





### 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





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







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



YEARS 5–6 (FY 2024–25) Launches and Landings

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



### Modernized ClinicalTrials.gov

An official website of the United States govern     NIH     National Library of Medici     Network for Bathehapdore, Informatio	ment Here's how you know ~	PRS Login	
ClinicalTrials.gov			
Find Studies × Study Basics ×	Submit Studies  V Data and API  V Policy  V About  V	My Saved Str 4:23 4	I 奈 ■
	ClinicalTrials.gov is a place to learn about clinical studies from around the world.	clinicaltrials.go	v
	The U.S. government does not review or approve the safety and science of all studies listed on this website. + Read our full <u>disclaimer</u> for details.	An official website of the United States gov Here's how you know ~ NIH National Library of Med National Center for Biotechnology Inform	vernment licine nation
	Focus Your Search (all filters options))	ClinicalTrials.gov	
	Condition/disease	ClinicalTrials.gov is a play about clinical studies from the world	ce to lea m aroun
	Other terms  Other terms  Intervention/treatment  Other terms  Other t	The U.S. government does review or approve the safet science of all studies listed website.	not ty and d on this
	Location Search by address, city, state, or country and select from the dropdown list	Read our full <u>disclaimer</u> for	details.
	Study Status  Search	Focus Your Search (all filters optio	onal)
	NoteBook Pro	Search	

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# 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**



**USER ADOPTION** 





### **Nachiket Dharker**

PRS Product Owner

### **Modernized PRS**

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# **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

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### **PRS Beta: 2022**



					PRS Beta Home Page	•				
ecord List									Saved Views	🛓 Export
10 per page 👻	Viewing 1 - 10   36 rec	cords Y Clea	r Filters			ļ	Customize Colum	Search All		٩
View Record	Unique Protocol ID $\stackrel{\wedge}{\lor}$	Tags	NCT Number 🗘	Secondary IDs	Brief Title	Record Status	🕻 Last Update 🗸 🗸	Record Owner	Responsible Party $\stackrel{\wedge}{\lor}$	Problems
	Search this columnQ	-Select- •	Search this columnQ	Search this columnQ	Search this columnQ	-Select-	Select 📩	-Select- •	-Select- •	-Select- •
<u>Open</u>	TTTCrossover				Crossover Study Design Example	In Progress	2022-03-14 14:03	Stacey Arnold	[Sponsor]	Entry Not Completed     Never Release
<u>Open</u>	TTTParallel	PR			Parallel Study Design Example	Released	2022-03-10 14:03	Stacey Arnold	[Sponsor]	
<u>Open</u>	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
<u>Open</u>	TTTClusterRandomized	d R			Cluster Randomized Study Design Example (With Results)	In Progress	2021-11-09 15:11	Stacey Arnold	[Sponsor]	Entry Not Completed     Never Release
<u>Open</u>	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								14 <	1 2 3	4 > M
Tag Key: Re	sults DR Delayed Res	sults PR PRS Revie	ew NP No Longer Pr	ublic 🚺 Study Doc	cuments 🟦 XML	PRS Review Co	omments			About PRS
										📄 Give Feed



# **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**



multiple clicks."

2

8

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

	Protocol Section						
Neco	ord 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:						
<u>Edit</u>	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 Data Entry: Navigation in the Classic PRS (3)**

	Protocol Section
Neco	ord 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)

			Protocol Section
Nec	ord Summary Preview Edit All		Edit Study Status
<u>Edit</u>	Study Identification		Help Definitions
	Unique Protocol ID: Parallel Brief Title: A 24-W	* Record Verification Date:	Month: September 🗸 Year: 2017
	Official Title: Examp Secondary IDs:	* Overall Recruitment Status:	Completed  Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.
Edit	Study Status Record Verification: Septem		Tip: Day is not required for Anticipated dates.
	Overall Status: Comple Study Start: Februa	* § Study Start Date:	Month: February V Day: 01 Year: 2010 Type: Actual V Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).
	Primary Completion: August Study Completion: August	* Primary Completion Date:	Month: August  Day: 01 Year: 2011 Type: Actual  Final data collection date for primary outcome measure.
<u>Edit</u>	Sponsor/Collaborators Sponsor: National & WAR	* § Study Completion Date:	Month: August  Day: 01 Year: 2011 Type: Actual  Final data collection date for study.
	register( Responsible Party: Sponsor Collaborators:	Save Cancel * Requi * § Requi [*] Condi	ired ired if Study Start Date is on or after January 18, 2017 tionally 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."

