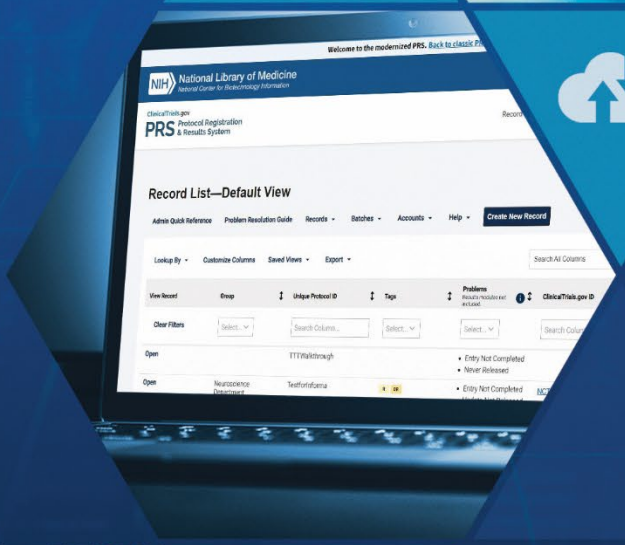
Report on the ClinicalTrials.gov Modernization Effort

Summary of Progress: 2023–24

November 2024



NIH National Library of Medicine

ClinicalTrials.gov

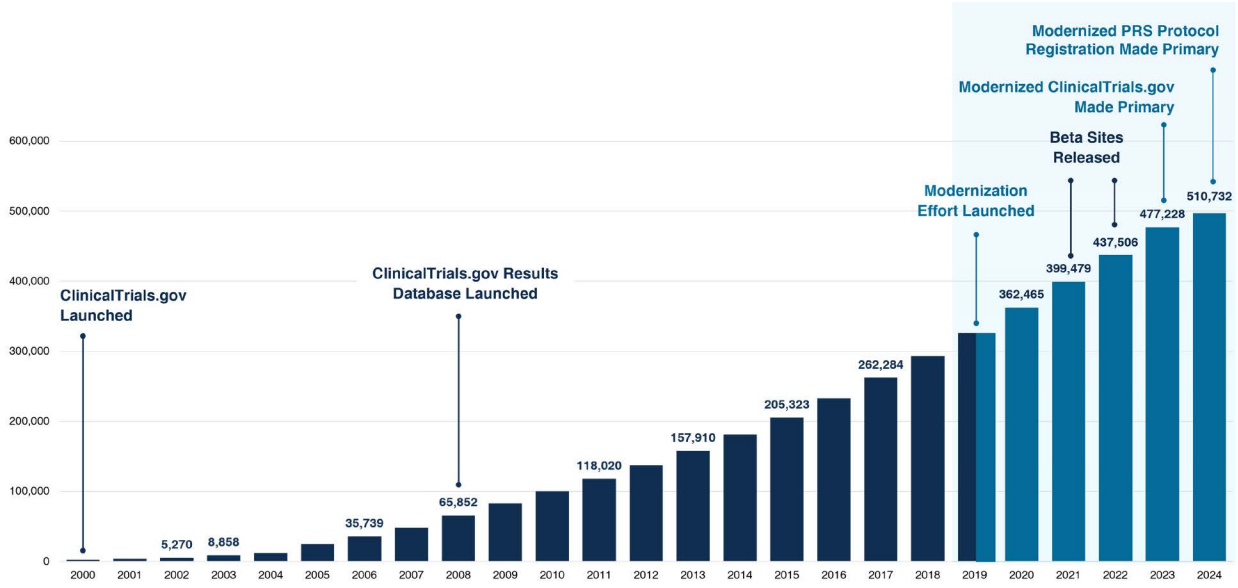
Contents

1. Introduction

Overview of ClinicalTrials.gov and the Modernization Effort

ClinicalTrials.gov, the world's largest public clinical research registry and results database, provides patients, families, health care providers, researchers, and others with access to information on a wide range of clinical studies. Operated by the National Library of Medicine (NLM), a component of the National Institutes of Health (NIH), this web-based resource includes records for over half a million clinical trials, observational studies, and expanded access programs. More than 113,000 visitors use the website daily to find and learn about clinical studies. Launched in 2000, ClinicalTrials.gov has grown considerably, in terms of both the number of records and the scope of information it contains, in conjunction with key policy and regulatory events (figure 1).

Figure 1. Total number of study records posted per year on ClinicalTrials.gov and timeline of related major events, from February 29, 2000, to September 30, 2024



In August 2019 NLM initiated an effort to modernize the ClinicalTrials.gov public website and components of the Protocol Registration and Results System (PRS) to ensure that ClinicalTrials.gov continues to be a trusted premier public health resource that provides maximum value to the public well into the future. The approach to modernization involves three key activities: stakeholder engagement, product development, and technical infrastructure enhancements. The multiyear effort aims to deliver an improved user experience on an updated platform that will accommodate growth and enhance efficiency.

