modules: "Protocol Summary", "Study Identification", "Study Status", "Sponsors and Collaborators", "Oversight", "Study Description", "Conditions", "Study Design", "Arms and Interventions", "Outcome Measures", "Eligibility", "Contacts and Locations", "IPD Sharing Statement", and "References". The "Protocol Summary" module is selected, showing fields for "Study Identification", "Organization's Unique Protocol ID" (TTTWalkthrough), "Brief Title" (Example for TTT Walkthrough), "Acronym", "Study Type" (Interventional), "Official Title" (This is a Demo Example Record), and "Secondary IDs". A green box highlights the "Edit Study Identification" button within the "Study Identification" field. A "Feedback" button is visible in the bottom right corner of the interface.

Side Panel Navigation

- After record creation, users can access any module for data entry. Information does not need to be entered in order.
- Users can also access each module from within the protocol summary.
- The Edit Mode toggle allows users to view a record in read-only mode or make edits.

Record Summary: Validation and Review Dashboard

System Validation and Review Dashboard

Protocol Validation Review Comments

1 Error

There are 1 errors that need to be corrected before this record can be submitted for PRS Review.

1 Warning

There are 1 warnings that, if not corrected, may lead to issues during the PRS Review process.

0 Notes

This record has no notes at this time.

Section Overview

Protocol Section	Errors	Warnings	Notes
Study Identification >	0	0	0
Study Status >	0	0	0
Sponsors and Collaborators >	0	0	0
Oversight >	0	0	0
Study Description >	0	0	0
Conditions >	0	0	0
Study Design >	0	0	0
Arms and Interventions >	1	1	0
Outcome Measures >	0	0	0
Eligibility >	0	0	0
Contacts and Locations >	0	0	0
IPD Sharing Statement >	0	0	0
References >	0	0	0

Protocol Validation Tab

- Errors, warnings, and notes are tallied on the left.
- Modules with errors are flagged; clicking on the module name takes the user directly to the module.

Record Summary: Validation and Review Dashboard (cont.)

Protocol Validation **Review Comments**

3 Major Issues

Major issues must be fixed before the record can be published. Major issues may be about the study record as a whole or about specific modules of the protocol.

4 Advisory Comments

Advisory comments should be addressed to improve the clarity of the study record. Advisory comments may be about the study record as a whole or about specific modules of the protocol.

General Record Comments

These include any comments about the overall record.

Overall Record	Major	Advisory
General Comments >	0	0

Module-Specific Comments

These include comments about individual protocol modules.

Protocol Module	Major	Advisory
Study Identification >	0	0
Study Status >	0	0
Sponsors and Collaborators >	0	0
Oversight >	0	0
Study Description >	1	0
Conditions >	0	1
Study Design >	0	0
Arms and Interventions >	0	1
Outcome Measures >	2	2
Eligibility >	0	0
Contacts and Locations >	0	0
IPD Sharing Statement >	0	0
References >	0	0

Review Comments Tab

- Major issues and Advisory Comments are tallied on the left.
- Modules with Major Comments are flagged; clicking on the module name takes the user directly to the module.

Poll Question #2

Which of the topics below would you like to see in a Fast Forward demonstration video?