3

"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
Protocol Summary	
Study Identification	Otudu Identification
Study Status	
Sponsors and Collaborators	Organization's Unique Protocol ID
Dversight	Test_Parallel_1
Study Description	Brief Title Parallel Study Design Example_1
onditions	Acronym
tudy Design	ABC
rms and Interventions	Study Type Interventional
utcome Measures	Official Title
igibility	Parallel Study Design Example_1
ontacts and Locations	Secondary IDs
D Sharing Statement	Edit Study Identification
eferences	



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







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

Edit Mode Disabled	Study Status	3		
Protocol Summary				
Study Identification				
Study Status	Use this module to enter the start and completion dates for the study, as well as the study's recruitment status.			
Sponsors and Collaborators	* Required * S Required if Study Start Date is on or after January 18, 2017			
Oversight	[*] Conditionally required			
Study Description	Desard Varification Date t			
Conditions	Record Vermouto			
Study Design	Month *		Year *	
Groups and Interventions	Dec	~	2023	
Outcome Measures				
Eligibility	Overall Recruitment Stat	us * 🚹		
Contacts and Locations	If you select "Suspended," "Terminated," or "Withdrawn," an explanation of why the study was stopped is required.			
IPD Sharing Statement	Not yet recruiting			
References				

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### 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:	<ul> <li>Chris Souhrada (csouhradaUser)</li> <li>Investigator Peter (PIPeter)</li> <li>Investigator Venka (PIVenka)</li> </ul>		
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.					
		ME	mail all users with access		
No Acc	ess (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		
Save					

#### **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		Close 🗙	No	Access (106)	Access List (1)		
By defaul give acce	t, a record is only accessible to the f ss to additional users, select one or	Record Owner and the Administrato more from the User List below.	ors for an organization. To ail all users with access		Username	•	Name	Contact
	Username	Name	Contact		Search	Column	Search Column	
	Search Column adevereuxt2	Search Column Austin Devereux T2	Email	<b>~</b>	adevereux	t2	Austin Devereux T2	🞽 Email
	adevereuxt3 adevereuxt4	Austin Devereux T3 austin devereux t4 AustinTestArct2	Email		adevereux	t3	Austin Devereux T3	🞽 Email
	AFine ambergeris	Anna Fine annice bergeris	Email		adevereux	t4	austin devereux t4	🚩 Email
	AustinSuperPRSDev	Austin Devereux benprstestsuper	ビ Email					
Save	Cancel							



### **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	<ul> <li>Fix issues in Protocol Registration</li> <li>Results data entry (Participant Flow, Baseline Characteristics, Outcome Measures, Adverse Events)</li> <li>Other results modules</li> <li>Study document upload</li> <li>Results validations</li> <li>Fix issues and address critical feedback in Results</li> <li>Adverse Events upload</li> <li>Results QA/QC functionality</li> <li>Delayed results</li> <li>XML upload</li> </ul>	Optimized database design Move to cloud Improved system architecture Optimized database performance and data integrity

