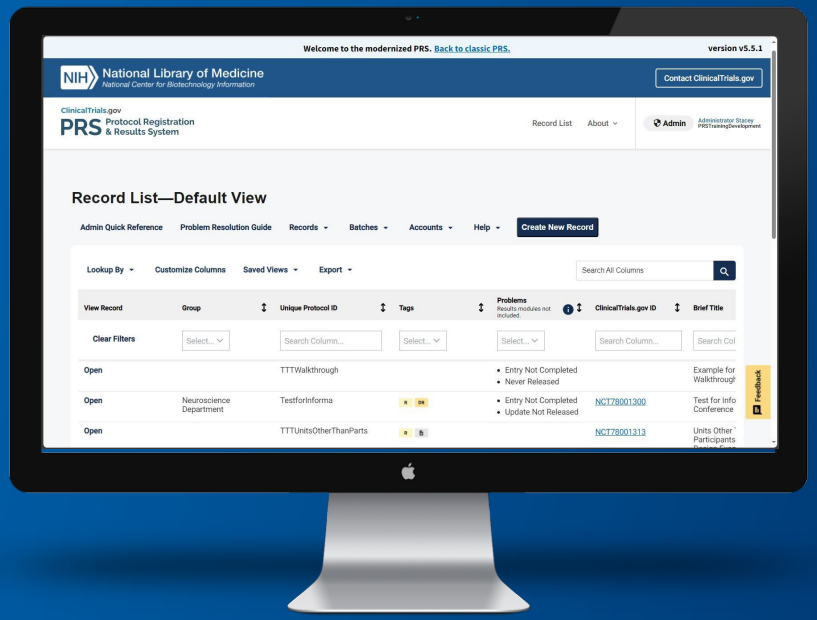


National Library of Medicine

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

Webinar

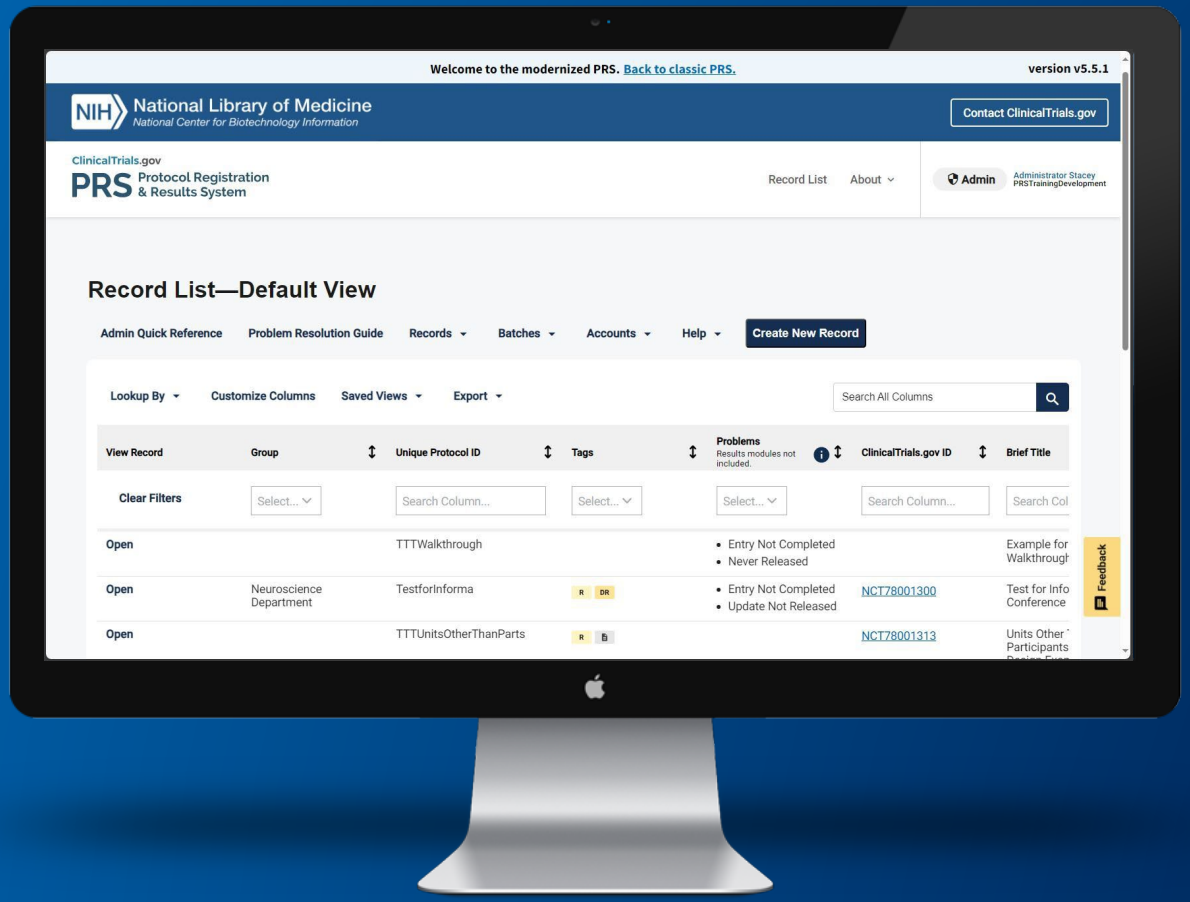
October 8, 2024 | 1 p.m. ET

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

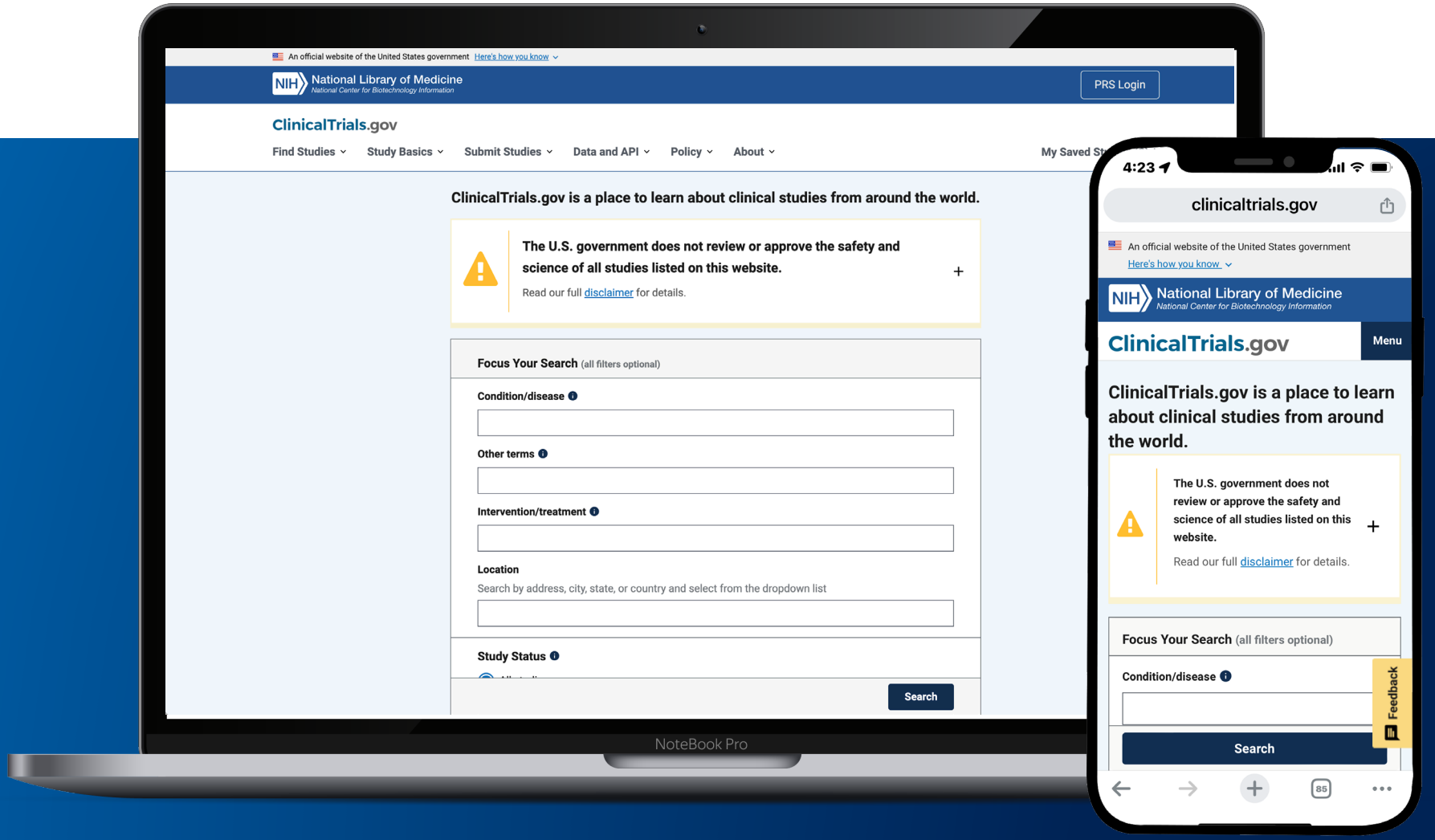
YEAR 4 (FY 2023)
Releases and Refinements

