March 25, 2025

Volume 14, Issue 1

Clinical Research Newsletter

A Newsletter for Clinical Research Professionals

Announcements

- The Clinical Trials Office website has an informational page on ClinicalTrials.gov.
- Previous Clinical Research Newsletters and Brown Bag Sessions can be found on the CTO website.
- The research handbooks are accessible through LabArchives.

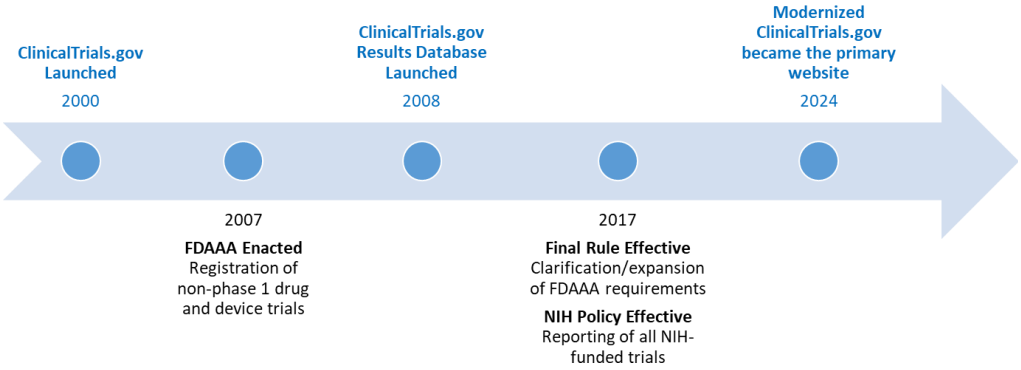
Clinical Trials Office, Columbia University

ClinicalTrials.gov: PRS Modernization Effort

ClinicalTrials.gov is a well-known clinical research registry and results database, providing patients, families, health care providers, researchers, and the general public with access to information on a wide range of clinical studies. Maintained by the National Library of Medicine (NLM) under the National Institutes of Health (NIH), this web-based resource includes records for over 530,000 clinical trials, observational studies, and expanded access programs.

ClinicalTrials.gov has grown considerably since launching in 2000, in terms of both the number of records and the scope of information it contains, in conjunction with key policy and regulatory requirements.

In August 2019, NLM initiated an ongoing effort to modernize the Protocol Registration and Results System or PRS (register.clinicaltrials.gov) as well as the ClinicalTrials.gov public site (www.clinicaltrials.gov) to ensure that ClinicalTrials.gov continues to be a trusted leading public health resource. The multiyear effort aims to deliver an improved user experience on an updated platform that will accommodate growth and enhance efficiency well into the future.

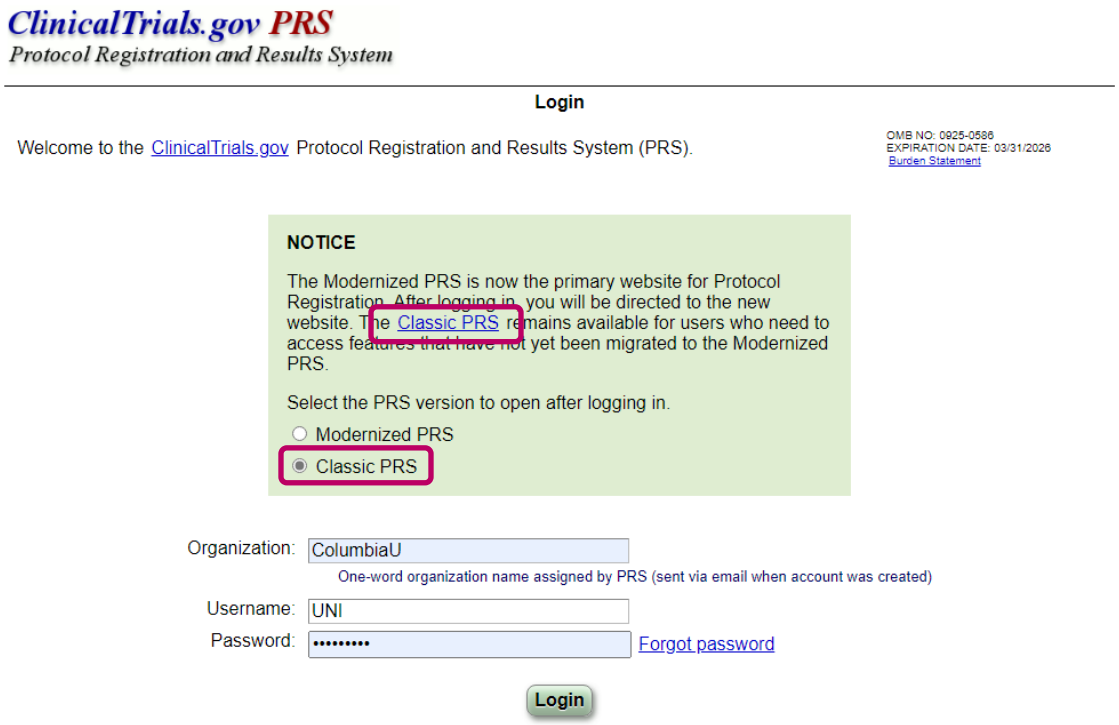


Since last year, registered users can choose to use the new website (**Modernized PRS**). The **Classic PRS** is still available and is recommended for registration, results reporting, and record release. During this transitional period, we are providing the FAQ below as NLM continues to release updates and refinements, conduct usability testing and evaluation to the PRS site until it can stand alone.