Updated 9.30.24 ClinicalTrials.gov

### Thank You for the Feedback

# 4 Weeks



#### 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.



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





#### Stacey Arnold PRS Subject Matter Expert

# Navigating the Modernized PRS



### Landing Page: Record List

National Library of Medicine       Contract ClinicalTrials over         Image: Contract ClinicalTrials over       Contract ClinicalTrials over         Image: Contract ClinicalTrials over       Record List About ~ <ul> <li>A down</li> <l< th=""><th></th><th>Welcome to th</th><th>e modernized PRS_Bac</th><th>k to classic PRS</th><th>_</th><th></th><th>version v5.5</th></l<></ul>		Welcome to th	e modernized PRS_Bac	k to classic PRS	_		version v5.5
Control       Record Dispersion         Control       Market Control         Control       Control         Conte New Record       Control	NIH National Library of Medicine		in modernized riks. <u>But</u>			Contact	ClinicalTrials.gov
• Outcome to the Modernized PRS1 Please use it to enter, review, and submit a study protocol.           • Core ×             • Wex seemlessly with the classic PRS by raving changes on one website and moving to the other.           • Core ×             • Records with Results, Delayed Results, and Study Documents can only be opened in classic PRS.           • Record List — Default View           • Amin Quick Reference         • Poblem Resolution Guide         • Record         • Record         • Core ×         • Record List — Default View         • Export +         • Core New Record         • Enter Column.         • Enter New R	InicalTrials.gov PRS Protocol Registration & Results System				Record List Ab	out ~ 🍳 Admin	Administrator Stacey PRSTrainingDevelopme
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       Search Columns	<ul> <li>Welcome to the Modernized PRS</li> <li>Work seamlessly with the classic PRS by :</li> <li>Note that you may have to go to the class</li> <li>Records with Results, Delayed Results, and</li> </ul>	5! Please use it to enter, revisaving changes on one website and mo sic PRS to resolve some validation issue nd Study Documents can only be opene	<b>iew, and submit a</b> ving to the other. <sup>IS.</sup> ed in classic PRS.	study protocol.		с	lose X
Lookup By •       Customize Columns       Saved Views •       Export •       Search All Columns       Q         View Record       Group       I Unique Protocol ID       I       Tags       I Problems Recults modules not included.       I ClinicalTrials.gov ID       I Brief Title       I Record S         Clear Filters       Select •       S							
View Record       Group       Unique Protocol ID       Tags       Problems Reduits modules not middles not middles not       ClinicalTrials.gov ID       Brief Title       Record S         Clear Filters       Select ✓       Search Column       Select ✓       Search Column       Select       Search Column       Select         Open       TTTWalkthrough       ITTWalkthrough       Entry Not Completed Never Released       NCT78001300       Test for Informa       In Progr         Open       Neuroscience Department       TTTUnitsOtherThanParts       R       In       NCT78001313       Units Other Than Sludy Design Example       Public	Record List—Default View	Admin Quick Reference	Problem Resolution Gui	de Records <del>-</del> Bat	tches 👻 Accounts 🗸	- Help - Create N	lew Record
Clear Filters       Select       Select       Select       Select       Select       Search Column       Select       Search Column       Select       Select       Select       Search Column       Select	Record List—Default View	Admin Quick Reference	Problem Resolution Gui	de Records <del>-</del> Bat	tches - Accounts - Seal	Help - Create M	lew Record
Open       TTTWalkthrough       Entry Not Completed Never Released       Example for TTT Walkthrough       In Progr In Progr In Progr         Open       Neuroscience Department       TestforInforma       n on Northeouse       Entry Not Completed Update Not Released       NCT78001300 Conference       Test for Informa Conference       In Progr In Progr Public         Open       TTTUnitsOtherThanParts       n on       NCT78001313       Publics Study Design Example       Public         Open       TTTG/update/opendeciend       NeuroBelend       NeuroBelend       Clupte Dedeciend       Terms	Record List—Default View         Lookup By ~       Customize Columns       Saved         View Record       Group       1	Admin Quick Reference	Problem Resolution Gui	de Records - Bat Problems Results modules not michaded.	tches - Accounts - Sea ClinicalTrials.gov ID 1	Help - Create M cch All Columns	lew Record Q Record S
Open     Neuroscience Department     TestforInforma     non     Entry Not Completed Update Not Released     NCT78001300     Test for Informa Conference     In Progr       Open     TTTUnitsOtherThanParts     n     n     NCT78001313     Units Other Than Participant     Public       Open     TTTUnitsOtherThanParts     n     n     NCT78001313     Units Other Than Participant     Public	Lookup By ~       Customize Columns       Saved         View Record       Group       Clear Filters	Admin Quick Reference	Problem Resolution Gui	de Records - Bar Problems Results modules not included. Select ~	tches  Accounts Sear ClinicalTrials.gov ID Search Column	Help - Create M cch All Columns Brief Title Search Column	Record Select
Open     TTTUnitsOtherThanParts     R     B     NCT78001313     Units Other Than Participants Study Design Example     Public       Open     TTTUINtsOtherThanParts     R     B     NeuroPartecipants     Study Design Example     Public	Lookup By ~       Customize Columns       Saved         View Record       Group       Clear Filters         Clear Filters       Select ~         Open       Clear Filters	Admin Quick Reference Views - Export - Unique Protocol ID Search Column TTTWalkthrough	Problem Resolution Gui	de Records - Bar Problems Reculter modules not included. Select ~ • Entry Not Completed • Never Released	tches  Accounts Sear ClinicalTrials.gov ID Search Column	Help - Create M cch All Columns Brief Title Search Column Example for TTT Walkthrough	Record S Record S Select In Progr
Ones TTTC/ustorDecdomized - NaverDeleased ChusterDecdomized Associ	Lookup By ~       Customize Columns       Saved         View Record       Group       C         Clear Filters       Select ~       C         Open       Neuroscience       Department	Admin Quick Reference         IViews - Export -         Unique Protocol ID         Search Column         TTTWalkthrough         TestforInforma	Problem Resolution Gui	de Records - Bar Problems Reculter modules not Reculter modules not Select ~ Entry Not Completed Never Released Entry Not Completed Update Not Released	tches - Accounts - Sear ClinicalTrials.gov ID 1 Search Column	Help -     Create N       cch All Columns     \$       Brief Title     \$       Search Column     \$       Example for TTT     Walkthrough       Test for Informa Conference     \$	Record S Record S Select In Progr
	Record List—Default View         Lookup By ~       Customize Columns       Saved         View Record       Group       1         Clear Filters       Select ✓       1         Open       Department       1         Open       Neuroscience       Department         Open       Neuroscience       1         Open       Neuroscience       1	Admin Quick Reference         IViews • Export •         Unique Protocol ID       1         Search Column         TTTWalkthrough         TestforInforma         TTTUnitsOtherThanParts	Problem Resolution Gui	de Records - Bar Problems Reculter modules not Reculter modules not Select ~ Entry Not Completed Never Released Entry Not Completed Update Not Released	tches - Accounts - Sear ClinicalTrials.gov ID 1 Search Column NCT78001300 NCT78001313	Help     Create N       ch All Columns        Brief Title     ‡       Search Column     ‡       Example for TTT     Walkthrough       Test for Informa Conference     ‡       Units Other Than Participants Study Design Example     ‡	Record S Record S Select In Progr In Progr Public