- 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**

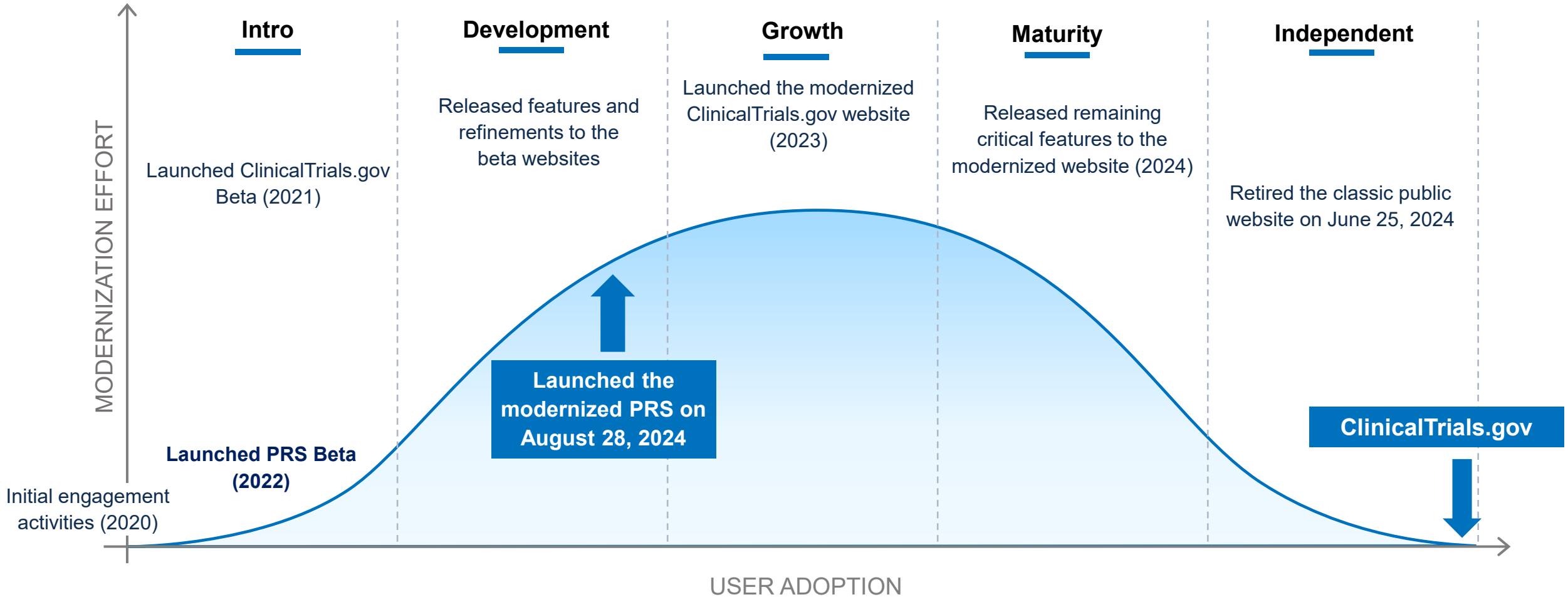
Modernized ClinicalTrials.gov



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	

Modernization Lifecycle



Nachiket Dharker
PRS Product Owner

Modernized PRS

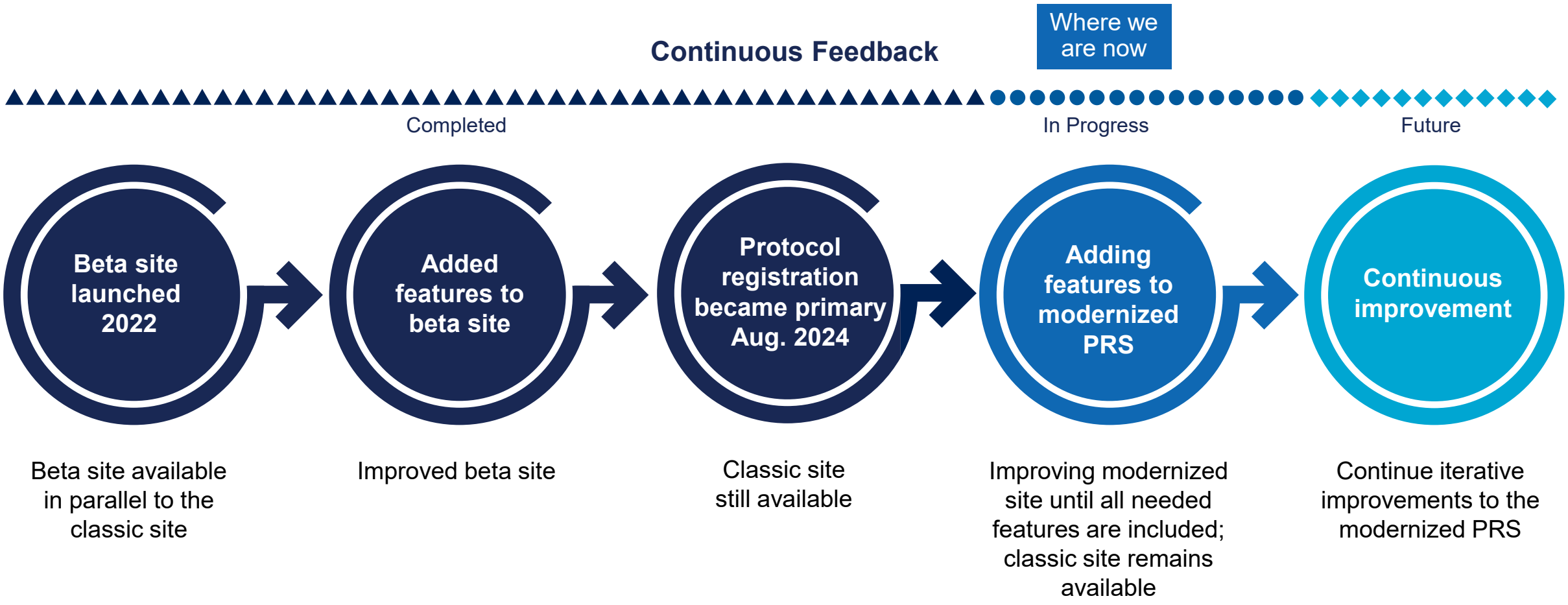
Poll Question #1

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

A. Yes

B. No

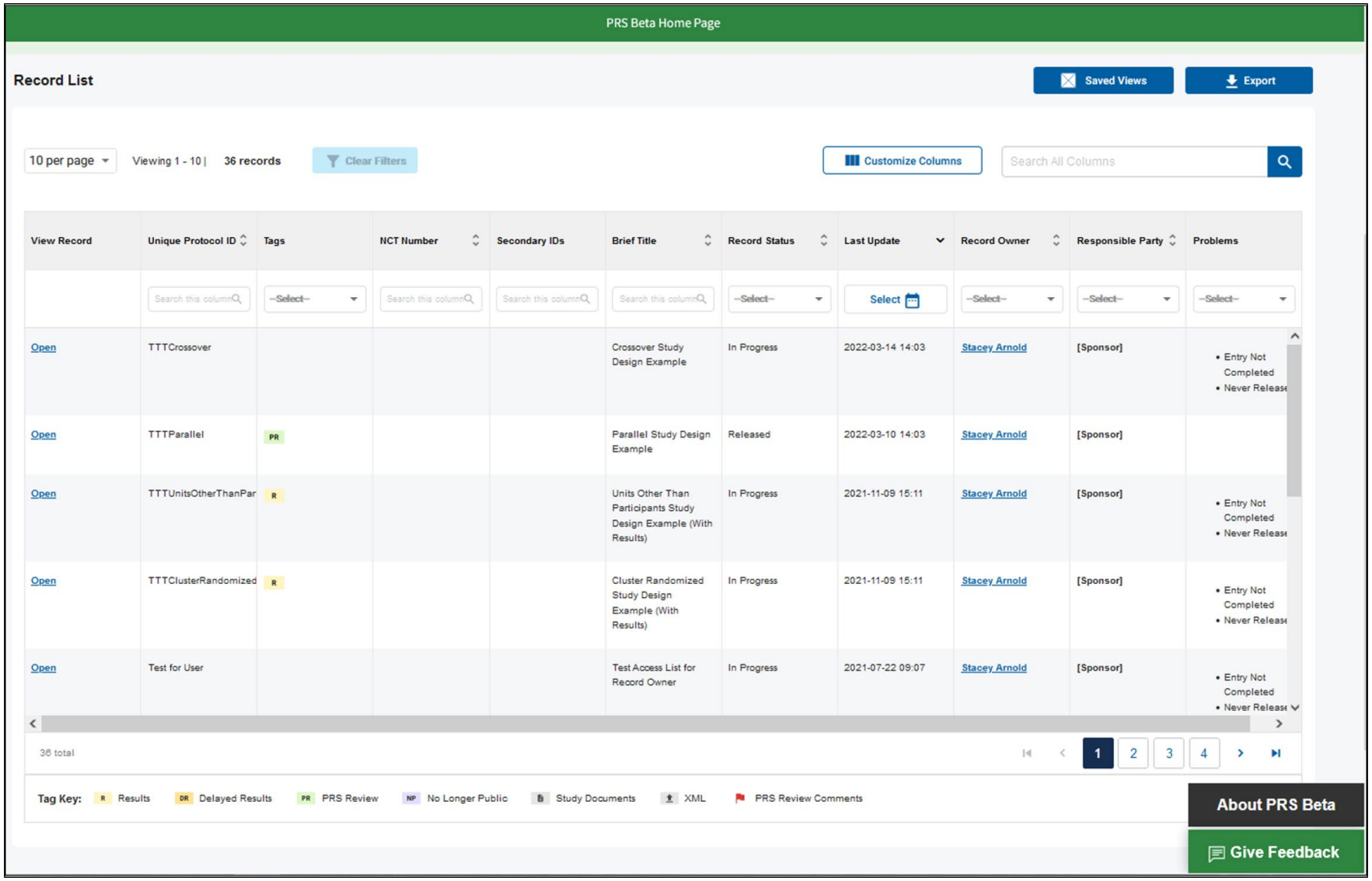
How Users See PRS Changes



Updated 9.30.24

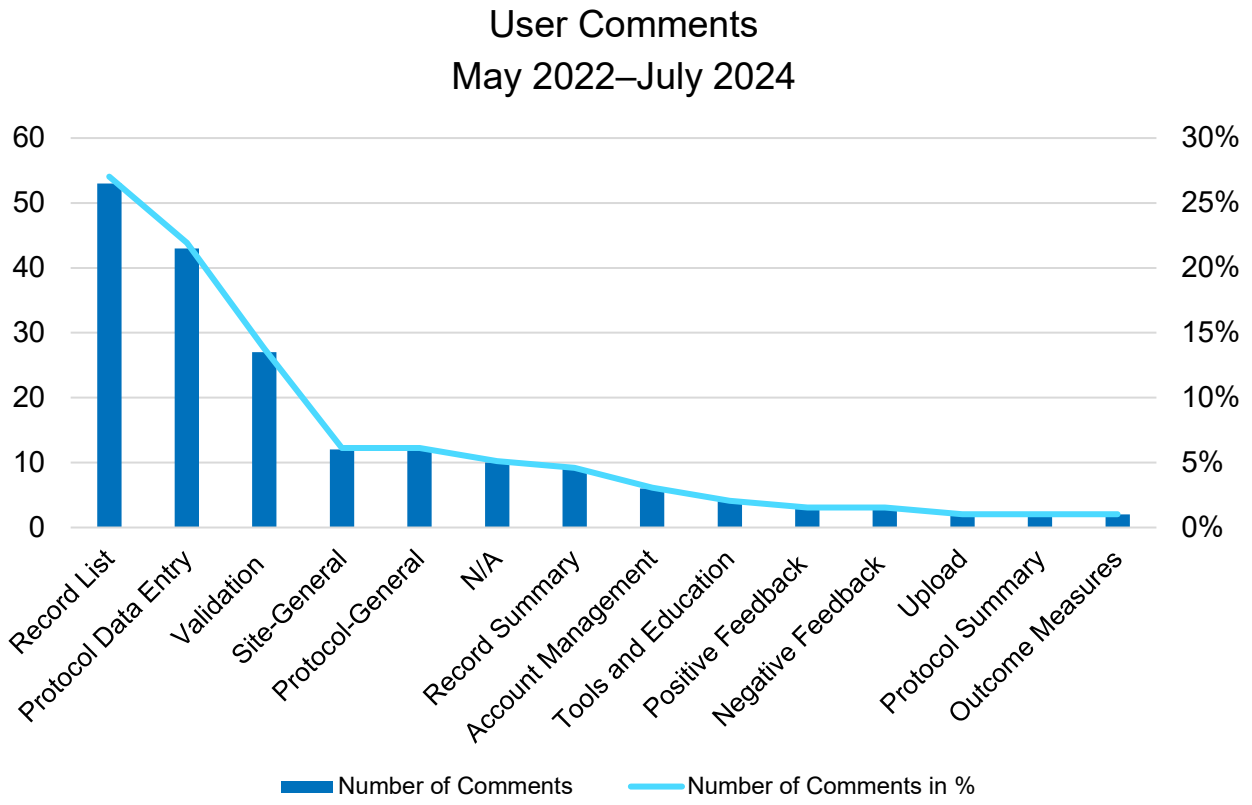
PRS Beta: 2022

Beta site launched 2022



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."

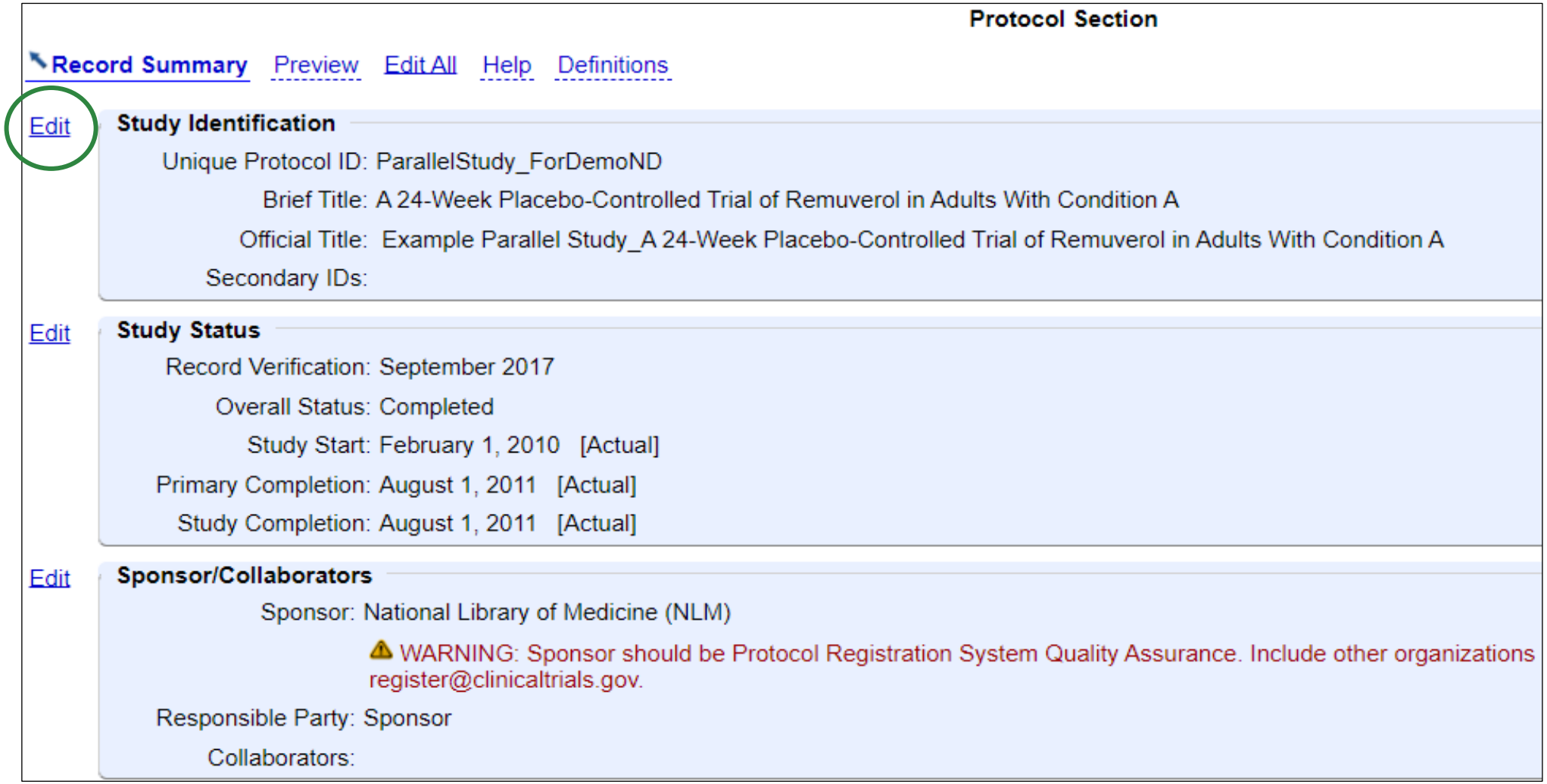
"When inputting information. . . there is a fair amount of toggling between screens. . . It would be beneficial to have all information in one place."

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

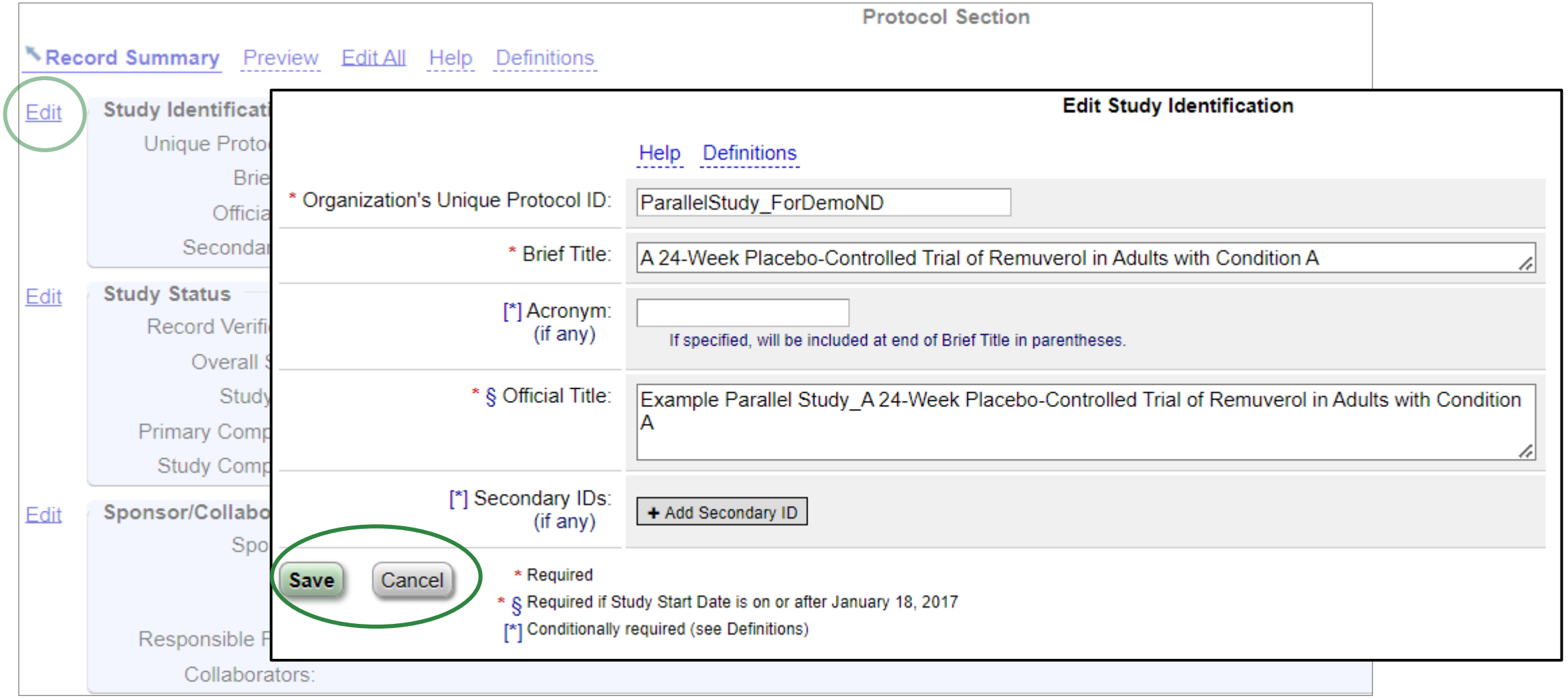
"Improved navigation and user-friendly features are needed to facilitate registration and results reporting."

"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)

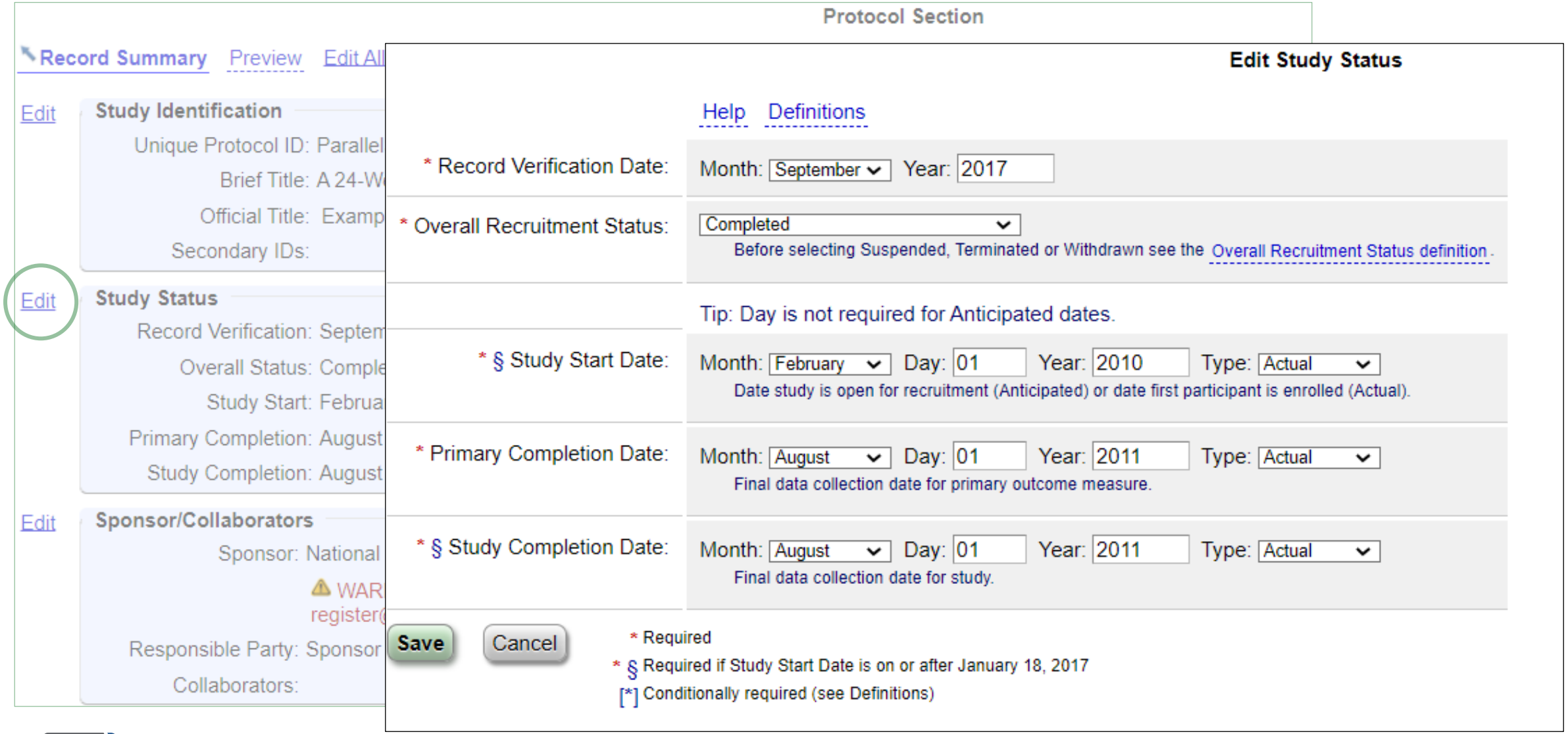


Protocol Data Entry: Navigation in the Classic PRS (2)



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

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



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."