Overview of the 2023–24 Modernization Summary Report

This report, the fourth and final report on the full modernization effort, provides a summary of the ClinicalTrials.gov modernization effort from October 2023 to September 2024. It

presents an update on the modernized ClinicalTrials.gov public website, which replaced the classic ClinicalTrials.gov public website upon its retirement in June 2024; development of the Modernized PRS (formerly PRS Beta); progress on modernization's strategic goals; stakeholder input received during the reporting period; the modernization communication strategy; research undertaken to support the modernization effort; and future modernization activities.

Early in this effort, we adopted three strategic goals that defined the desired outcomes, or effects, of modernization: (1) Clinical trial information is current, complete, and reliable; (2) Anyone can easily find and use information about clinical trials; and (3) Trial information, resources, and tools provide value to the research ecosystem. These goals have helped structure the efforts of the ClinicalTrials.gov team members involved in modernization, who are listed in appendix A. The abbreviations used in this report are listed in appendix B. More detailed information about the history of ClinicalTrials.gov and the first four years of the modernization effort can be found on the ClinicalTrials.gov modernization page.

In August 2024, PRS Beta became the Modernized PRS and the default website for protocol registration. This transition made it easier for users to test the website and provide feedback on performance and usability of the modernized website. This feedback is essential to the continued development of the Modernized PRS.

Current Phase of the Modernization Effort

The multiyear effort to modernize ClinicalTrials.gov began in 2019 and will continue through 2025 (figure 2).

Figure 2. ClinicalTrials.gov modernization milestones, by year

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

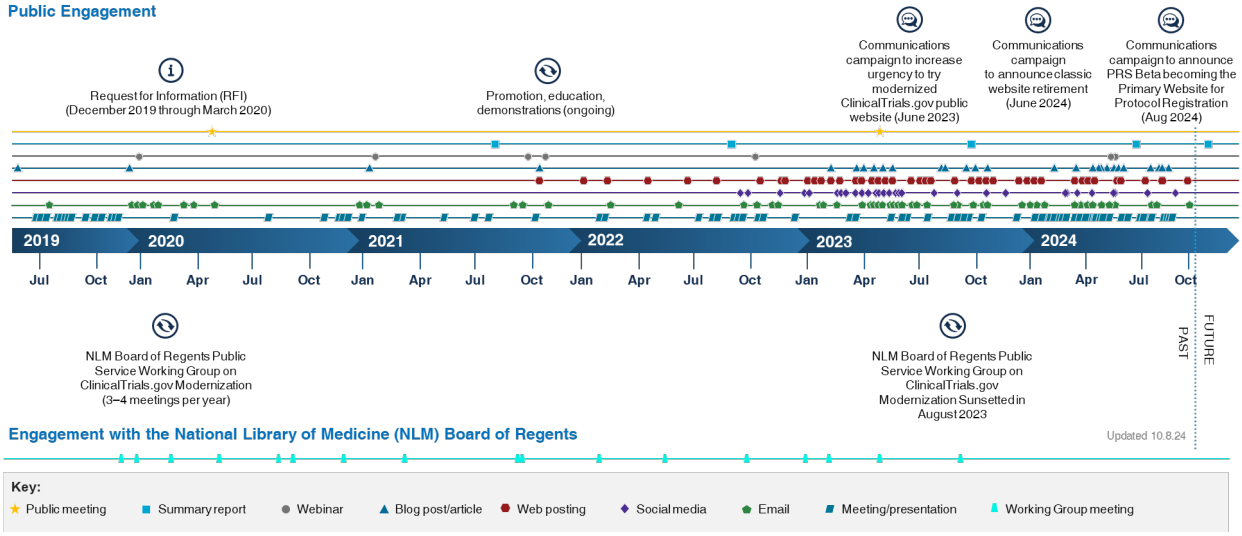
YEAR 4 (FY 2023)
Releases and Refinements
- Launched the Modernized ClinicalTrials.gov website

YEARS 5–6 (FY 2024–25)
Launches and Landings
- Retired the classic ClinicalTrials.gov website on June 25, 2024
- Launched the Modernized PRS Protocol Registration on August 28, 2024

In years 1 and 2, NLM prioritized engagement and development, conducting broad stakeholder engagement activities and focused user research; assembling cross-functional Agile modernization teams; and establishing the foundation for an updated technical infrastructure. Year 2 culminated with the launch of the first release of ClinicalTrials.gov Beta. Year 3 marked the launch of PRS Beta and a focus on the implementation of both beta site experiences, while stakeholder engagement and user research activities and updates to the technical infrastructure continued. All the activities that occurred during years 1–3 to identify stakeholder needs and the work to develop an iterative, user-centered design came together in year 4 as the modernized ClinicalTrials.gov became the primary website and assumed the main URL (https://ClinicalTrials.gov/) in June 2023 and updates to PRS Beta continued to be released. The main achievements of year 5 were more updates and refinements, further user testing and stakeholder engagement, the retirement of the classic ClinicalTrials.gov public website, and the launch of the Modernized PRS protocol registration and protocol quality-assurance (QA)/quality-control (QC) functionality.

