

Top Questions and Answers about the Transition to the Modernized ClinicalTrials.gov and Modernized PRS

Responses to top questions about the transition to the modernized ClinicalTrials.gov website and the modernized Protocol Registration and Results System (PRS) are provided below.

Modernized ClinicalTrials.gov

1. When will the classic version of ClinicalTrials.gov be retired?

The <u>classic ClinicalTrials.gov</u> will be retired on June 25, 2024. At that time, the classic <u>application programming interface</u> (API), a tool to help researchers and developers access the data in ClinicalTrials.gov study records, will also be retired. Users should make every effort to familiarize themselves with the modernized website beforehand.

2. Is there a new API available to replace the classic API?

The classic API will be retired on June 25, 2024, and users should transition to the modernized API before then. An <u>API migration guide</u> is available to help users transition from the classic website's API to the modernized API. Additional support materials include documentation on the <u>Study Data Structure</u> and <u>Search Areas</u> pages of the modernized website.

As background, the application programming interface, or API, is a tool to help researchers and developers access the data in ClinicalTrials.gov study records. The <u>ClinicalTrials.gov API version 2.0</u> for the modernized website was finalized in February 2024 and has been updated several times since then.

3. I bookmarked pages on the classic ClinicalTrials.gov website. Will my bookmarks still work?

During the transition to the modernized ClinicalTrials.gov, regulatory and other informational content is being migrated from the classic website. After content is moved, users who try to view the information on the classic site will be automatically redirected to the equivalent information on the modernized site. Some of this content has been reorganized or restructured, but all the essential information is still there. As the remaining content is migrated to the modernized website, additional redirects will be put in place. Many bookmarks will still work after the classic website has been retired, although there may be occasional broken links. Content migration will be completed before the classic website is retired on June 25, 2024. Please use this time to update your bookmarks.

4. Are the search results on the modernized and classic ClinicalTrials.gov websites the same?

As a result of improvements to the ClinicalTrials.gov search function, search results are not the same on the modernized and classic websites; the modernized website's search results are more targeted and refined. This is due to significant differences between the search algorithms for the two websites, resulting in a different number of results being returned for the same search. Examples of the differences in the search logic include the following:

- With the modernized website's search logic, synonym recognition is more precise.
- On the modernized website, if a location and distance are specified on the search form, the search results will be biased by proximity to the closest location for every study.

We created a <u>Search Areas</u> guide that describes the differences between the search logic for the classic website and the modernized website. Please see this guide for more examples like these.

5. When the classic ClinicalTrials.gov website is retired, will I see my favorite features on the modernized ClinicalTrials.gov website?

Many features of the classic website are now available on the modernized website, including the search function, study record details, the ability to download study results in CSV and JSON formats, a modernized API, the ability to save studies, and the ability to create an RSS feed to save searches. Before the classic website is retired, all relevant content will be migrated, and the record history will be updated so that users can compare versions of a study record. After the classic website is retired, we will continue to improve features of the modernized website and, potentially, add new features. User feedback and usage information will inform decisions about which additional features will be completed and in what order. To learn about the latest updates to the modernized ClinicalTrials.gov, please visit the Release Notes page.

6. Can I save my search?

Yes, the modernized ClinicalTrials.gov provides an RSS feed, which allows users to save a search from the search results page. Alternatively, users can save and download individual studies from their searches. More detailed instructions are available on the modernized website.

7. Will the information about the Final Rule (42 CFR Part 11) currently located at https://prsinfo.clinicaltrials.gov continue to be available?

All the information and documents found on the Final Rule (42 CFR Part 11) Information page (https://prsinfo.clinicaltrials.gov) have been incorporated into the modernized ClinicalTrials.gov website for convenience and ease of access. This includes resources on formatting and submitting studies and results, information on PRS accounts, regulatory information, and the protocol registration and results data element definitions. As of June 25, 2024, users will be automatically redirected from https://prsinfo.clinicaltrials.gov to the relevant page on the modernized ClinicalTrials.gov website. Please make sure to update your bookmarks and links to the new URLs.

Modernized PRS (PRS Beta)

1. What features are available in the modernized PRS?

Currently, users can complete the entire protocol registration process and submit the Protocol Section of a study record to ClinicalTrials.gov for review using the modernized PRS. Users can control who can access a record and email others with record access directly from the modernized PRS Record List, as well as copy and download the Protocol Section of their records. PRS Administrators can access the Planning View and Public Site View to manage records, and reviewers can add, edit, and delete comments on protocol registration records directly in the modernized PRS.

2. If I'm working in the classic version of the PRS, will my updates also appear in the modernized PRS?

Yes. Any information entered and saved in one version of the PRS will be available in the other, so your work will be accessible in either version and will not be lost. For example, you can make changes to a record using the modernized PRS, and those changes will also be saved in the classic PRS. We encourage data submitters to use the modernized PRS to work on real study records as much as possible.

3. Can PRS users switch between the modernized PRS and the classic PRS?

Yes, users can switch between the modernized PRS and the classic PRS. To access any functionalities that are not yet available in the modernized PRS, users will need to return to the classic PRS. Any changes users make using either the classic or modernized PRS will appear in both. Please note that users should save their work *before* switching between the two versions of the PRS.

4. Currently, how many records can users view and export information about using the modernized PRS?

Users can view and export columns of data for all of the records associated with their account in the modernized PRS.

5. When will the modernized PRS be completed?

Development of the modernized PRS is continuing in 2024 as we build tools to submit study results and to view the record history and status. These features will tentatively be released later this year, and we will communicate the progress made on the modernized PRS as releases occur (for example, through the <u>Release Notes</u> page and the <u>Hot Off the PRS!</u> e-bulletin).

6. How soon will the modernized PRS become the primary site?

During summer 2024, users will see the Record List of the modernized PRS when they first log in. Users will be able to submit their protocol registrations using the modernized PRS, but they will need to return to the classic PRS to complete their results submissions and to use other features, such as the protocol upload and account management, that are not available in the modernized PRS yet.

7. When will the classic PRS be retired?

The classic PRS will remain available until all components of the modernized PRS have been built and are fully functional. The timeline for retiring the classic PRS has not been determined yet, but retirement will not occur before 2025.

8. Can I practice using the modernized PRS before using it to submit my study record?

Features of the modernized PRS are first deployed in PRS Test, a sandbox environment where users can log in to explore features and practice registering a clinical trial. PRS Test is for training purposes only, and any changes made in PRS Test will not affect the actual PRS system. We encourage users to explore and become familiar with the modernized PRS using the PRS Test environment. If you need a PRS Test account, please contact us at register@clinicaltrials.gov.