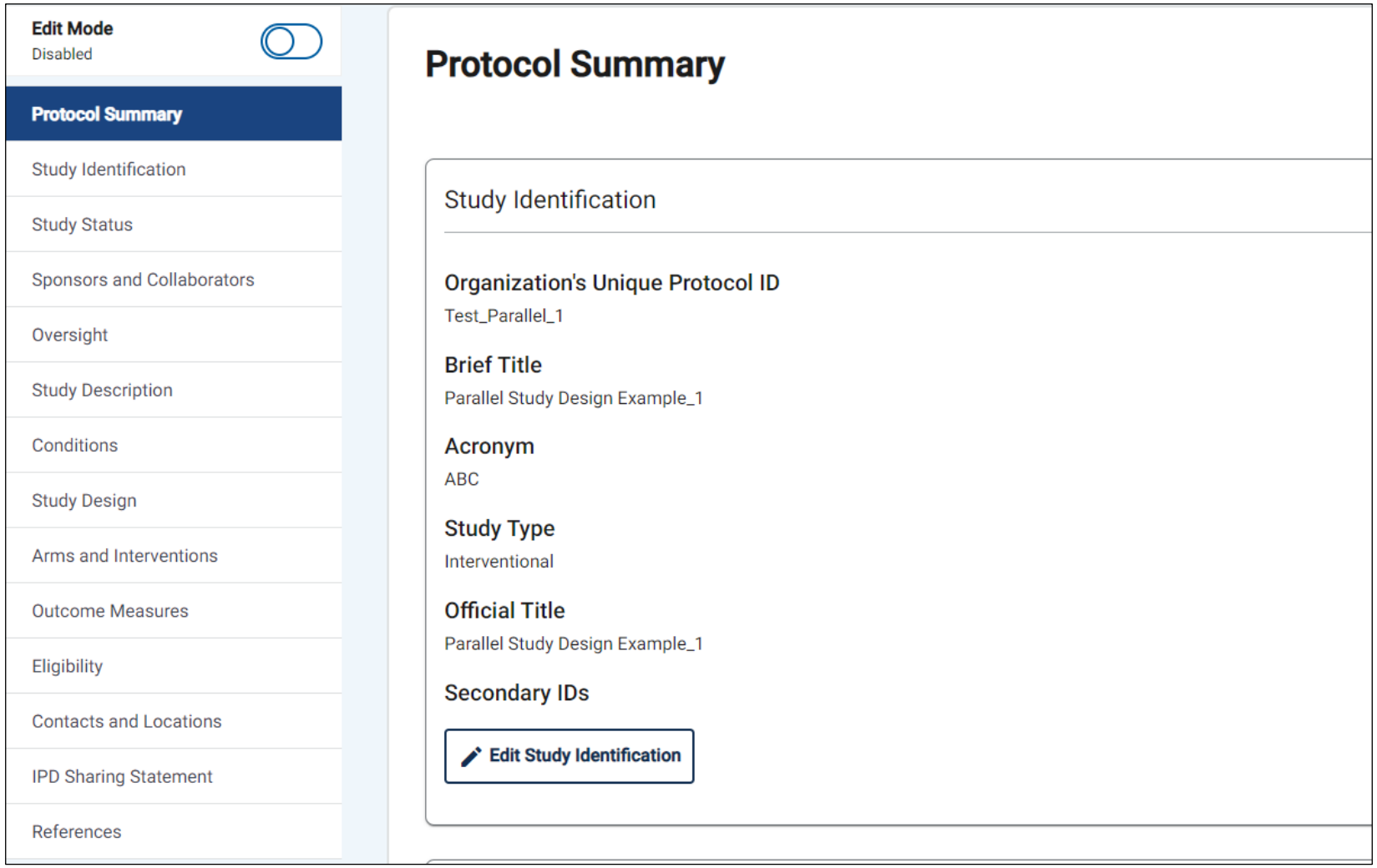
"It would be helpful to have contacts/locations towards the top since they are likely to change through the study. Fields that are rarely updated (e.g. Conditions, Oversight) could be further down."

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?

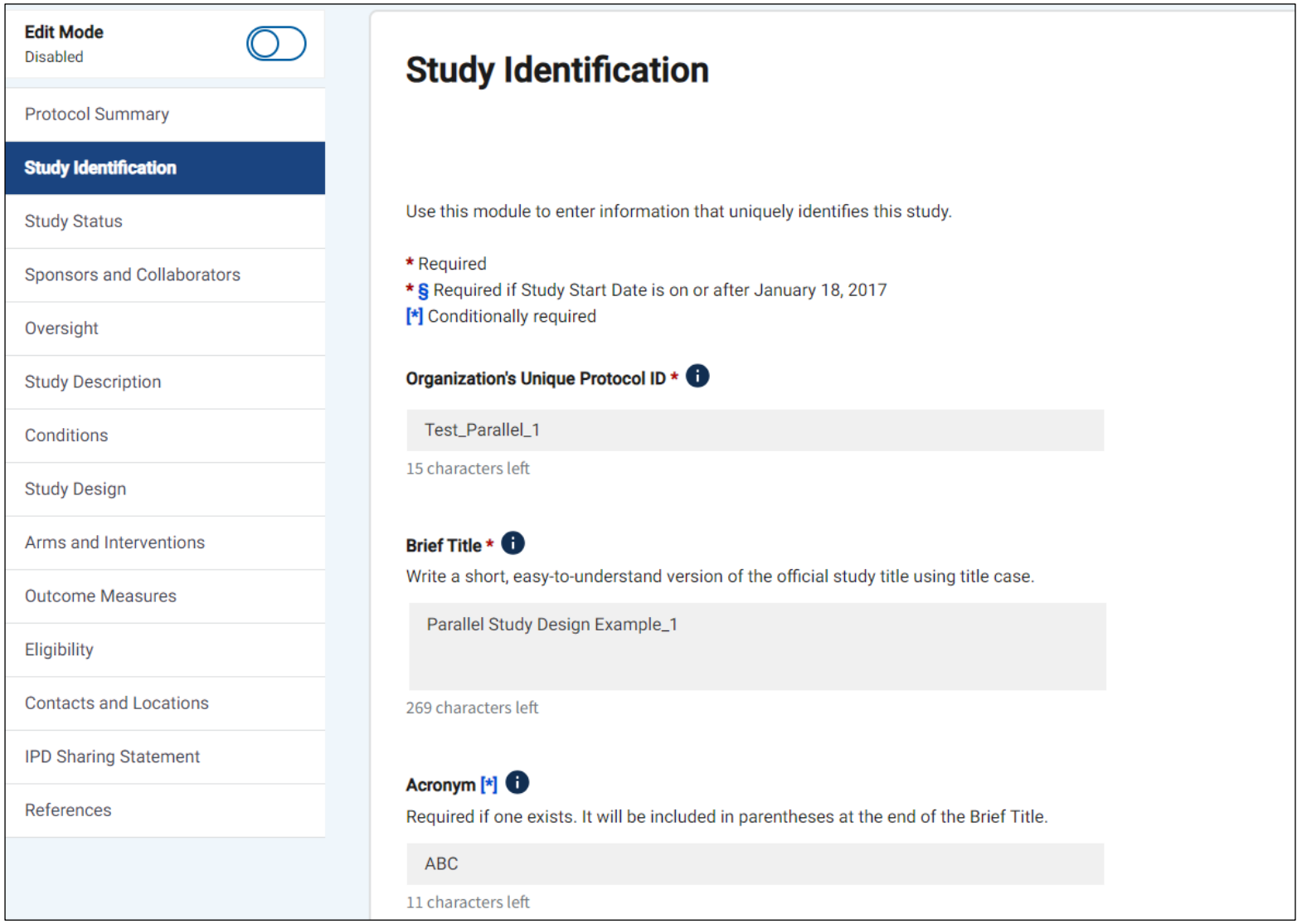
"One reason for grouping sections together would be so there is less clicking back and forth."

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

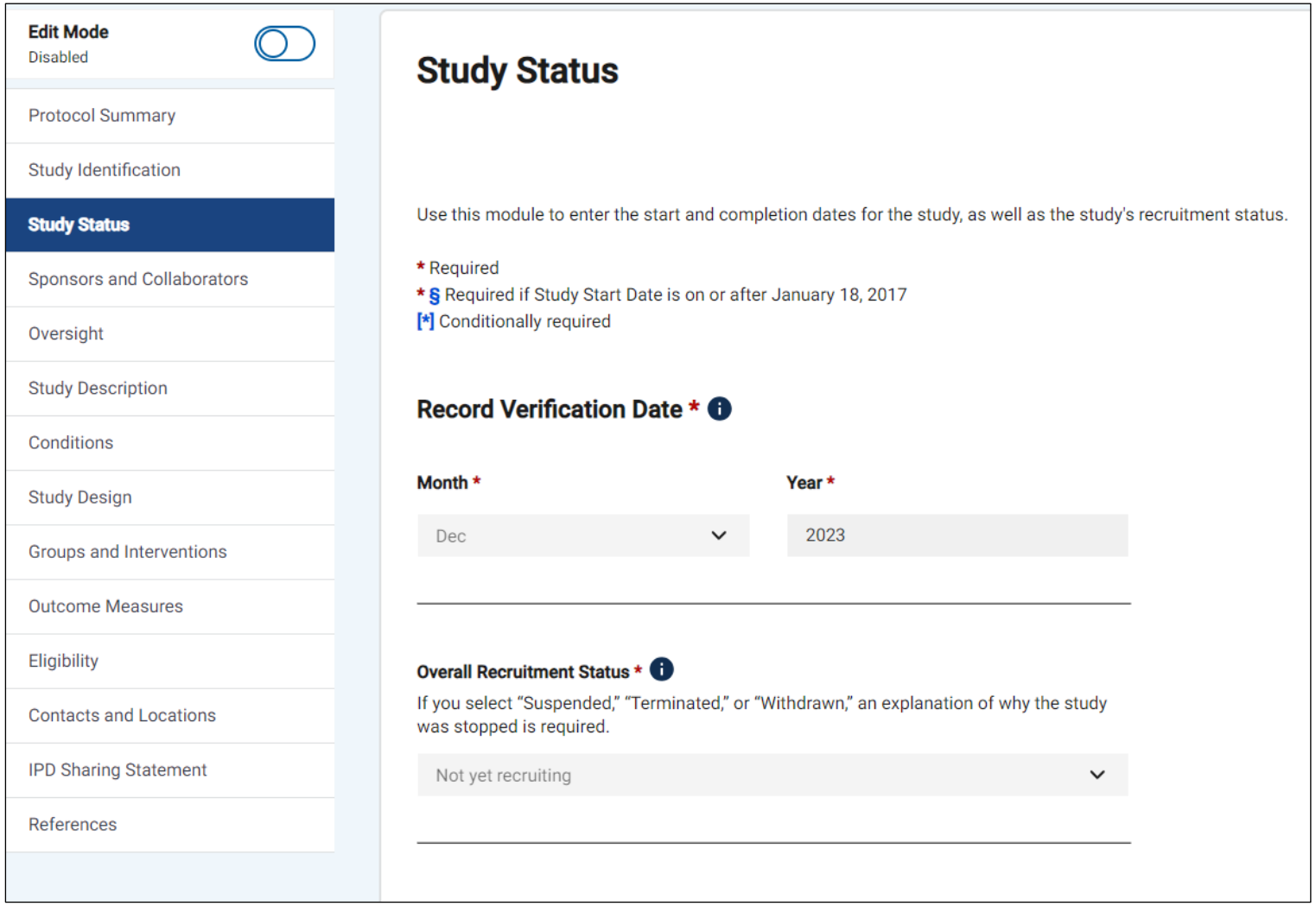
Protocol Data Entry: Navigation in the Modernized PRS (1)



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

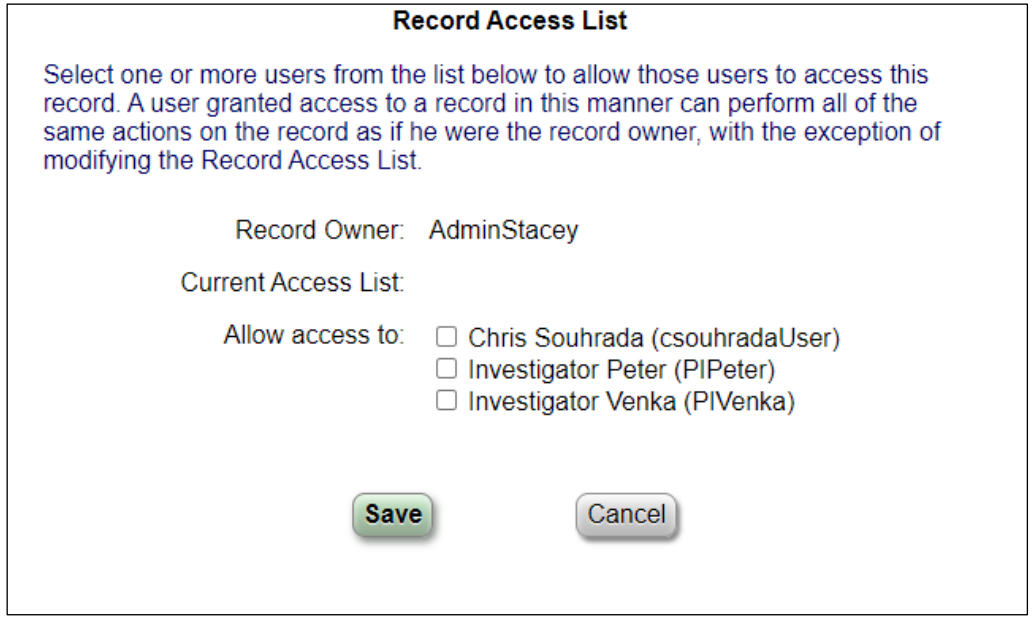


Protocol Data Entry: Navigation in the Modernized PRS (3)



Addressing User Feedback: Record Access (1)