### **Record List: Customizing Columns**

Lookup By 👻 🕻	Customize plumns Save	ed Views 👻 Export 👻				Search All Columns	۹
View Record	Group	Unique Protocol ID         1	Tags	Results modules not included.	ClinicalTrials.gov ID	1 Brief Title 1	Record
Clear Filters	Select 🗸	Search Column	Select V	Select 🗸	Search Column	Search Column	Selec
Open		TTTWalkthrough		<ul><li>Entry Not Completed</li><li>Never Released</li></ul>		Example for TTT Walkthrough	In Prog
Open	Neuroscience Department	TestforInforma	R DR	<ul><li>Entry Not Completed</li><li>Update Not Released</li></ul>	NCT78001300	Test for Informa Conference	In Prog
Open		TTTUnitsOtherThanParts	R		NCT78001313	Units Other Than Participants Study Design Example	Public
Open		TTTClusterRandomized	DR	Never Released		Cluster Randomized Study Design Example	Approv
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		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)	Approv
Open	Neuroscience Department	TTTDose_EscalationR	R	<ul><li>Entry Not Completed</li><li>Never Released</li></ul>		Dose Escalation Study Design Example (with Results)	In Proș
Open		TTTClusterRandomizedR	R	Entry Not Completed     Never Palaased		Cluster Randomized	In Proç