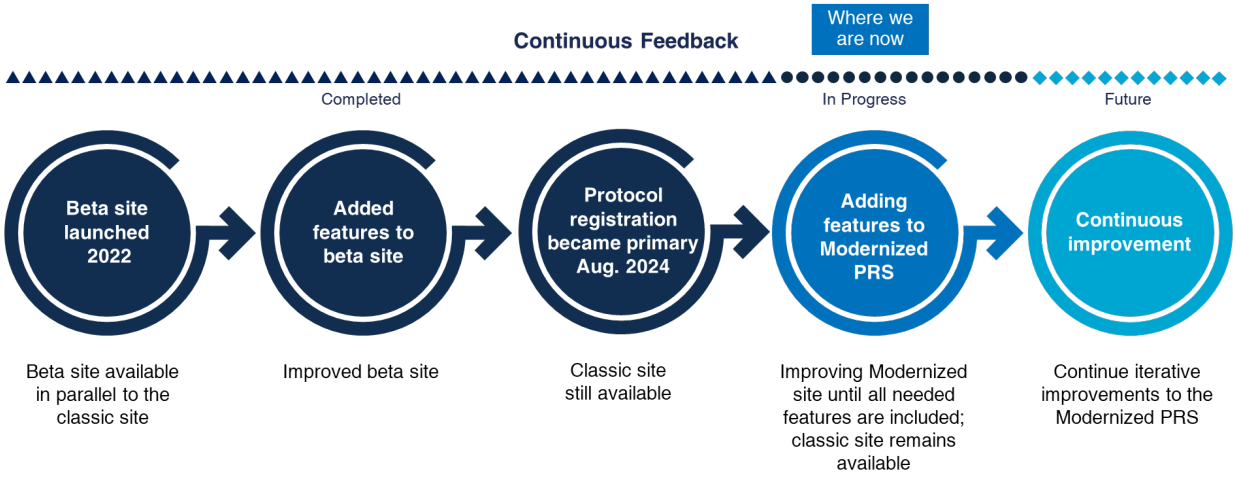
Modernization work during this reporting period, and continuing through 2025, is being guided by a strategic roadmap that groups tasks and events by the modernization approach's three key activity categories (stakeholder engagement, product development, and technical infrastructure enhancements). The stakeholder engagement component of the modernization effort is shown in figure 3.

Figure 3. Stakeholder engagement component of ClinicalTrials.gov modernization



As demonstrated throughout this report, users have been, and remain, central to the ClinicalTrials.gov team's approach to modernization. User feedback helps inform further development and improvements to the Modernized PRS (figure 4).

Figure 4. How users see changes in the development of the Modernized PRS



Activities and Achievements

October 2023 NLM Office Hours

NLM hosted office hours focusing on PRS Beta on October 3, 2023. The session was intended to orient PRS users to the PRS Beta interface, foster its use, and encourage feedback. The PRS subject matter expert discussed the modernization of the PRS and provided a mini tutorial on registering a study using PRS Beta. Following the presentation, a panel of team members answered questions from attendees. A total of 113 unique viewers attended the session, which was recorded and can be viewed here.

June 2024 Public Webinar

NLM hosted a public webinar on June 6, 2024, to provide a detailed look at the modernized ClinicalTrials.gov and PRS websites. During the webinar, ClinicalTrials.gov staff shared an update on the overall progress of the modernization effort and highlighted features of both sites. Special attention was paid to the retirement of the classic ClinicalTrials.gov website. The more than 500 webinar attendees also had the opportunity to interact with ClinicalTrials.gov staff. A recording of the presentation, the slides, and a transcript are available here.

Retirement of the Classic ClinicalTrials.gov

Following an extensive communication and stakeholder engagement campaign, the classic ClinicalTrials.gov public website was retired on June 25, 2024, and the modernized ClinicalTrials.gov became the sole website experience. Continuous iterative improvements to the modernized ClinicalTrials.gov are ongoing. For example, in response to user feedback, and to improve transparency and increase user trust, a Planned Features on ClinicalTrials.gov

page with specific information about planned features was added to the site. Users can access this page via the About menu or through dynamic information alerts that appear when users attempt to access certain planned features using classic website URL paths.

Modernized PRS Becomes the Primary Website for Protocol Registration

On August 28, 2024, PRS Beta became the Modernized PRS and the primary website for study protocol registration. When users log into PRS, they now see the modernized Record List. Study records without Results, Delayed Results, or Study Documents, will open in the Modernized PRS. Users seeking to manage accounts, upload records, access certain help materials, and open study records with sections still under development are redirected to the Classic PRS. Because the Modernized PRS still has features under development, users should use the Classic PRS to review their records and resolve any validation errors or warnings. This milestone was featured in an *NLM Technical Bulletin* article, "The ClinicalTrials.gov PRS Beta Will Soon Become the Primary Website for Protocol Registration" (861 views).

Releases

During the reporting period, additional features and enhancements informed by usability testing and user feedback were regularly released to the modernized ClinicalTrials.gov and PRS websites. Information about those releases is provided in section 2 of this report; the releases are also summarized on the ClinicalTrials.gov Release Notes and PRS Beta Release Notes webpages.