Classic PRS

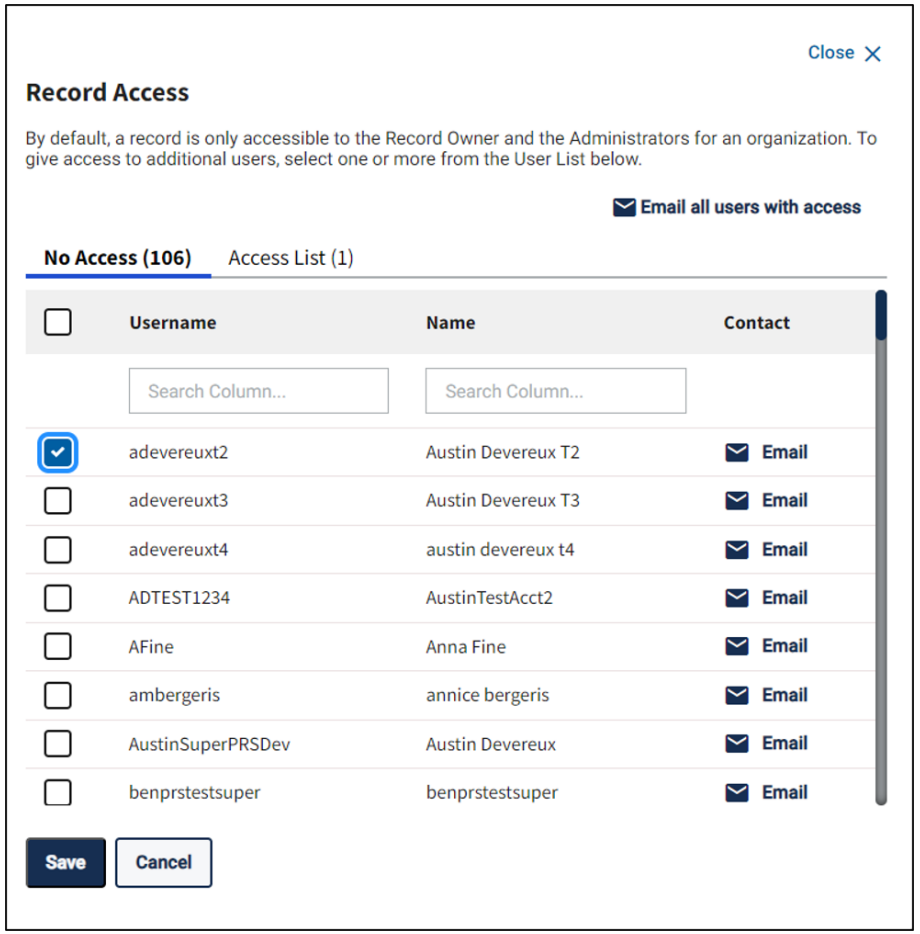


Feedback before Modernization Began

- 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

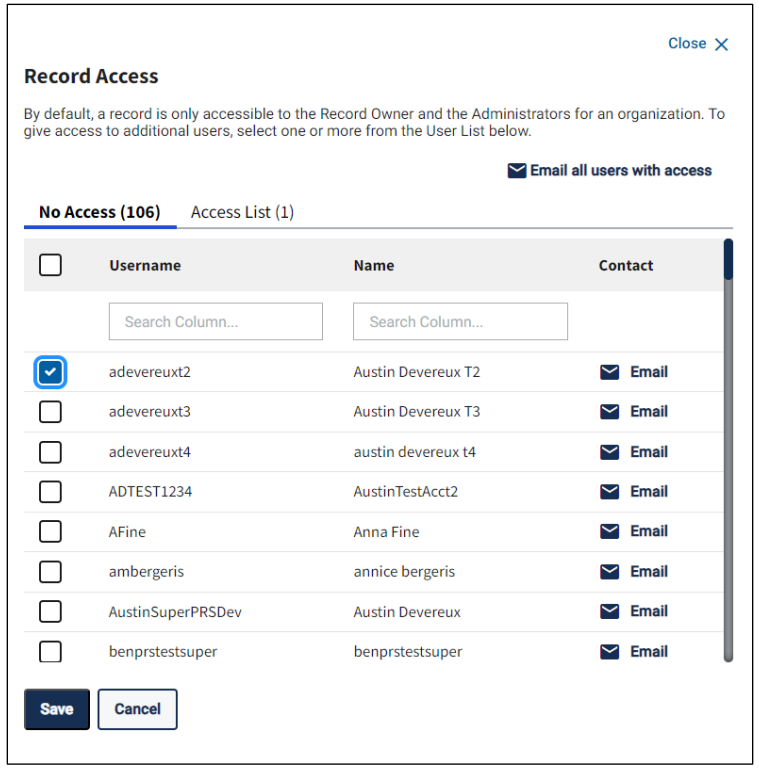


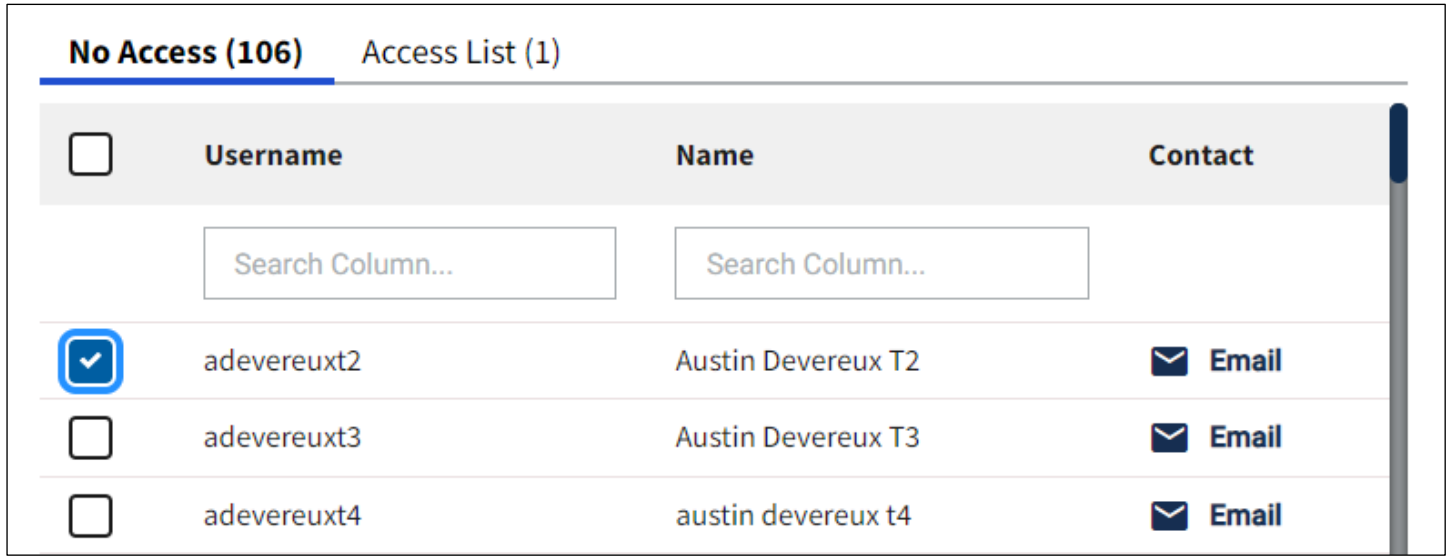
Feedback after the 1st Iteration

- 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





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.

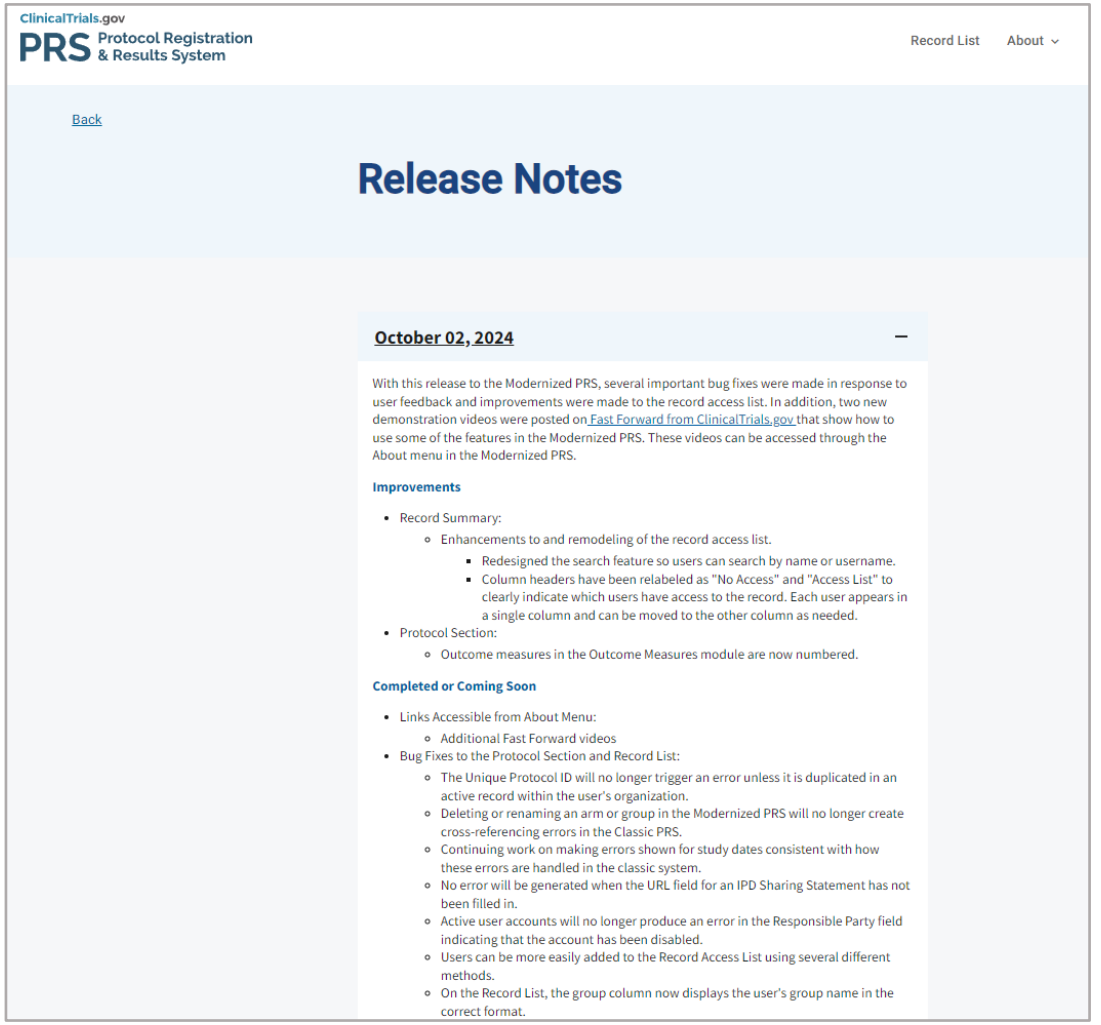
These figures represent comments/emails received during the 4 weeks following the August 28, 2024, release.

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.



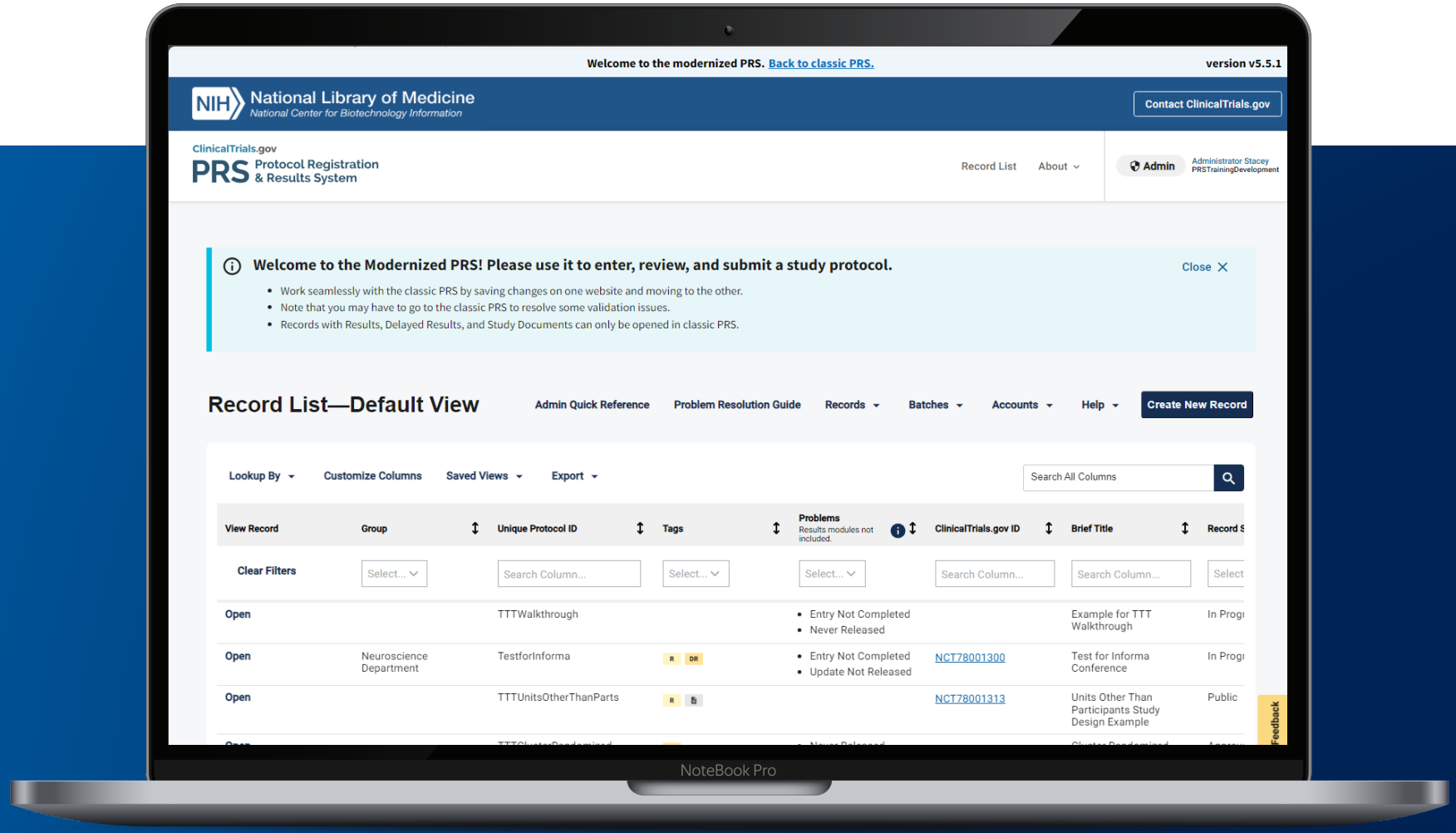
register.clinicaltrials.gov/prs/beta/public/release-notes-prod

Stacey Arnold
PRS Subject Matter Expert

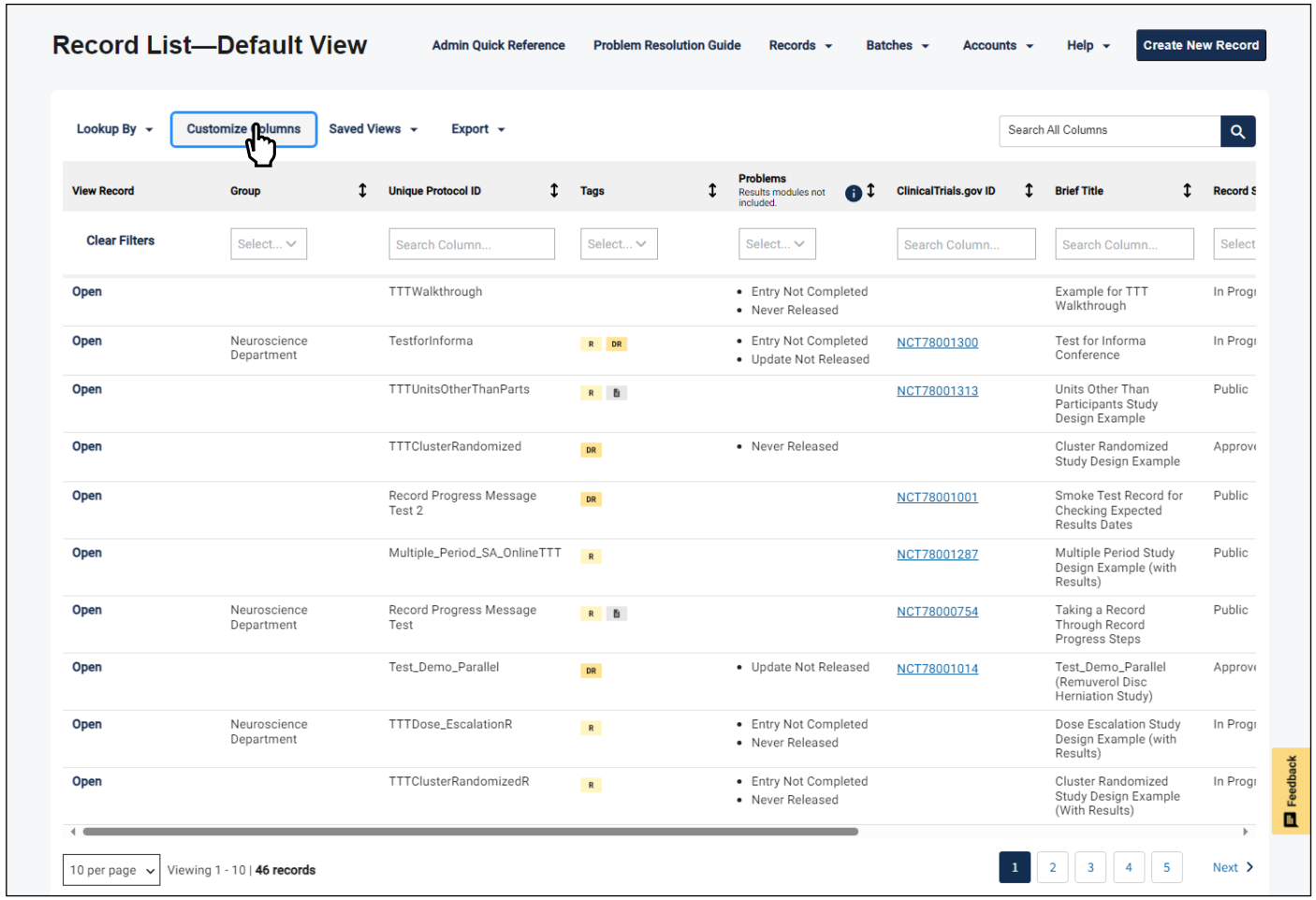
Navigating the Modernized PRS

NIH National Library of Medicine

Landing Page: Record List



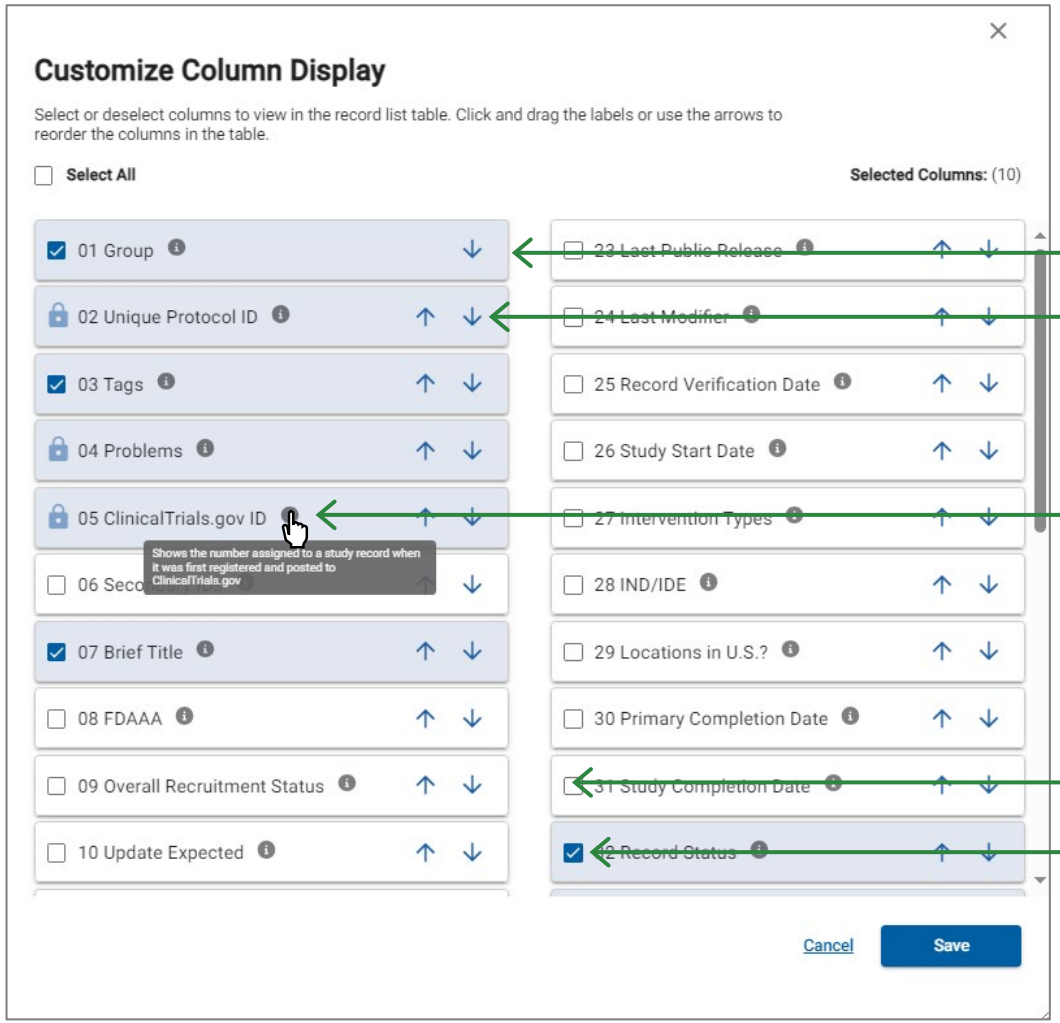
Record List: Customizing Columns



New Features of the Modernized PRS

- Ability to reorder columns

Record List: Customizing Columns (cont.)