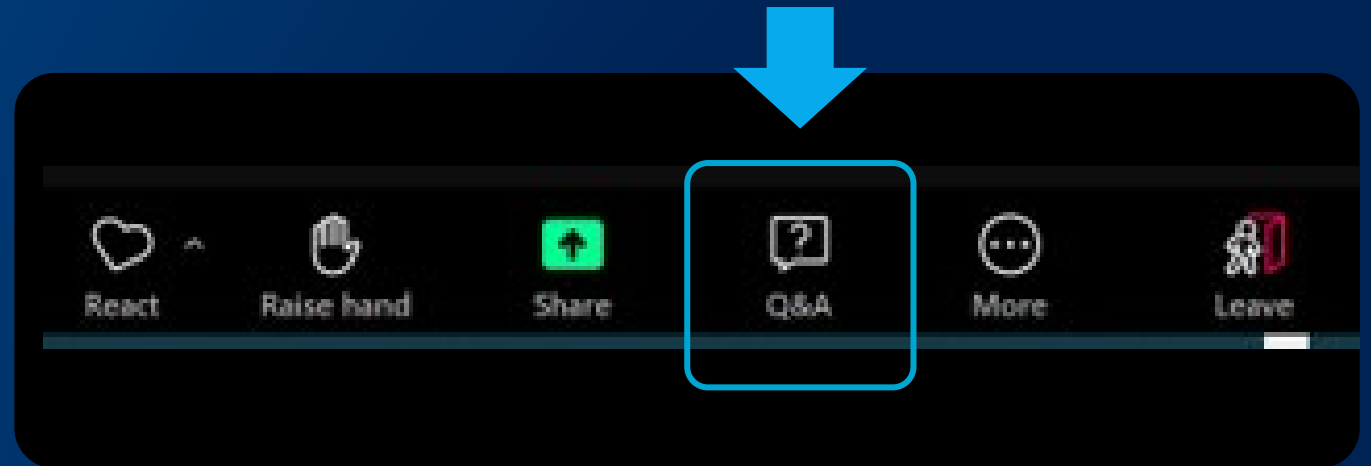
- A. How to add users to the access list for a record
- B. How to update the Protocol Section of an existing record
- C. How to find information on the Record Summary page
- D. Other



Moderated Q&A Instructions

We welcome your questions for our presenters.

To bring up the Q&A box, click on the Q&A icon on your Zoom menu bar.



| Key Takeaways

- The modernized PRS is now available for Protocol Registration to boost real world experience.
- Continuous feedback is encouraged and helps us prioritize the work.
- All features are still available in the classic PRS, and some tasks must be completed in classic.

Classic PRS Log-in

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](#) Protocol Registration and Results System (PRS).

OMB NO: 0925-0588
EXPIRATION DATE: 03/31/2026
[Burden Statement](#)

NOTICE
The Modernized PRS is now the primary website for Protocol Registration. After logging in, you will be directed to the new website. The [Classic PRS](#) remains available for users who need to access features that have not yet been migrated to the Modernized PRS.

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password: [Forgot password](#)

Login

See [How to Apply](#) on ClinicalTrials.gov for information on how to apply for a PRS account.

See [PRS Guided Tutorials](#) for assistance with entering registration and results information in the PRS.

[Send email to ClinicalTrials.gov PRS](#) Administration.

[U.S. National Library of Medicine](#) | [U.S. National Institutes of Health](#) | [U.S. Department of Health & Human Services](#) | [HHS Vulnerability Disclosure](#)

Classic PRS Log-in: Tip

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](#) Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 03/31/2026
[Burden Statement](#)

NOTICE
The Modernized PRS is now the primary website for Protocol Registration. After logging in, you will be directed to the new website. The [Classic PRS](#) remains available for users who need to access features that have not yet been migrated to the Modernized PRS.
Select the PRS version to open after logging in.
☒ Modernized PRS
☐ Classic PRS

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password: [Forgot password](#)

Login

See [How to Apply](#) on ClinicalTrials.gov for information on how to apply for a PRS account.
See [PRS Guided Tutorials](#) for assistance with entering registration and results information in the PRS.
[Send email to ClinicalTrials.gov PRS Administration](#).

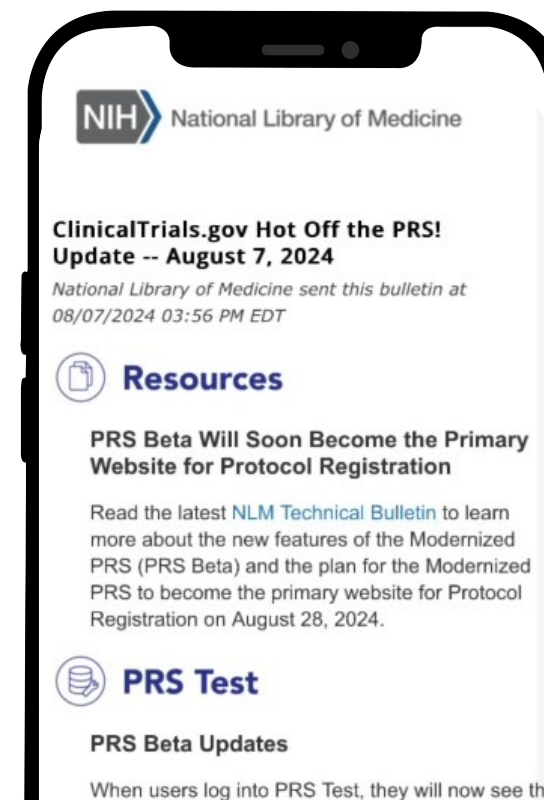
[U.S. National Library of Medicine](#) | [U.S. National Institutes of Health](#) | [U.S. Department of Health & Human Services](#) | [HHS Vulnerability Disclosure](#)