2. Product Releases

Modernized ClinicalTrials.gov

2023–24 Releases and the Retirement of the Classic Website

During the reporting period, there were 10 feature releases to the modernized ClinicalTrials.gov website, which are described below. Also, in June 2024 the modernized ClinicalTrials.gov website became the only public website, and the classic ClinicalTrials.gov site was retired.

The October 26, 2023, release included the addition of instructions for creating an RSS feed on the search results page. In addition, the Modernization page was moved from the classic website to the modernized site.

As part of the January 9, 2024, release, content from PRSinfo was migrated to the modernized ClinicalTrials.gov. Major Comments Posted was added to the record history for single versions of a study record. In addition, the copy function was added for study records.

The February 6, 2024, release included the addition of a new field and glossary definition for gender-based eligibility. PRS help resources from the classic ClinicalTrials.gov were also added to the modernized site.

The March 19, 2024, release included the migration of additional content from the classic website to the modernized site, including how-to content. Results submission events were added to the record history, and the API Migration Guide page was updated.

The April 30, 2024, release featured the addition of a site map. Study structure data field updates were made to the application programming interface (API), and links were updated on the FDAAA 801 and the Final Rule page. Content migration from the classic website to the modernized website continued.

The May 21, 2024, release included the addition of a **Record History** button to the More Information section of the study record. The Study Details accordion labels were revised. In addition, the migration of content from the classic website to the modernized site was completed.

The June 5, 2024, release featured the addition of the RIS file format as a download option for search results and study records. The compare feature was added to the record history, allowing two versions of a study record to be viewed in either a merged or side-by-side format.

As part of the June 20, 2024, release, an alternative, wider display option was added to the table view of search results. In addition, the list of study publications was reorganized. Final preparations were also made for the retirement of the classic ClinicalTrials.gov website.

On June 25, 2024, the classic ClinicalTrials.gov website was retired. The modernized ClinicalTrials.gov became the exclusive website experience for learning about and searching for clinical studies.

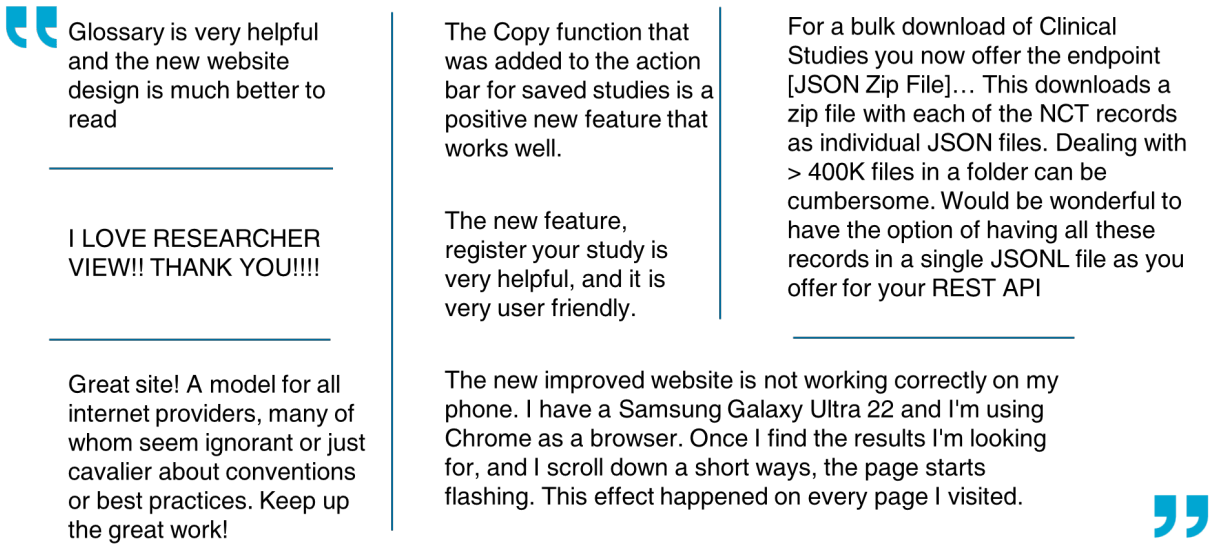
As part of the July 22, 2024, release, the ability to sort search results by the newest or most relevant study records was added. The Modernization Transition Top Questions Adobe PDF file was updated and converted to a webpage.

The September 19, 2024, release included remodeled card and table views of the search results page, as well as enhancements to the Focus Your Search page.