Drag and drop with mouse

Move with up/down arrows

Click for information

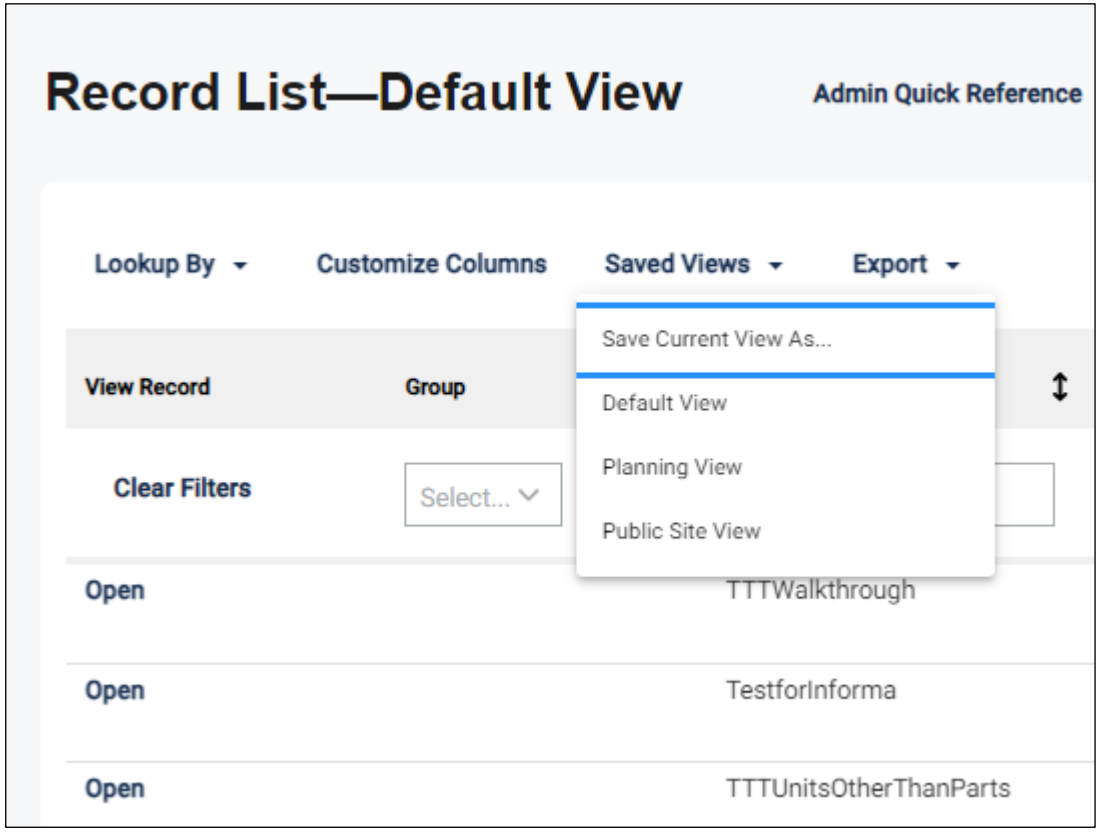
Deselect columns

Select columns

New Features of the Modernized PRS

- Ability to reorder columns

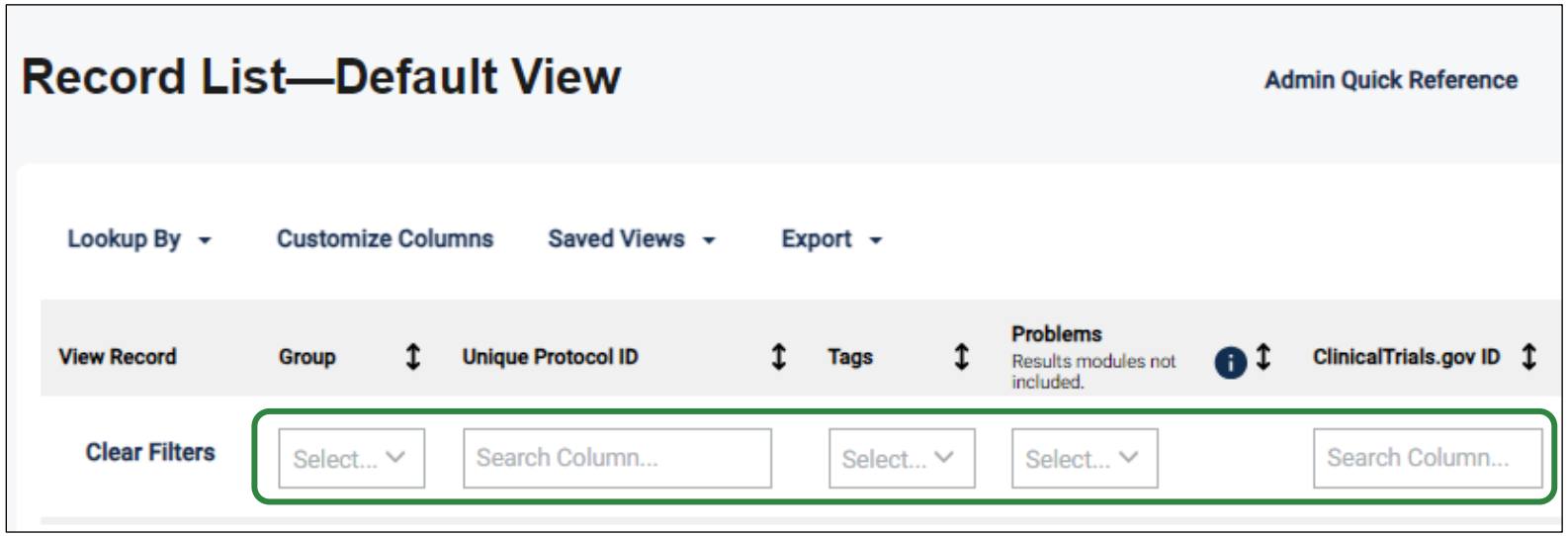
Record List: Saving Views



New Features of the Modernized PRS

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

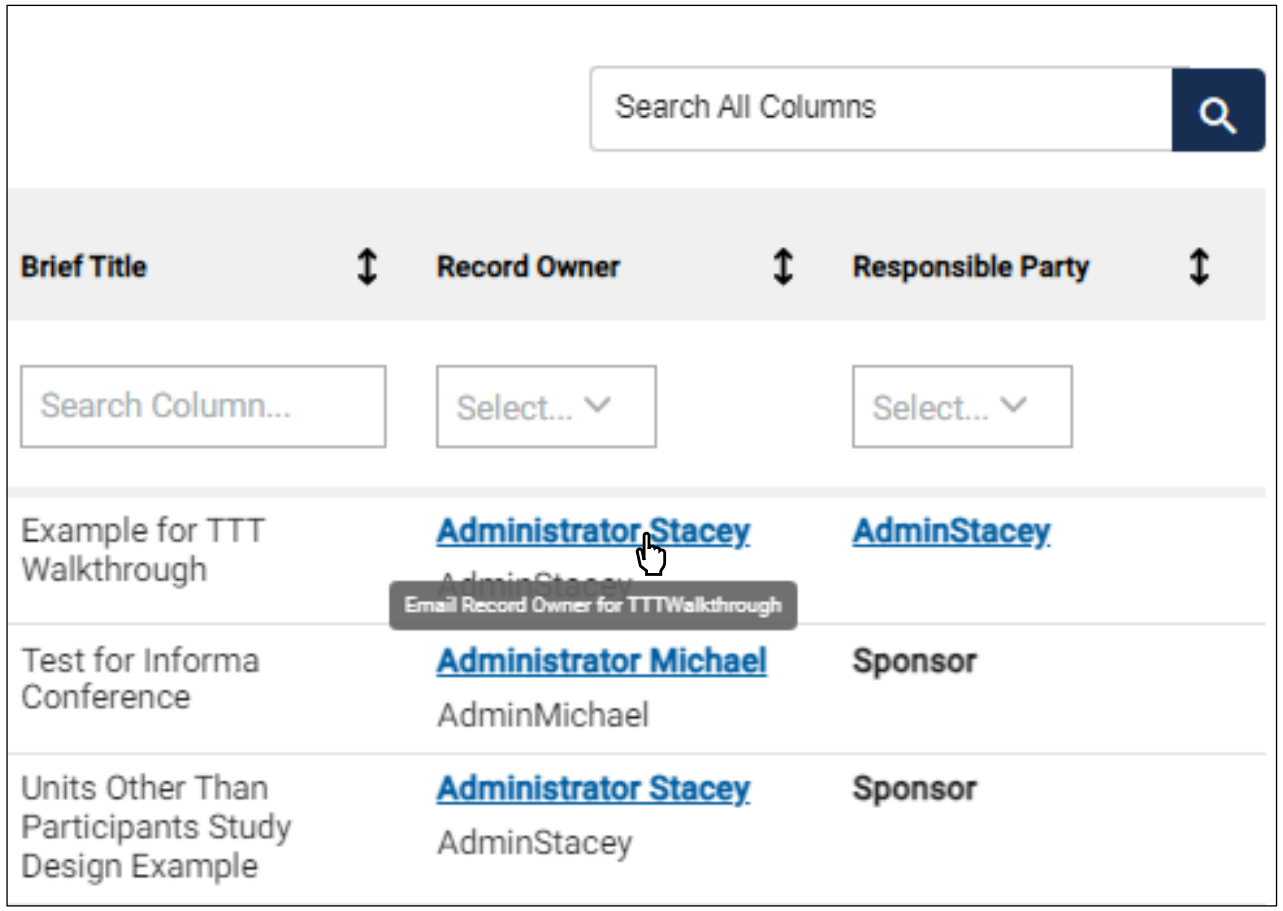
Record List: Filtering Columns



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

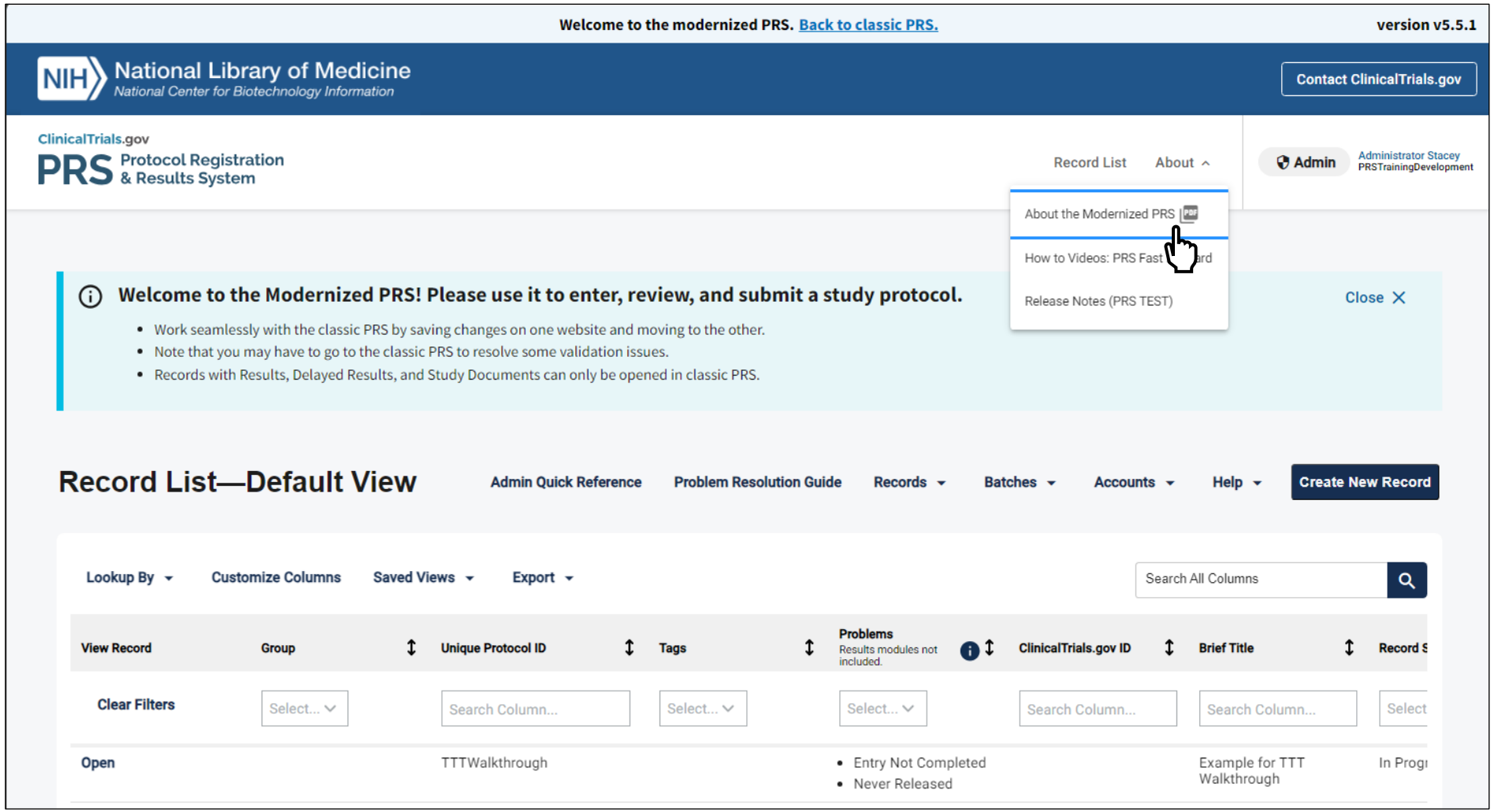
Record List: Sending Emails



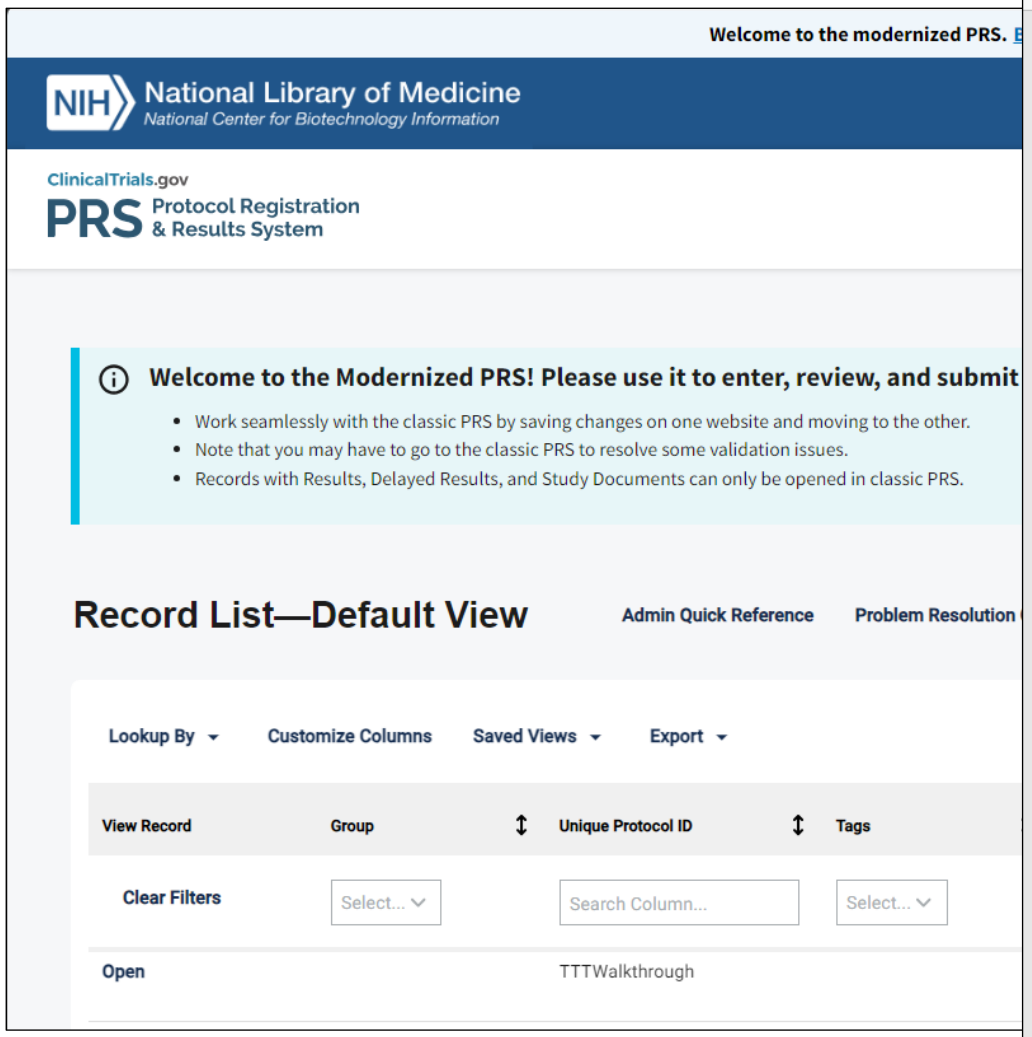
New Features of the Modernized PRS