Communications

We will continue to keep you updated using a variety of methods:

- Website updates
 - News and Updates
 - Release notes
 - Banners
 - Top transition questions
 - Annual reports
- Hot Off the PRS! e-bulletins
- Conference presentations
- Live webinars and video demonstrations
- *NLM Technical Bulletin* articles and NCBI Insights blog posts
- Social media posts

such as a streamlined design and optimization for mobile devices, in the latest NCBI Insights Blog: ow.ly/SXcS50SpgUH



Moderated Q&A (#1–2)

Q I am seeing differences between the modernized and classic PRS record lists. Do I need to report them? Do I need to do anything to resolve the differences?

A Yes, please report any differences you see using the Feedback button on the modernized website. We are working to resolve the differences, and you can rely on the classic system as your source of truth.

Q Will training materials be updated?

A New PRS-specific demonstration videos are available, and the About the Modernized PRS document has also been updated. The PRS User's Guide is consistent with submission requirements. We will update additional training materials (e.g., PRS Guided Tutorials) in the future.

Moderated Q&A (#3–4)

Q Is PRS XML upload available?

A Yes, the classic PRS XML upload is available, and development of the modernized PRS XML upload is planned.

Q I am seeing names displayed in the Group column that seem different from what I expect. Were the names changed by ClinicalTrials.gov?

A No. In the Group column of the Record List, the Full Group Name was being displayed in place of the Group Name. We took your feedback, and the names now match those used in the classic PRS.

Moderated Q&A (#5–6)

Q Do you still want me to provide feedback if it has been reported already?

A Yes, please send feedback. It helps us know if it is an ongoing issue.

Q When will the results be available in the modernized PRS?

A Some results modules will be available in PRS Test later this year. We have no timeframe yet for making the modernized results module the primary experience.



Stacey Arnold
PRS Subject Matter Expert



Nachiket Dharker
PRS Product Owner

Moderated Q&A

| Next Steps

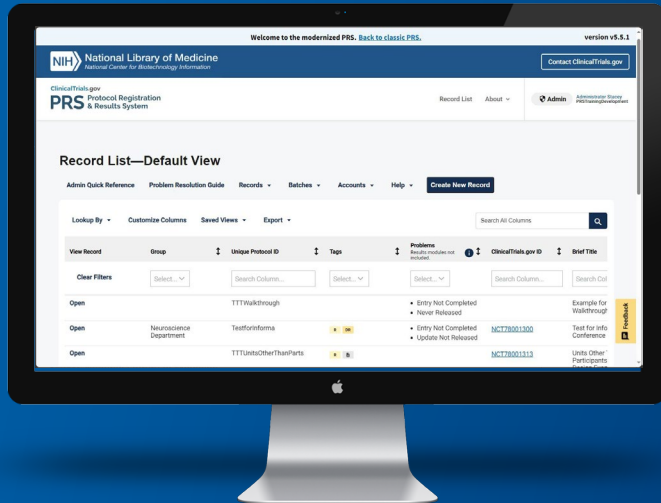
NLM will:

- Announce in Hot Off the PRS! when the meeting recording is available
-

Attendees are asked to:

- Continue to provide their feedback on the modernized PRS and ClinicalTrials.gov website

Thank You!



Learn More



Find out about the modernization effort:

<https://clinicaltrials.gov/about-site/modernization>



**Stay up to date with the
Hot Off the PRS! e-bulletin:**

<https://bit.ly/33qcZBb>



Contact us:

register@clinicaltrials.gov