Metrics and Evaluation, Including User Feedback

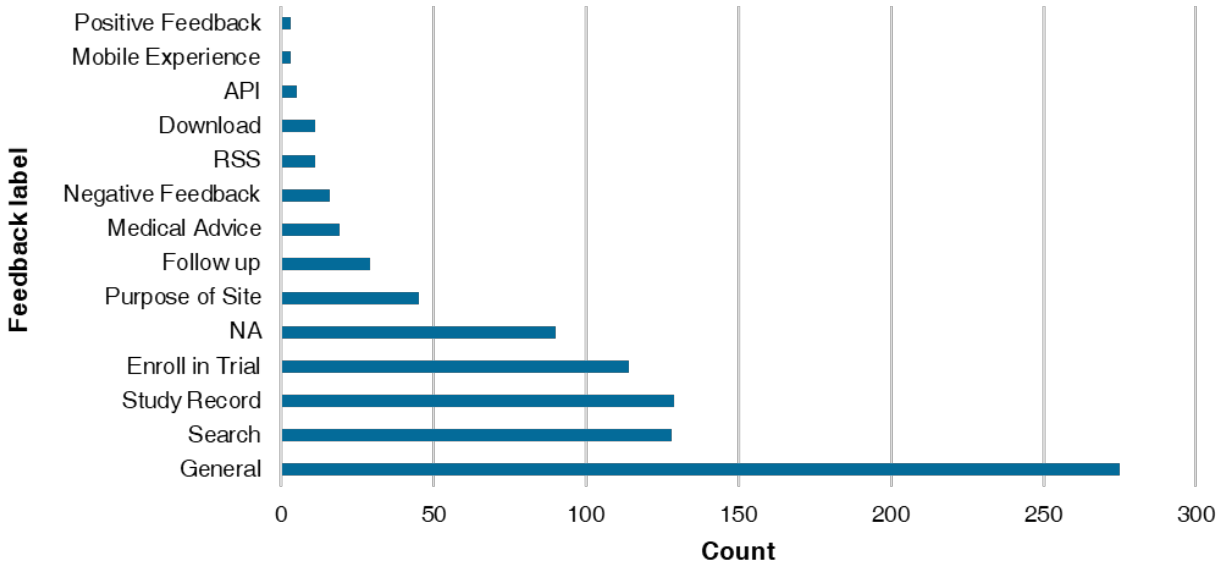
Since the launch of ClinicalTrials.gov Beta in December 2021, the modernization team has accepted user feedback via the site's **Feedback** button and through surveys and usability testing. Between October 2023 and July 2024, for example, the team assessed and analyzed more than 1,700 comments from users. Sample user feedback is shown in figure 5. The team reads every comment received, identifying bugs and other issues as well as user requests, and integrates this feedback into the design and development process to help shape subsequent releases and planned features. The team continued to review and analyze feedback from users as part of our continuous improvement efforts.

Figure 5. Sample feedback on the modernized ClinicalTrials.gov



For a three-month period after the retirement of the classic ClinicalTrials.gov website (July–September 2024), the modernization team implemented an additional layer of user feedback analysis to allow the team to rapidly address any critical usability or experience issues. This added layer involved an increase in the frequency of feedback reviews from biweekly to daily and the creation of a triage team and process that resulted in issues being researched more quickly and resolutions being traceable. Figure 6 provides a snapshot of the areas that users have inquired about following the retirement of the classic site.

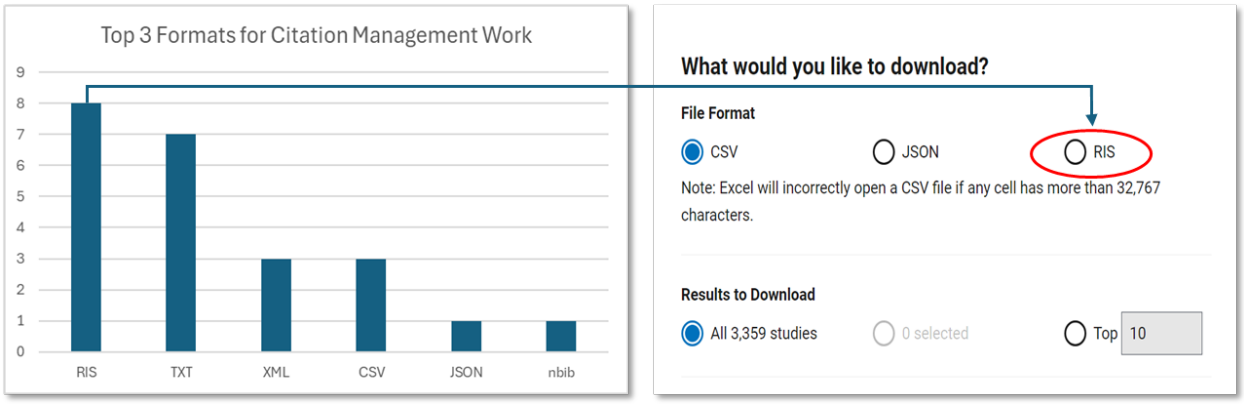
Figure 6. Cumulative User Feedback (Post Classic)*



*Note: Some user feedback comments may be counted multiple times, as each comment may have multiple feedback labels assigned.