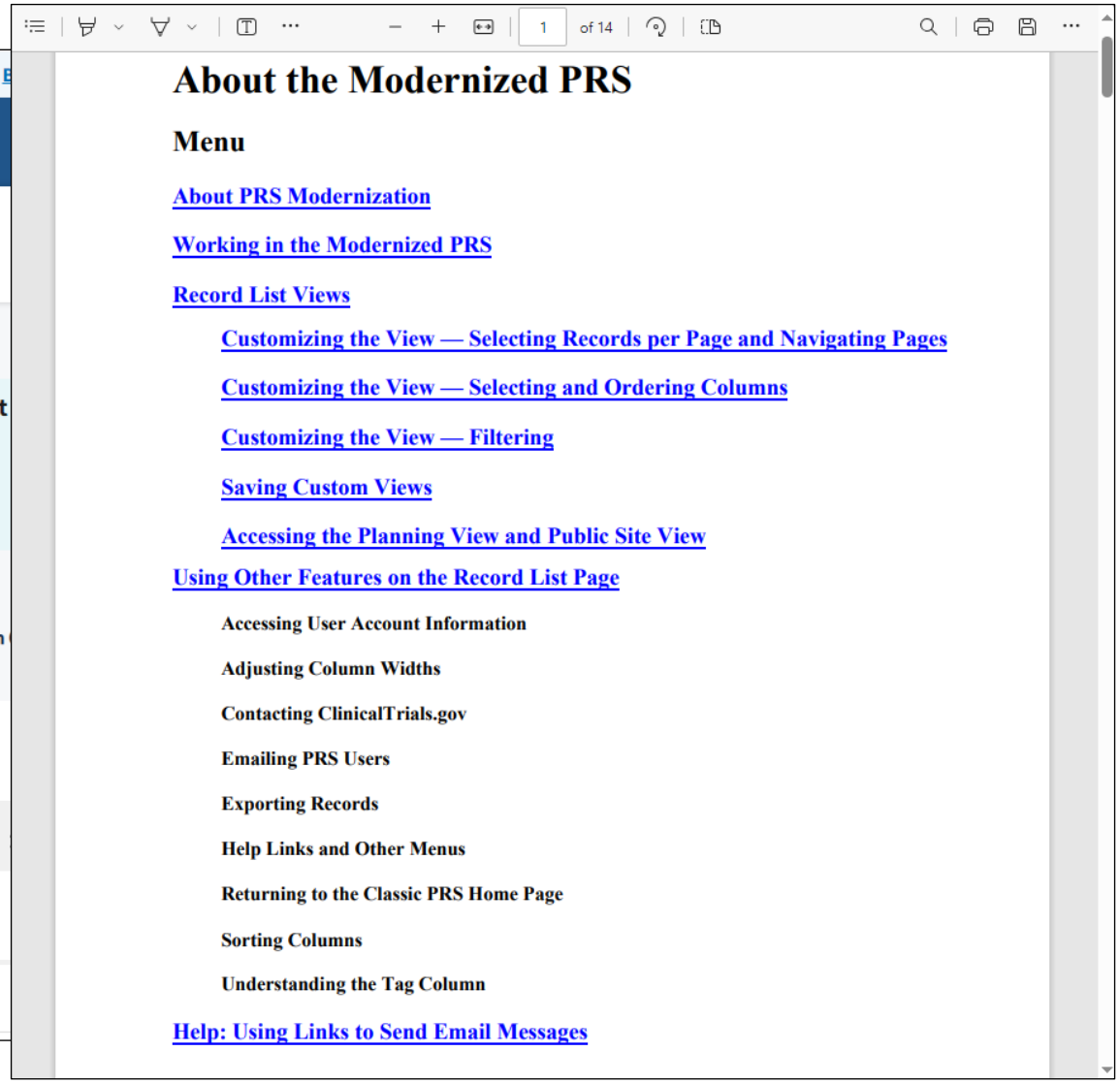
- Ability to reorder columns
- Ability to save views and access all views from a single location
- Ability to filter data in all columns
- Ability to click on names to send emails without having to open a record

About the Modernized PRS

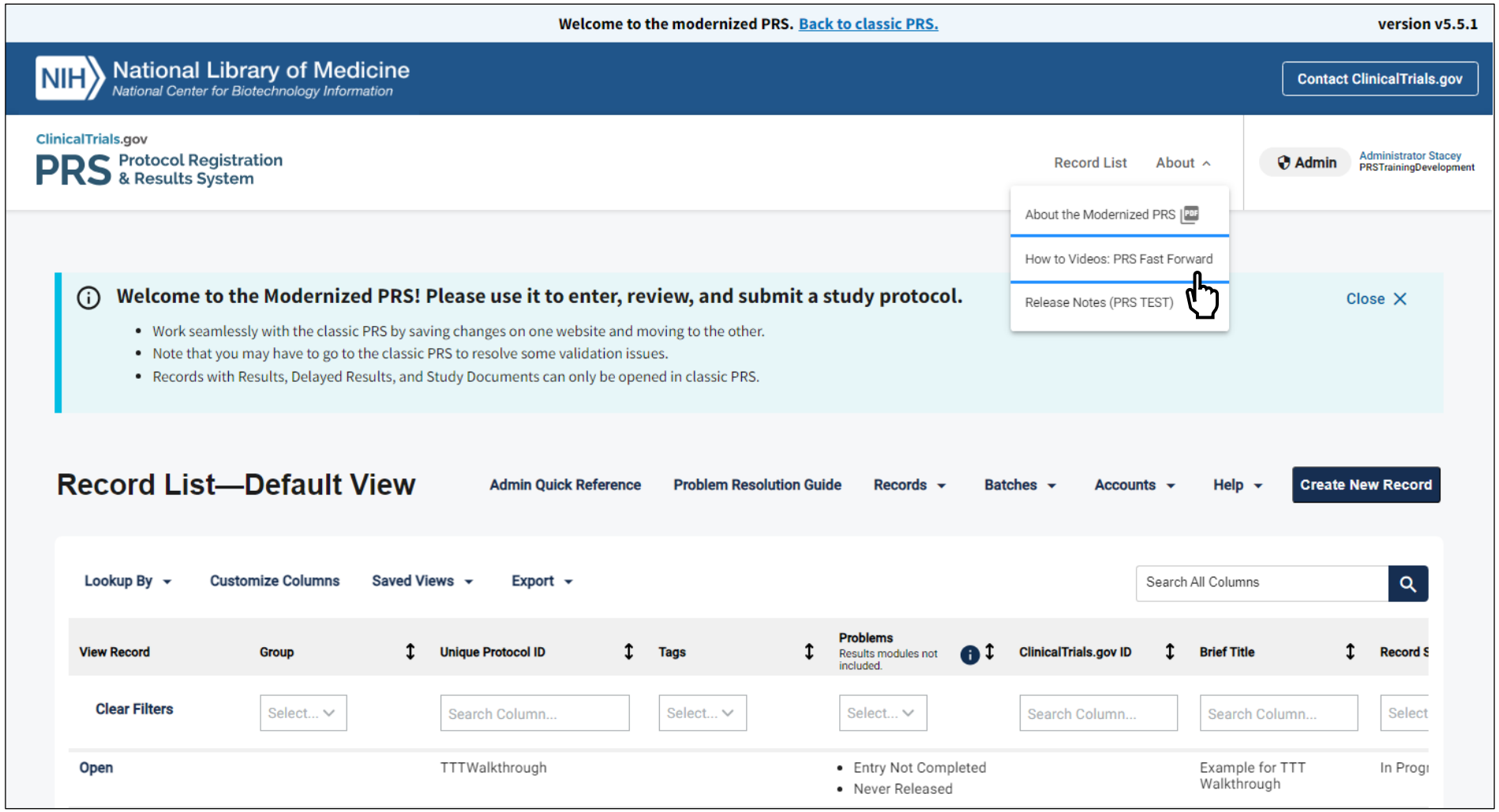


About the Modernized PRS (cont.)

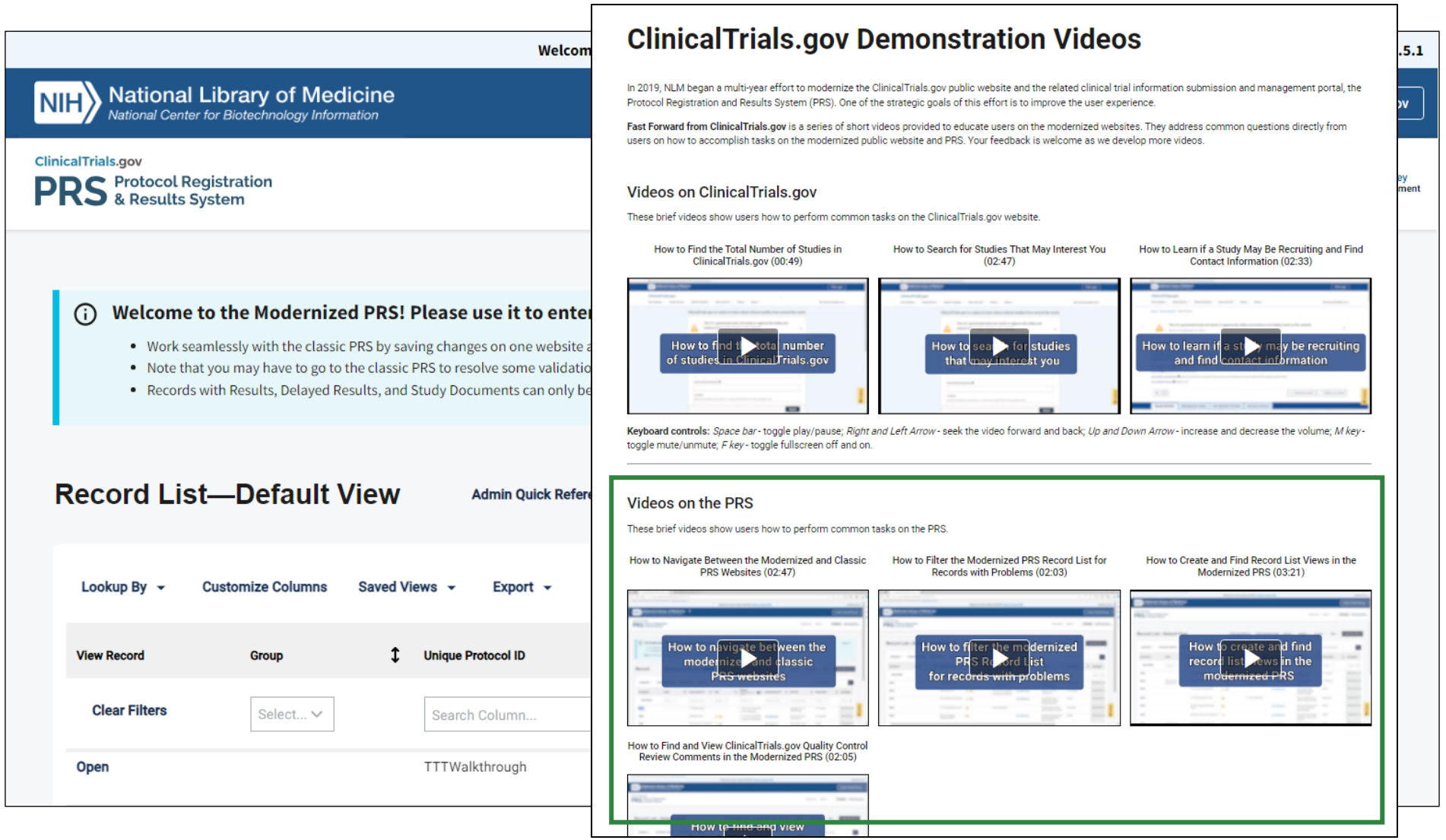




Fast Forward Videos



Fast Forward Videos (cont.)



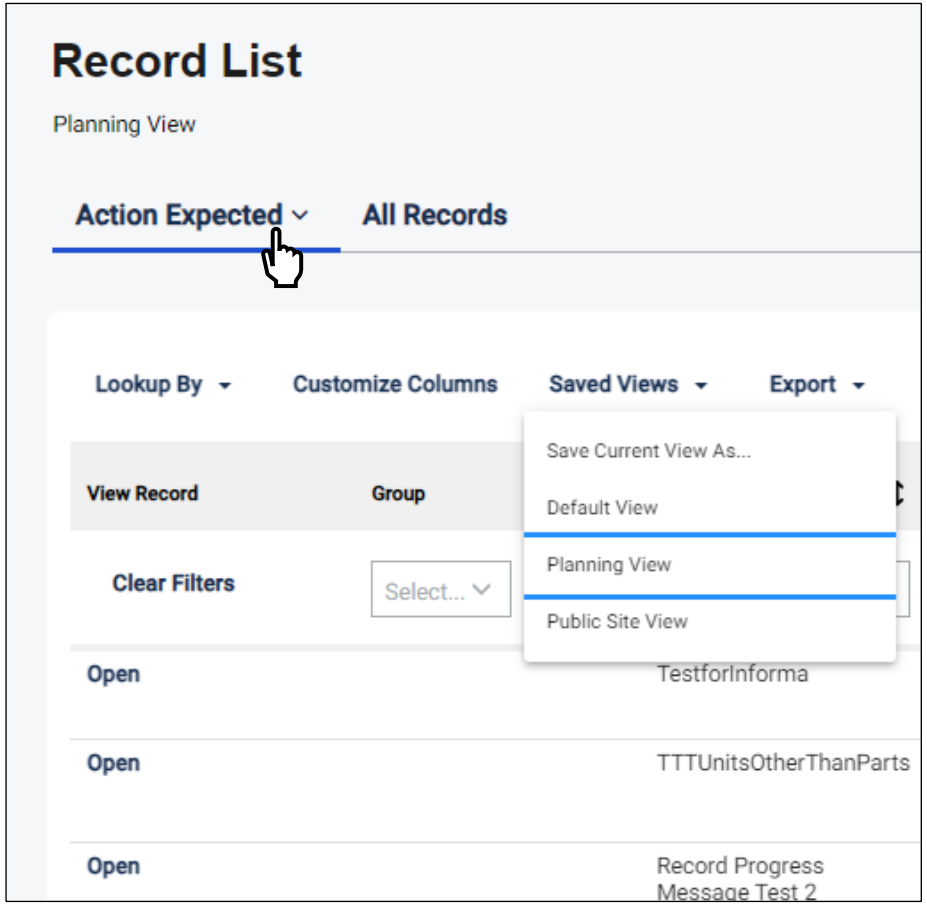
Fast Forward from ClinicalTrials.gov

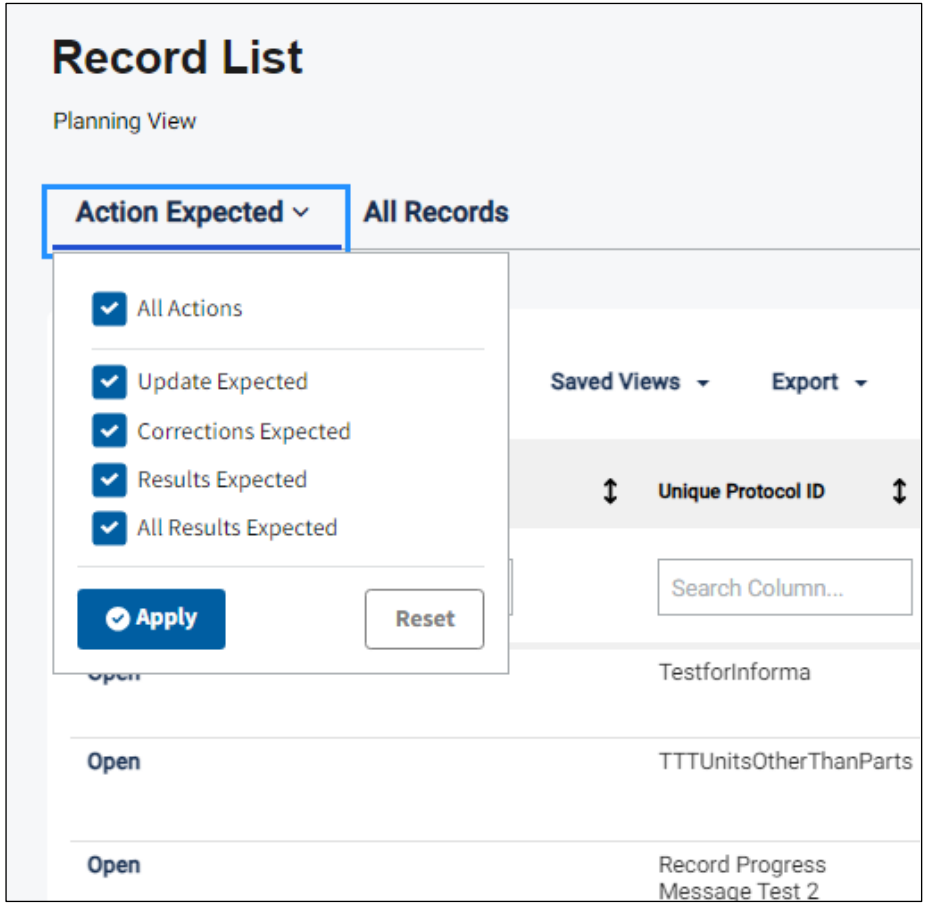
Series of videos that include tips for using the modernized PRS:

- 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

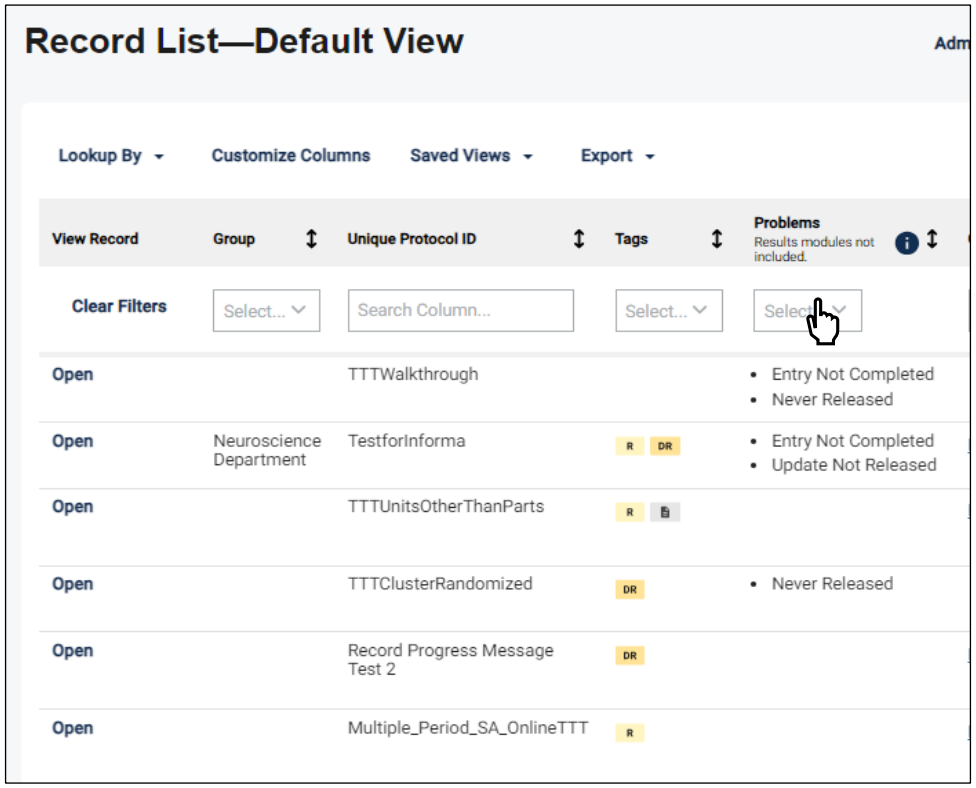
Demo Videos

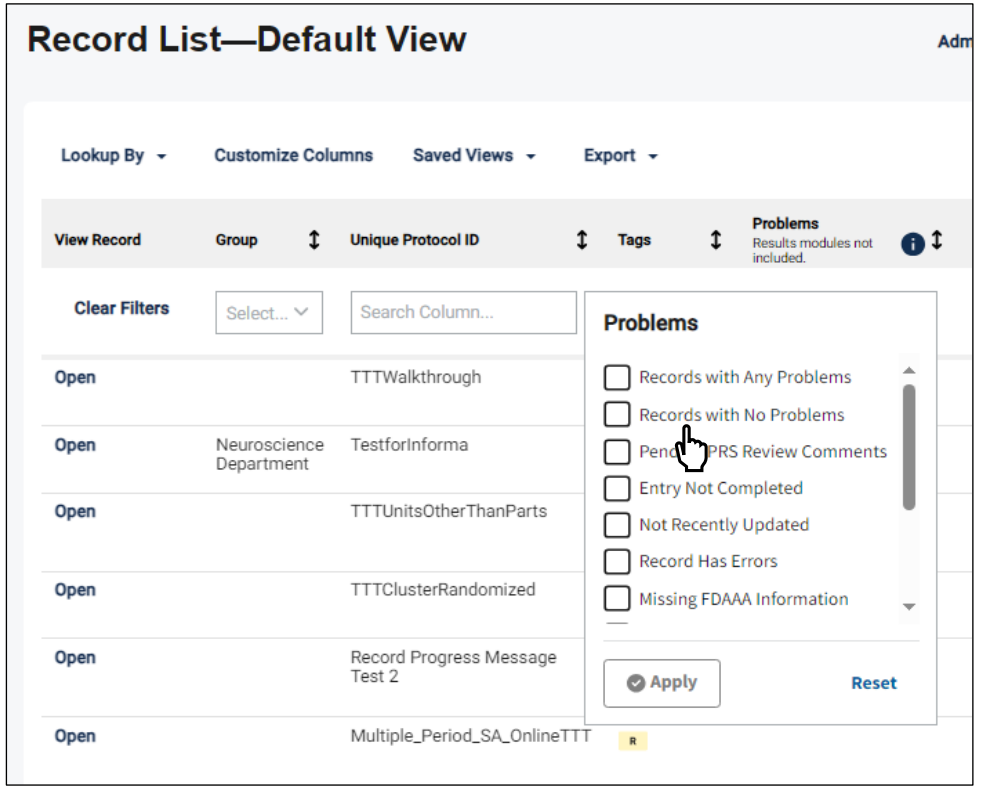
Action Expected and Records with Problems (1)

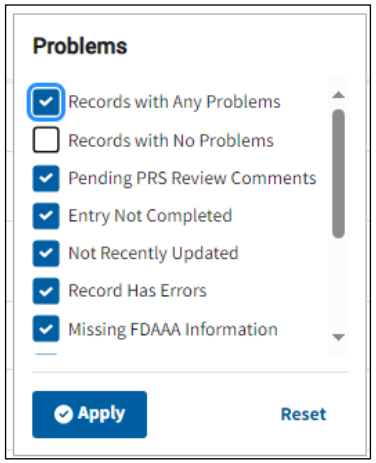




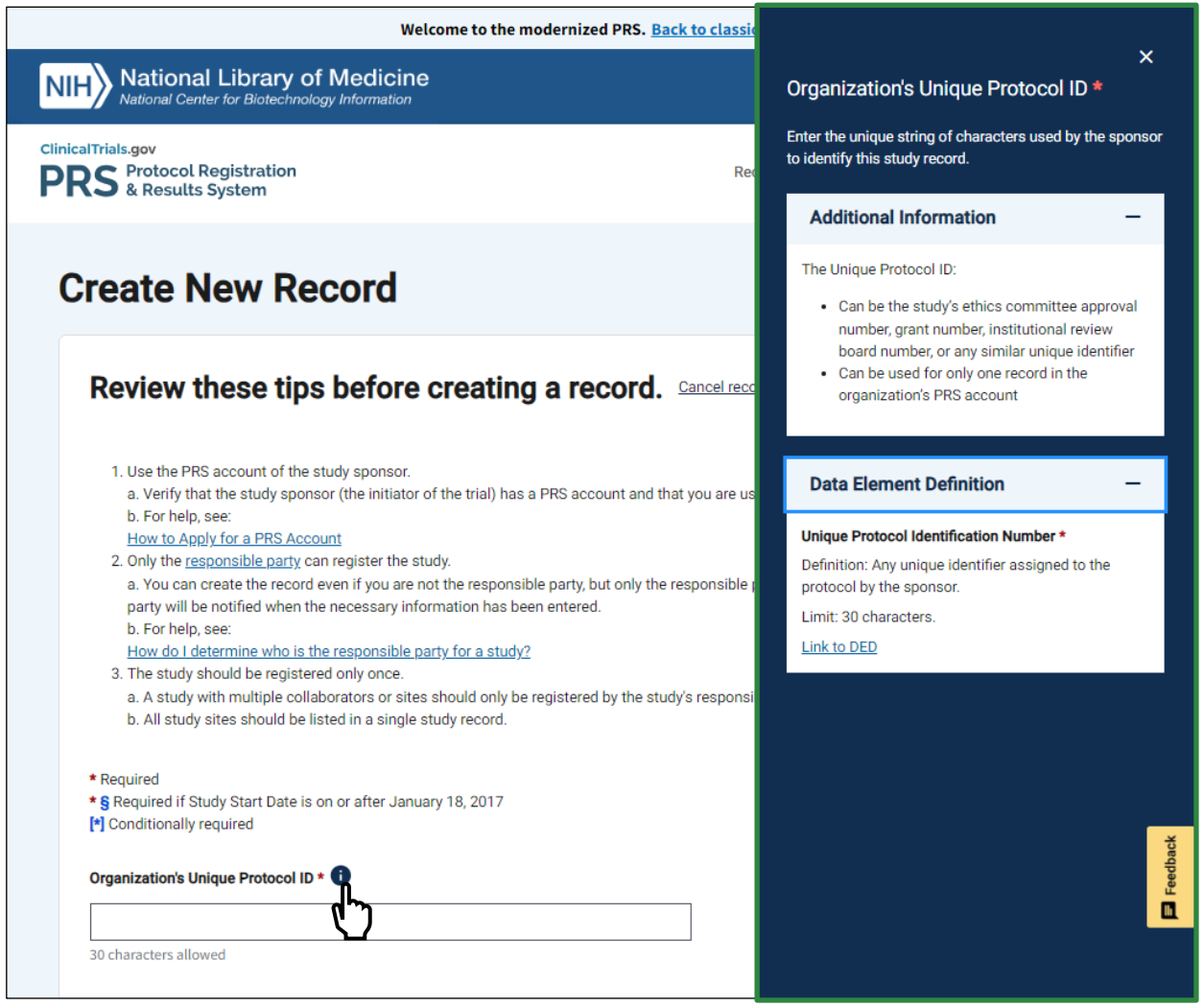
Action Expected and Records with Problems (2)







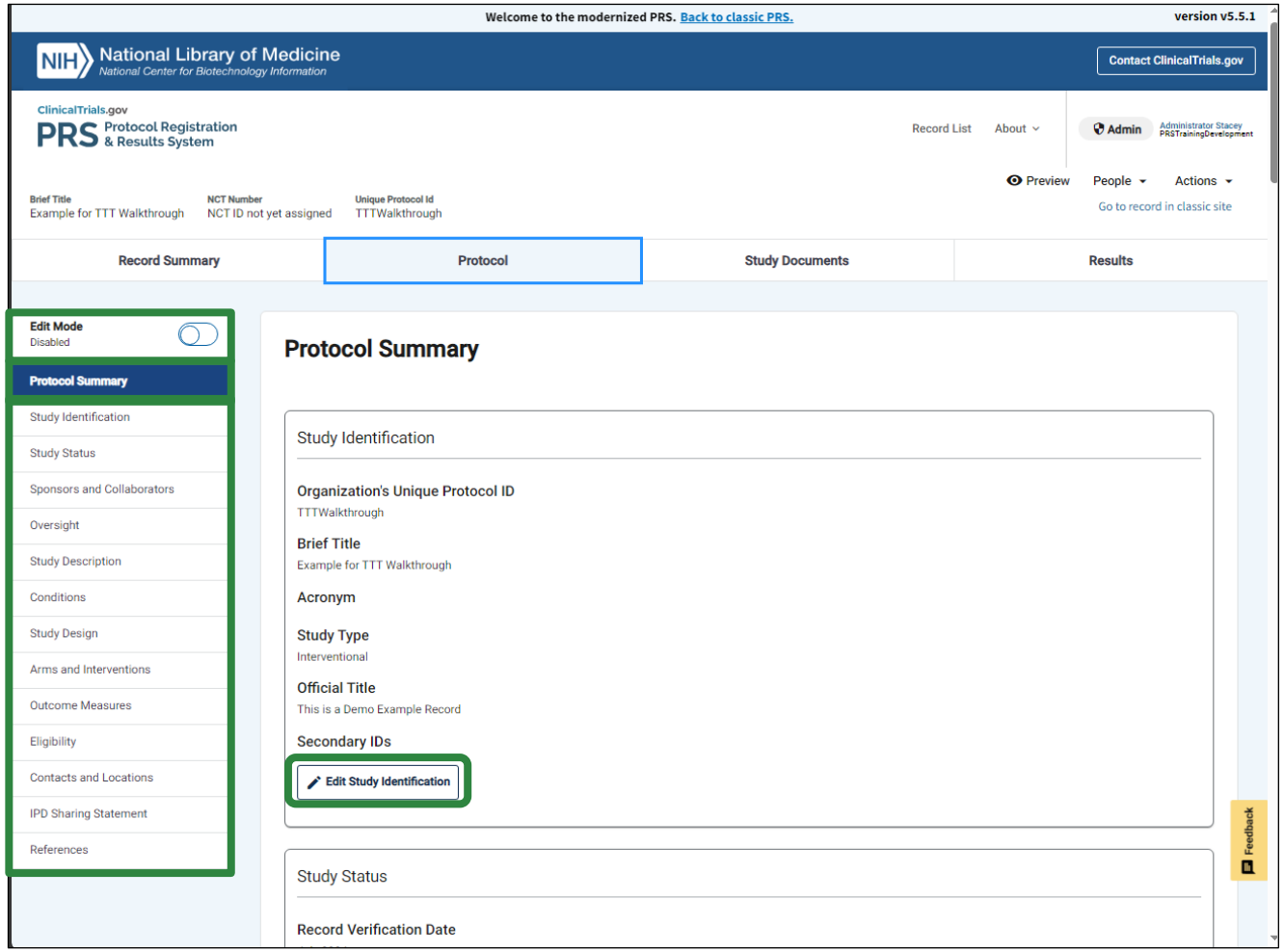
Help Drawer



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.

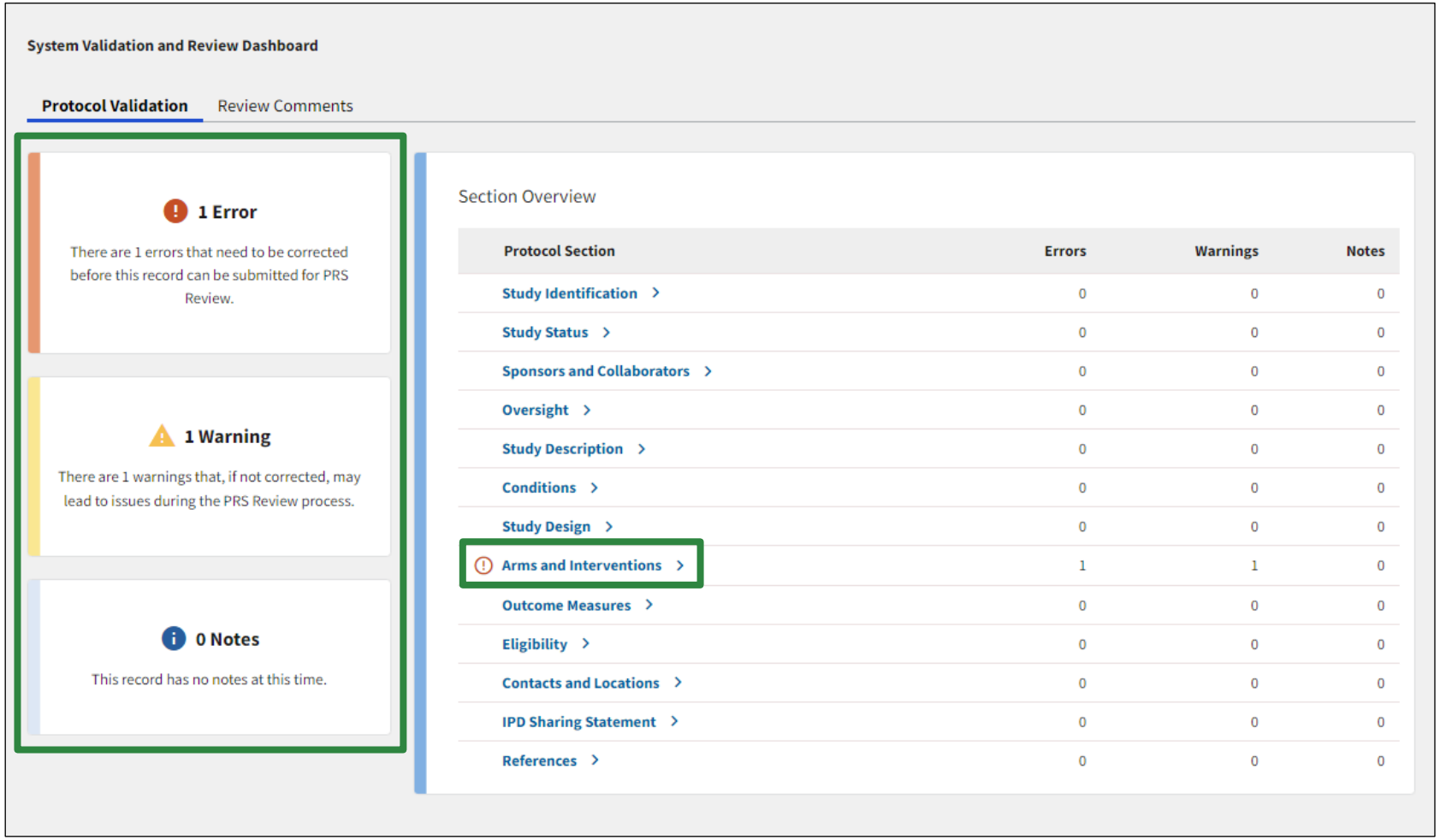
Side Panel Navigation



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.