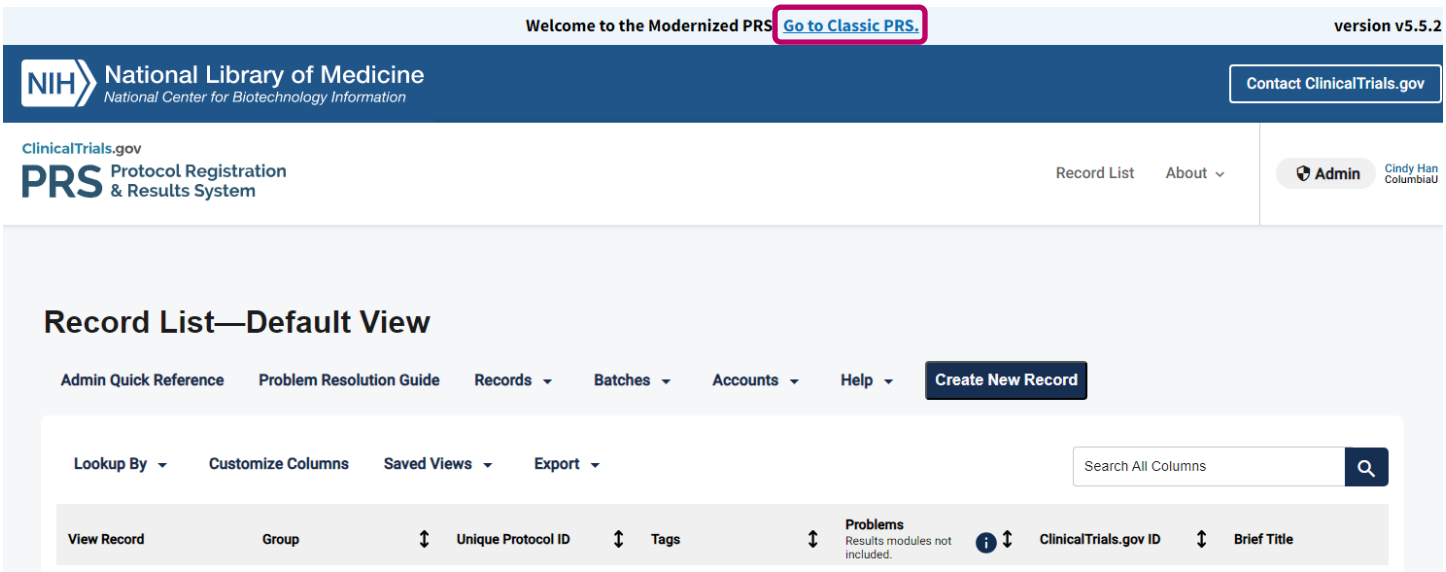
FREQUENTLY ASKED QUESTIONS

Can I still access the Classic PRS?

Yes. The Modernized PRS is now the primary website for Protocol Registration. However, the Classic PRS remains available for users who need to access features that have not yet been migrated to the Modernized PRS. On the PRS Login page, click the "**Classic PRS**" link within the green text box before you login (i.e., enter your organization, username and password). The green box will extend to show additional options, where you can select the PRS classic version to open straightaway (as **indicated** in the below image).



If you did not select "Classic PRS" upon login, you will be directed automatically to the new website. Another way to access the Classic PRS is to simply click on the link that says "**Go to Classic PRS**" on the top of the webpage (as **indicated** in the below image).



Why does the Modernized PRS display error messages that are not present in the Classic PRS?

Modernization of the PRS site is in progress and the NLM is continually refining and updating features. As updates are in progress, you may see **ERROR** messages in the Modernized PRS that prevent you from completing and releasing a record. At this time, the Classic PRS should be considered the "source of truth" and be used to register, maintain records, and enter results.

When will the Classic PRS be retired?

The Classic PRS will remain accessible until all features of the Modernized PRS are complete and functional. There is no set deadline for retirement of the Classic PRS, and the Classic PRS will be available through 2025 and possibly beyond.

Can I enter results in Modernized PRS?

The Modernized PRS now includes the first modules of the Results Section. Users can view and edit data in the "Participant Flow," "Limitations and Caveats," and "More Information" modules. The latest release also includes several fixes made in response to user feedback. The other results modules ("Baseline Characteristics," "Outcome Measures," and "Adverse Events") are still under development. Users can go to the Classic PRS to work on these modules and submit results. As a reminder, data entered and saved in either the Classic or Modernized PRS will be present in the other system.

Have registration and results reporting deadlines changed as a result of the Modernized PRS?

There have been no changes to the types of studies that require registration or the deadline by which the studies must be registered and results reported. Applicable Clinical Trials (ACTs) and studies subject to the NIH Policy require registration no later than 21 days following enrollment of the first participant. Results are due no later than one year from the primary and study completion date.

For investigators that hope to publish with a journal, based on the International Committee of Medical Journal Editors (ICMJE) policy, registration is required prior to enrollment of the first participant. We recommend ClinicalTrials.gov registration for any study type (observational, interventional, registry, etc.) if there is a desire to publish.

For more information, refer to Clinical Research Newsletter Volume 5, Issue 4.

HELPFUL RESOURCES

- Clinical Trials Office (CTO) ClinicalTrials.gov Informational Page
- Applicable Clinical Trial (ACT) Checklist
- Protocol Registration Data Element Definitions for Interventional and Observational Studies
- Modernization Overview
- Modernization Transition Top Questions

Please contact **PRS Help** at ClinicalTrialsGov@cumc.columbia.edu if you have a NIH -funded clinical trial that requires study registration and results reporting under the NIH policy.

Clinical Trials Office (CTO)

Our mission is to facilitate quality clinical trial research by providing the CU research community with comprehensive administrative services that help move trials quickly from initial proposal through contract execution. We also provide regulatory support for FDA-regulated research.

We're on the Web!

Visit us at:

https://research.columbia.edu/clinical-trials-office

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PRS Help:

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