As noted previously, users have been central to the team's approach to modernization. For example, after reviewing 107 download-related comments, the team found that the most frequently mentioned use case for downloading trial records was importing them into a citation management software tool such as EndNote (48 comments). Furthermore, users requested that a file format other than the existing ones (CSV and JSON) be added to the modernized ClinicalTrials.gov website before the retirement of the classic site. The team contacted 18 individuals located in the United States, the European Union, and Asia from academic, governmental, pharmaceutical, health care, and other sectors, who had previously submitted a download-related comment in an effort to learn more about the software they use and the file formats they need. Their feedback revealed that the RIS and TXT file formats were used most frequently, and the result was an improved design that now offers RIS, which is compatible with widely used applications in clinical trials research, such as EndNote, Covidence, RefWorks, and BibDesk, as an additional study record download file format option for a better user experience (figure 7).

Figure 7. User feedback in action



Future Releases and Features

Future ClinicalTrials.gov releases will focus on user experience enhancements that will help users more quickly identify and better manage studies of interest. Some features that were previously available on the classic ClinicalTrials.gov website, such as the ability to search for studies on a map, the ability to search for studies by topic, and an expert search option, will be completed on the modernized site. The team is also continuing work to rewrite the data-ingest process, which pulls data from the PRS to populate the study records on the ClinicalTrials.gov website.

More information about new features and functionality for ClinicalTrials.gov will be provided on the website's Release Notes page. Important updates are also shared via the Hot off the PRS! e-newsletter, through blogs, and via webinars.

Modernized PRS (formerly PRS Beta)

2023–24 Releases

During this reporting period, there were nine releases, which are described below. Most releases occurred first in PRS Test, the sandbox version of PRS, before they were released into the PRS production website. Efforts during this period were mainly focused on expanding functionality to PRS Beta.

As part of the November 16, 2023, release, updates to PRS Beta were released to the PRS production system. Added functionality included the ability to approve and release study records and the ability to change the status of a protocol registration record directly in PRS Beta. Additional pop-out help content explaining record dates and other information was added to the Record Summary page.

As part of the February 15, 2024, and February 21, 2024, releases, updates to PRS Beta were first released to the PRS Test system and then to the production system. PRS Reviewer QA/QC comments were added to the Record Summary page in PRS Beta and were made visible to data submitters.

On March 21, 2024, updates to PRS Beta were released to PRS Test, and on April 25, 2024, these updates were released to the production system. The 1,000-record limit was removed after improvements to the Record List's loading speed. With these releases, protocol registration records could be reviewed directly in PRS Beta, and reviewers could add, edit, and delete comments on those records. A new Secondary ID Type was added to the Study Identification data element.

The May 20, 2024, release to PRS Test marked the beginning of development of the Results Section modules, starting with the Participant Flow module. An edit toggle was added to the Results Section.

As part of the June 20, 2024, release to PRS Test, improvements were made to the Record List page, including styling changes and new drop-down menus to access content in the classic PRS. Also, an edit toggle was added to the Protocol Section.

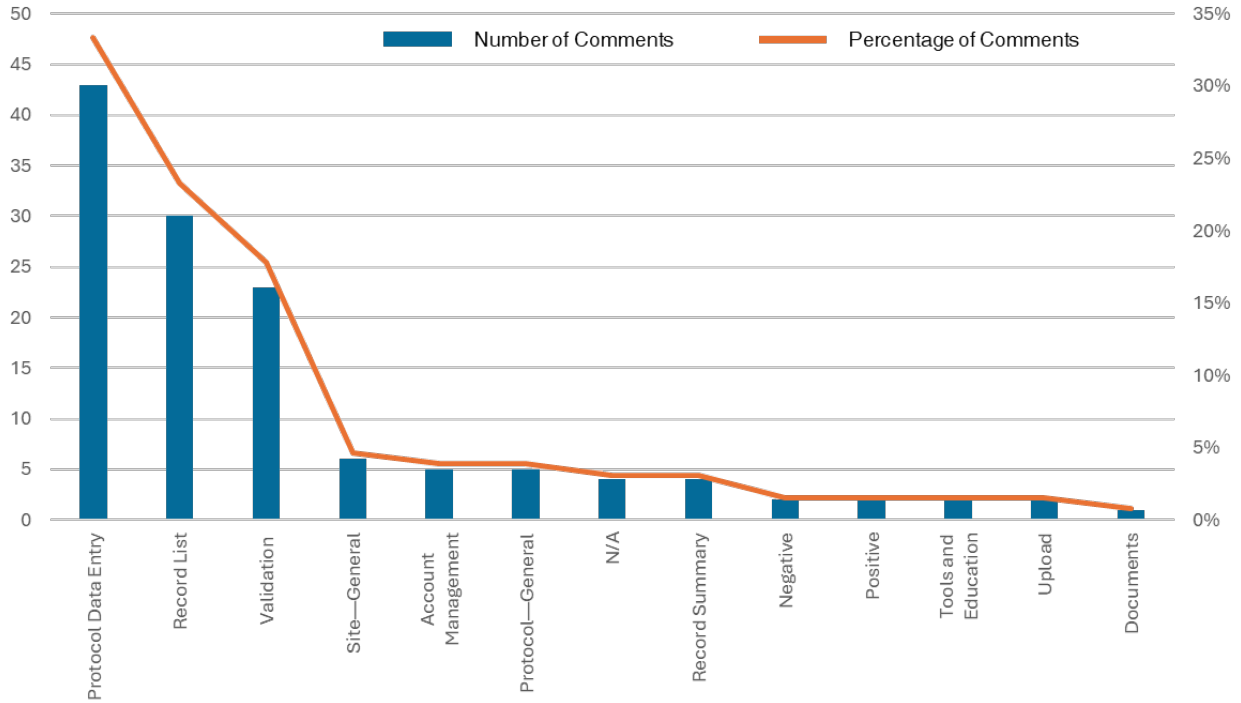
As part of the July 24, 2024, release, updates made in PRS Test were released to the production system. These included the improvements made to the Record List page in June. With this release, all study records, except those with results, delayed results, or study documents, would now open by default in PRS Beta. In addition, a pop-up was added to redirect users to the classic PRS if their records included results, delayed results, or study documents.