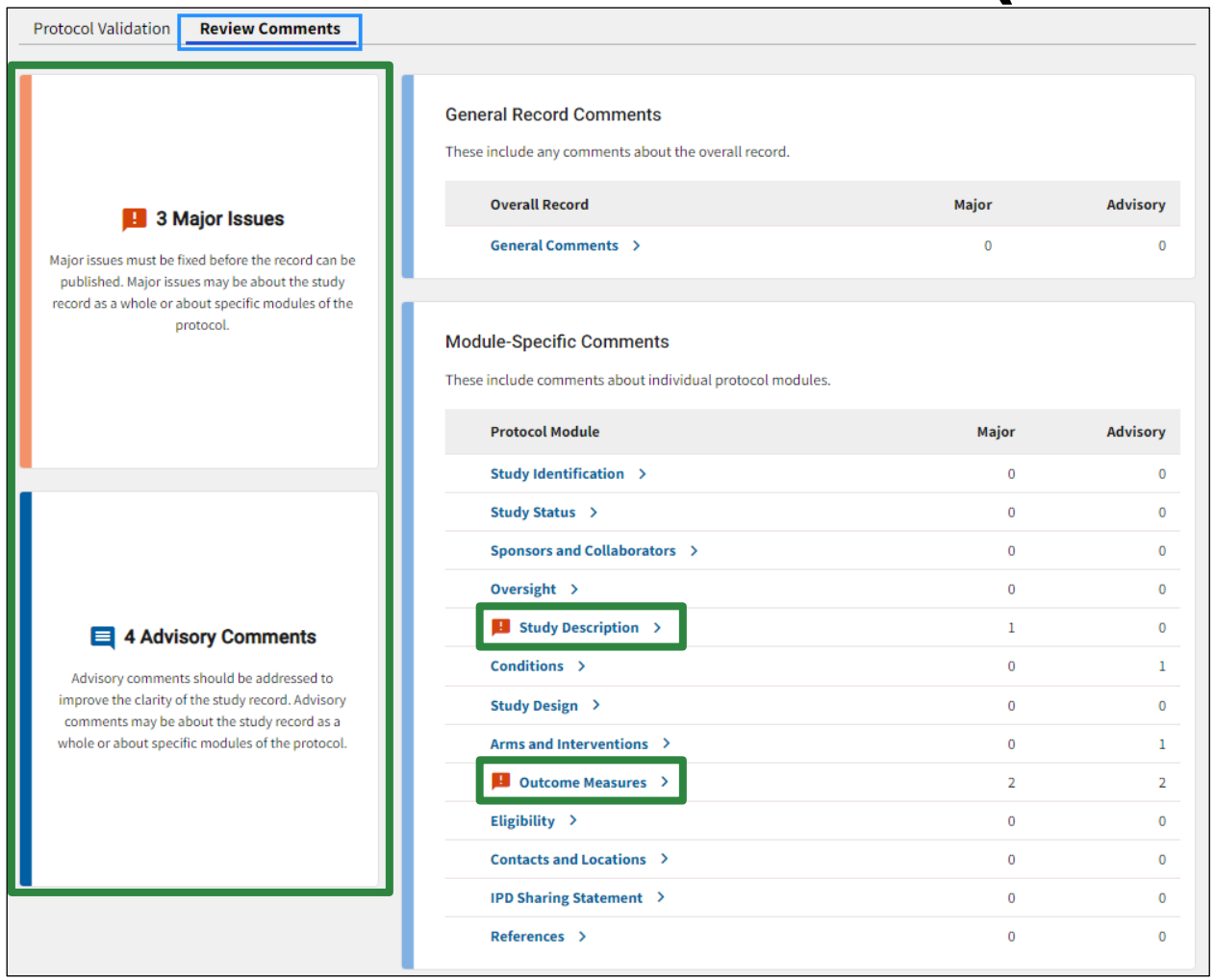
Record Summary: Validation and Review Dashboard



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.)



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

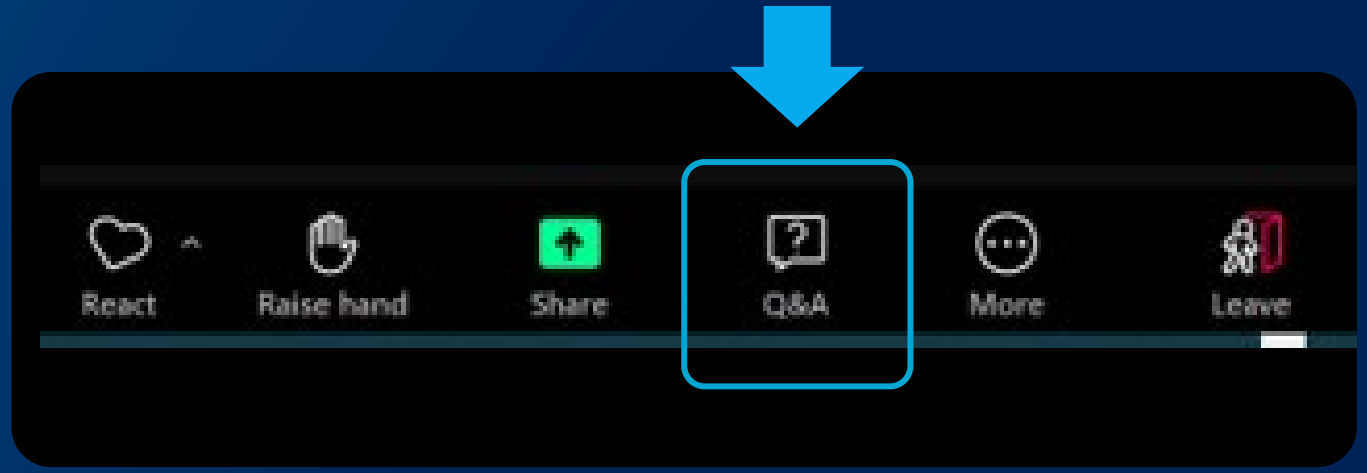
C. How to find information on the Record Summary page

D. Other

Moderated Q&A Instructions

We welcome your questions for our presenters.

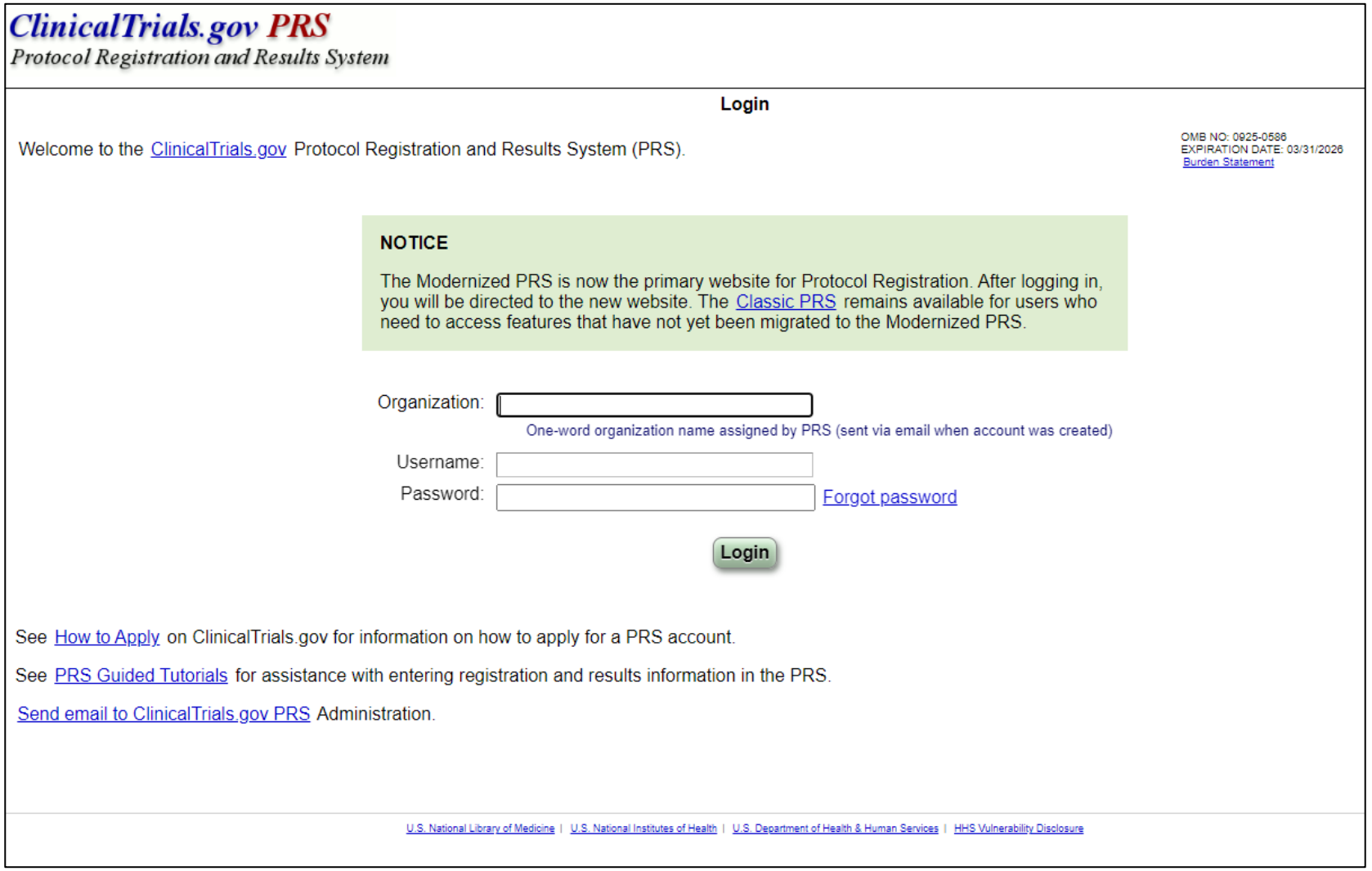
To bring up the Q&A box, click on the Q&A icon on your Zoom menu bar.



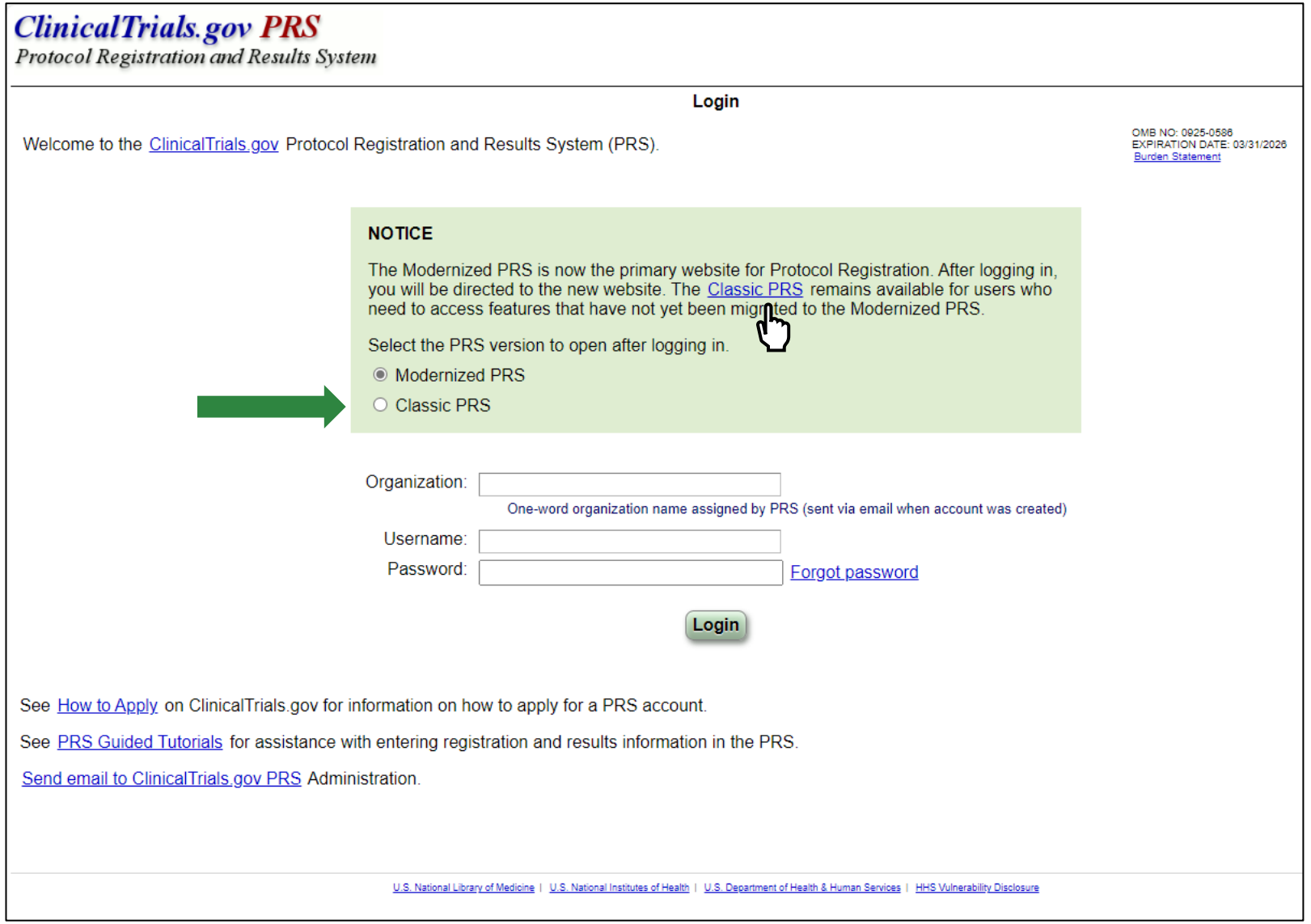
Key Takeaways

- 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



Classic PRS Log-in: Tip

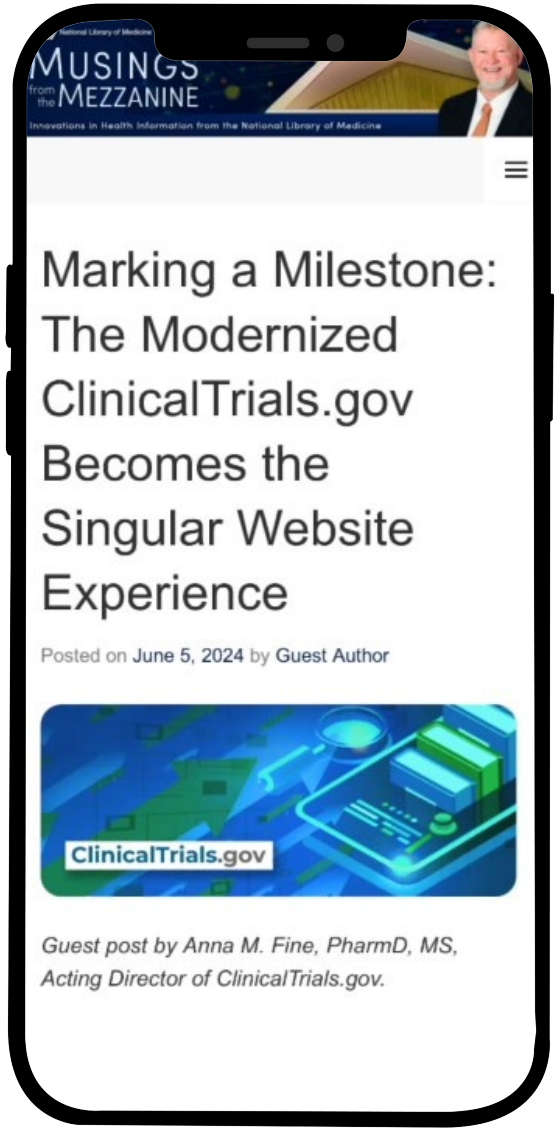


Communications

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

NIH National Library of Medicine



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?**

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

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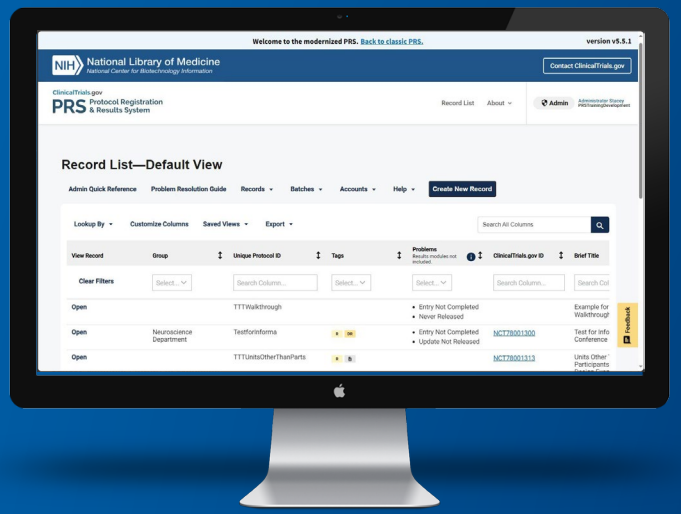
Attendees are asked to:

- 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