#### New Features of the Modernized PRS

Ability to reorder columns

# Record List: Customizing Columns (cont.)



#### 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 Lis	Record List—Default View Admin Quick Reference							
Lookup By 👻	Customize Co	lumns Saved Views <del>-</del>	- Exp	oort 👻				
View Record	Group 🗘	Unique Protocol ID	t	Tags 🗘	Problems Results modules not included.	(i) ClinicalTrials.gov ID 🗘		
Clear Filters	Select Y	Search Column		Select Y	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**

	Sea	rch All Columns	٩
Brief Title	Record Owner	Responsible Party	\$
Search Column	Select 🗸	Select 🗸	
Example for TTT Walkthrough	Administrator S Email Record Owner for TTT	<u>Malkthrough</u>	
Test for Informa Conference	Administrator M AdminMichael	<u>Aichael</u> Sponsor	
Units Other Than Participants Study Design Example	Administrator S AdminStacey	tacey 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	c PRS. version v5.5.1
NIH National Library of Medicine National Center for Biotechnology Information	Contact ClinicalTrials.gov
ClinicalTrials.gov PRS Protocol Registration & Results System	Record List About Administrator Stacey
	About the Modernized PRS
<ul> <li>Welcome to the Modernized PRS! Please use it to enter, review, and submit a study pr</li> <li>Work seamlessly with the classic PRS by saving changes on one website and moving to the other.</li> <li>Note that you may have to go to the classic PRS to resolve some validation issues.</li> <li>Records with Results, Delayed Results, and Study Documents can only be opened in classic PRS.</li> </ul>	rotocol. Release Notes (PRS TEST) Close X
Record List—Default View Admin Quick Reference Problem Resolution Guide Rec	cords - Batches - Accounts - Help - Create New Record
View Record Group 1 Unique Protocol ID 1 Tags 1 Results mod	dules not 🚯 🗘 ClinicalTrials.gov ID 🗘 Brief Title 🇘 Record S
Clear Filters Select V Search Column Select V Select V	. V Search Column Search Column
Open TTTWalkthrough • Entry N • Never F	Not Completed Example for TTT In Progr Released Walkthrough



### About the Modernized PRS (cont.)

	$:=   \forall \lor \forall \lor   \blacksquare \cdots - + \boxdot   1 \text{ of } 14   \Im   (\square \bigcirc $
Welcome to the modernized PRS. 5	About the Modernized PRS
NIH National Library of Medicine	Menu
ClinicalTrials.gov	About PRS Modernization
PRS & Results System	Working in the Modernized PRS
	Record List Views
	Customizing the View — Selecting Records per Page and Navigating Pages
() Welcome to the Modernized PBSI Please use it to enter review and submit	Customizing the View — Selecting and Ordering Columns
Work seamlessly with the classic PRS by saving changes on one website and moving to the other.	Customizing the View — Filtering
<ul> <li>Note that you may have to go to the classic PRS to resolve some validation issues.</li> </ul>	Saving Custom Views
<ul> <li>Records with Results, Delayed Results, and Study Documents can only be opened in classic PRS.</li> </ul>	Accessing the Planning View and Public Site View
	Using Other Features on the Record List Page
Pacard List Default View Admin Quick Paterance Problem Persolution	Accessing User Account Information
	Adjusting Column Widths
	Contacting ClinicalTrials.gov
Lookup By - Customize Columns Saved Views - Export -	Emailing PRS Users
	Exporting Records
View Record Group Chique Protocol ID Tags	Help Links and Other Menus
	Returning to the Classic PRS Home Page
Select V	Sorting Columns
Open TTTWalkthrough	Understanding the Tag Column
	Help: Using Links to Send Email Messages

...

### **Fast Forward Videos**

Welcome to the modernized PRS. <u>Back to classic PRS.</u>	version v5.5.1
NIH National Library of Medicine National Center for Biotechnology Information	Contact ClinicalTrials.gov
ClinicalTrials.gov PRS Protocol Registration & Results System	Record List About About Administrator Stacey PRSTrainingDevelopment
	About the Modernized PRS 🔤 How to Videos: PRS Fast Forward
<ul> <li>Welcome to the Modernized PRS! Please use it to enter, review, and submit a study protocol.</li> <li>Work seamlessly with the classic PRS by saving changes on one website and moving to the other.</li> <li>Note that you may have to go to the classic PRS to resolve some validation issues.</li> <li>Records with Results, Delayed Results, and Study Documents can only be opened in classic PRS.</li> </ul>	Release Notes (PRS TEST)
Record List—Default View Admin Quick Reference Problem Resolution Guide Records - E	Batches - Accounts - Help - Create New Record
Lookup By 👻 Customize Columns Saved Views 👻 Export 👻	Search All Columns Q
View Record Group Croup Unique Protocol ID Tags Results modules not Included.	ClinicalTrials.gov ID ClinicalTrials.gov ID Strief Title Record S
Clear Filters     Select >     Select >     Select >	Search Column Search Column
Open TTTWalkthrough • Entry Not Completed • Never Released	Example for TTT In Progr Walkthrough



### Fast Forward Videos (cont.)





# 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





H National Library of Medicine

### Action Expected and Records with Problems (1)

Record List		
Action Expected ~	All Records	
Lookup By + Cus	stomize Columns	Saved Views - Export -
View Record	Group	Save Current View As Default View
Clear Filters	Select ∨	Planning View Public Site View
Open		TestforInforma
Open		TTTUnitsOtherThanParts
Open		Record Progress Message Test 2

Record List	
Action Expected ~ A	All Records
All Actions	
<ul> <li>Update Expected</li> <li>Corrections Expected</li> </ul>	Saved Views - Export -
Results Expected	Unique Protocol ID
C Apply	Reset
орен	TestforInforma
Open	TTTUnitsOtherThanParts
Open	Record Progress Message Test 2



### Action Expected and Records with Problems (2)





# **Help Drawer**



#### **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**

	Welcome to the modernized	d PRS. Back to classic PRS.	version v5.5.1
NIH National Library of Medi National Center for Biotechnology Inform	icine <sup>ation</sup>		Contact ClinicalTrials.gov
ClinicalTrials.gov PRS Protocol Registration & Results System		Record	List About - CAdmin Administrator Statesy PSSTainingDevelopment
Brief Title NCT Number Example for TTT Walkthrough NCT ID not yet ass	Unique Protocol Id igned TTTWalkthrough		O Preview People      ✓ Actions      ✓     Go to record in classic site
Record Summary	Protocol	Study Documents	Results
Edit Mode Disabled Protocol Summary	rotocol Summary		
Study Identification	Study Identification		
Study Status			
Sponsors and Collaborators	Organization's Unique Protocol ID		
Oversight	Brief Title		
Study Description E	xample for TTT Walkthrough		
Conditions 4	Acronym		
Study Design S	Study Type		
Arms and Interventions	nterventional		
Outcome Measures	This is a Demo Example Record		
Eligibility	Secondary IDs		
Contacts and Locations	Edit Study Identification		
IPD Sharing Statement			ack
References			Feedt
2	Study Status		
F	Record Verification Date		

#### **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**

1 Error	Section Overview			
There are 1 errors that need to be corrected	Protocol Section	Errors	Warnings	No
before this record can be submitted for PRS Review.	Study Identification >	0	0	
	Study Status >	0	0	
	Sponsors and Collaborators >	0	0	
	Oversight >	0	0	
🛕 1 Warning	Study Description >	0	0	
here are 1 warnings that, if not corrected, may ead to issues during the PRS Review process.	Conditions >	0	0	
	Study Design >	0	0	
	① Arms and Interventions >	1	1	
	Outcome Measures >	0	0	
i) 0 Notes	Eligibility >	0	0	
This record has no notes at this time.	Contacts and Locations >	0	0	
	IPD Sharing Statement >	0	0	
	References >	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.)

otocol Validation Review Comments			
Agior 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.	General Record Comments These include any comments about the overall record. Overall Record General Comments >	<b>Major</b> 0	<b>Advisory</b> 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
4 Advisory Comments	Study Description >	1	0
Advisory comments should be addressed to	Conditions >	0	1
improve the clarity of the study record. Advisory comments may be about the study record as a	Study Design >	0	0
whole or about specific modules of the protocol.	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 Syst	tem	
	Login	
Welcome to the <u>ClinicalTrials.gov</u> Protocol	Registration and Results System (PRS).	OMB NO: 0925-0588 EXPIRATION DATE: 03/31/2028 Burden Statement
	<b>NOTICE</b> The Modernized PRS is now the primary website for Protocol Registration. After logging in, you will be directed to the new website. The <u>Classic PRS</u> 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: Forgot password Password: Forgot password Login	
See <u>How to Apply</u> on ClinicalTrials.gov for See <u>PRS Guided Tutorials</u> for assistance v <u>Send email to ClinicalTrials.gov PRS</u> Admi	information on how to apply for a PRS account. with entering registration and results information in the PRS. inistration.	
	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 OMB NO: 0925-0586 EXPIRATION DATE: 03/31/2026 Welcome to the <u>ClinicalTrials.gov</u> Protocol Registration and Results System (PRS). 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 migrinted to the Modernized PRS. Select the PRS version to open after logging in. Modernized PRS O 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 <u>PRS Guided Tutorials</u> 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



for mobile devices, in the latest NCBI Insights Blog: ow.ly/SXcS50SpgUH



PRS Beta Will Soon Become the Primary Website for Protocol Registration

Read the latest NLM Technical Bulletin to learn more about the new features of the Modernized PRS (PRS Beta) and the plan for the Modernized PRS to become the primary website for Protocol Registration on August 28, 2024.



#### PRS Beta Updates

When users log into PRS Test, they will now see the



Marking a Milestone: The Modernized ClinicalTrials.gov Becomes the Singular Website Experience

Posted on June 5, 2024 by Guest Author



Guest post by Anna M. Fine, PharmD, MS, Acting Director of ClinicalTrials.gov.

### 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?

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.

# 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.

Α

### Moderated Q&A (#3-4)

**Q** Is PRS XML upload available?

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

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!

		Welcome to the mode	ernized PRS. Back to	classic PRS.		version v5.5.
	ibrary of Medicin	e			Co	ntact ClinicalTrials.gov
PRS & Results Syn	istration stem			Record List Abo	sut - Q Ade	nin Administration Starry pict training Development
Descend Link	Defeutblin					
Admin Quick Reference	Problem Resolution G	W uide Records - Batches	<ul> <li>Accounts +</li> </ul>	Help • Create New Record		
Lookup By - C	ustomize Columns Sav	ed Views • Export •		Searc	h All Columns	٩
View Record	Group	1 Unique Protocol ID 1	Tags	Problems     Assults modules not     modules not     ①     ①     ①     ①	linicalTrials.gov ID	1 Brief Title
Clear Filters	Select	Search Column	Select Y	Select	Search Column	Search Col
Open		TTTWalkthrough		Entry Not Completed     Never Released		Example for Walkthrough
Open	Neuroscience Department	Testforinforma	× (0)	Entry Not Completed     Update Not Released	CT78001300	Test for info Conference
Open		TTTUnitsOtherThanParts	• 8	Ы	KT78001313	Units Other ' Participants
			Ś.			

#### 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: <a href="mailto:register@clinicaltrials.gov">register@clinicaltrials.gov</a>

NIH National Library of Medicine