As part of the August 7, 2024, release, updates to PRS Beta were released to PRS Test. With this release, PRS Beta became the Modernized PRS, and upon login to PRS Test, users were taken to the modernized Record List page. Study records, except for those with results, delayed results, or study documents, open by default in the Modernized PRS, and redirects were put in place to send users to the classic PRS to open any records containing that information, since those sections were still under development. In addition, improvements, including further styling changes, were made to the Record List page.

As part of the September 16, 2024, and September 30, 2024, releases, updates to the Modernized PRS were first released to PRS Test and then to the production system. Included were several important bug fixes made in response to user feedback, as well as improvements to the record access list. In addition, two new demonstration videos were made available.

The modernization team has continuously documented user feedback received via the site's **Feedback** button and emails sent directly to ClinicalTrials.gov. The team reads every comment received, prioritizes items for implementation, and determines how to specifically integrate the feedback. During the period August 10, 2023–July 30, 2024, before PRS Beta (now the Modernized PRS) became the primary website for protocol registration, users submitted approximately 100 comments about various aspects of the Modernized PRS (figure 8).

Figure 8. User comments before PRS Beta became the primary website



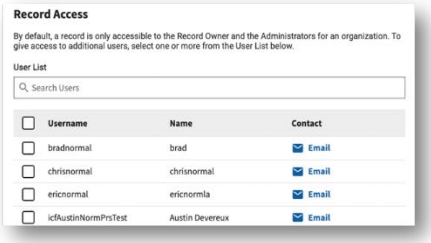
The team has also used the contact information provided in feedback to invite users to participate in usability testing. For example, in January 2024 the team asked data submitters to comment on sections of the protocol registration in PRS Beta, and in March the team conducted moderated usability testing of selected sections of the record summary in PRS Beta. The team incorporated this feedback when updating options for viewing records and resolving issues that had been identified before PRS Beta became the primary website for protocol registration. Listening to users is an ongoing process, and the team will continue to gather additional feedback on these and other features. Note that PRS Beta became the Modernized PRS in early August 2024.

A summary of recent user comments on the record summary is provided in figure 9.

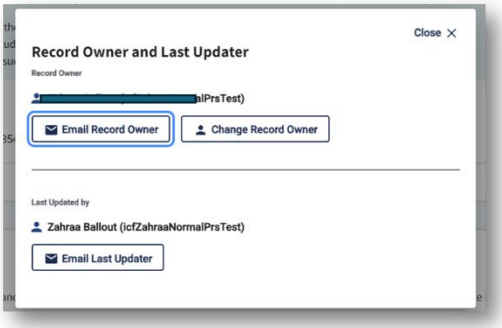
Figure 9. Sample desired improvements to the record summary from usability testing

1. Visual confirmation of who is being granted access to a record in the Record Access pop-up
2. Clear indication that multiple people can be granted access at once in the Record Access
3. Ability to email everyone who has access to a record at once
4. Clarify whether XML upload is available for results or only protocol registration
5. Ability to save a record as a PDF with changes tracked

(1, 2)



(3)



The findings from the sessions were instrumental in improving the experience of data submitters.

Future Releases and Features

Features under development for the Modernized PRS in 2024–25 include results submission, results QA/QC processes, and the Study Documents section. The team will also continue to enhance previously released features.

3. Progress on the Modernization Effort's Strategic Goals

Features included in the modernized ClinicalTrials.gov and PRS releases in 2023–24 that align with the modernization effort's strategic goals are described in the sections that follow, grouped by goal.

Goal 1: Clinical Trial Information Is Current, Complete, and Reliable

Efforts that align with modernization priorities related to strategic goal 1 included the following:

- Improving PRS functionality that supports intuitive use
  - Filters for Record List columns were updated to better meet user needs. For example, for columns with a finite set of display options, search windows were replaced with drop-down lists that present users with the selections they can choose from.
  - The Access List was redesigned in response to user feedback to make it easier to identify the members of an organization who have been granted access and to find additional members of the organization who should be allowed access.
  - Protocol Section QA/QC comments were implemented in a new way to allow data submitters to more easily view and address issues noted by QA/QC reviewers. The comments added by reviewers in each module now remain in the record until it is released again for subsequent review. This allows data submitters to see the comments in context without having to open a separate document.
  - A dashboard was added to the Record Summary page to provide a module-by-module overview of system-generated Errors and Warnings in the Protocol Section as well as an overview of the Major and Advisory Comments applied overall and to each of the Protocol Section's modules. Links that take users directly to the modules with issues to be addressed are included in both overviews, and each overview tallies the total number of validations or comments of each type that should be reviewed and, if possible, addressed.
- Modernizing content and providing access to classic content that will be modernized later
  - The modernized protocol registration QA/QC review process was implemented for reviewers, along with a reviewer dashboard that includes the assignment and review of records in a single interface.
  - Development began on the Participant Flow and Baseline Characteristics modules of the Results Section in the Modernized PRS. Design work also began for the remaining Results Section modules, for the Document Section, and for the Delayed Results Section.
  - Menus and links that redirect users to classic PRS content (e.g., Records, Batches, Accounts, and Help menus; Admin Quick Reference and Problem Resolution Guide links) were added to the Record List page. In addition, the review history was included on the Record Summary page, with links to the classic view of each version of the record that was released for PRS QA/QC review.

Goal 2: Anyone Can Easily Find and Use Information about Clinical Trials

Efforts that align with modernization priorities related to strategic goal 2 included the following:

- Improving the usability of the study record
  - Two versions of a study record can now be compared on the Record History tab, in either merged or side-by-side format.
  - All the sections of the study record as well as posted Major Comments can be viewed in the record history.
- Enhancing the functionality and features of ClinicalTrials.gov based on user feedback
  - The table view of the search results page can be expanded so that users can see more of the table without needing to scroll horizontally.
  - Functionality added to the search results page allows users to sort by newest study first, as well as by relevance.
  - Study record data can be downloaded in RIS format, allowing users to more easily use the data in third-party research and meta-analysis applications.

Goal 3: Trial Information, Resources, and Tools Provide Value to the Research Ecosystem

Efforts that align with modernization priorities related to strategic goal 3 included the following:

- Creating a robust, enhanced API service to support data interoperability and reuse by third parties
  - Augmented classic API support is available to ease migration to the modernized API.
  - A new API endpoint provides a mapping of all enumeration option values to descriptive text making it easier for data researchers to find what they are looking for.
  - More contextual help is available for API parameters, such as markdown specification, expression syntax, and operators to reduce the time and effort needed to effectively use the API.
  - Study records can be retrieved using either the current or obsolete ClinicalTrials.gov Identifier (NCT Number), simplifying integration with third-party applications.
- Developing tools based on advanced computational techniques, such as artificial intelligence (AI), to support aspects of the QA/QC review workflow
  - An AI-based decision support tool was integrated into the classic PRS to support the identification of outcome measures that lack sufficient scale information for interpreting results reported in the outcome measure data table. The tool utilizes advanced computational techniques to predict the presence of the Missing Scale Information major issue and features a customized user interface (UI) designed to streamline the commenting process.

4. Public Communications Related to Modernization and the Product Releases

Overall Approach

The ClinicalTrials.gov team has approached public communications about modernization with the intention of informing and educating both stakeholders and the general public. The team has focused not only on ensuring that data submitters, patients and their advocates, data researchers (including journal editors), and others have the basic information they need about the current state of the modernization effort but also informing users about what is to come. This dual focus has been accomplished by showcasing the modernized ClinicalTrials.gov and PRS features that are already available and sharing information about future plans. The team employs a variety of external engagement strategies, including the following:

- Disseminating communications through various channels (e.g., posting on NLM and National Center for Biotechnology Information (NCBI) social media channels)
- Briefing stakeholders and conducting targeted outreach to stakeholder groups, including reporting on the modernization effort to the NLM Board of Regents during its regularly scheduled meetings
- Hosting public meetings and webinars
- Attending and presenting at conferences, industry meetings, and other events
- Producing informational materials such as the Modernization Transition Top Questions page of the ClinicalTrials.gov website and the Fast Forward from ClinicalTrials.gov demonstration video series

When there is new information about the overall modernization effort or specific releases, an announcement is shared via the following:

- Hot Off the PRS! e-bulletin (more than 17,000 subscribers)
- News and Updates and ClinicalTrials.gov Modernization pages of ClinicalTrials.gov
- ClinicalTrials.gov Release Notes and PRS Beta Release Notes pages, where summaries of all releases are publicly available

During this reporting period, the June 2024 public webinar was the main high-profile event for sharing the latest modernization news with a wide audience and engaging with stakeholder communities. This webinar attracted 527 attendees.

Approach to Diversity

The first phase of the ClinicalTrials.gov modernization focused on educating the general public about the modernization effort, overall, and informing them of key dates such as the retirement of the classic ClinicalTrials.gov website. With the general public informed, the modernization team is now focused on reaching audiences from low-income communities

and historically underserved groups (e.g., Black/African American, Hispanic/Latino). The team is conducting research and initiating development of an outreach plan to engage with these groups through involving them with website usability testing and through enhancing materials on the website to better reach these audiences. The team is also engaged with other diversity-focused NIH offices and external groups.

This effort will ensure the inclusion of diverse audiences in the design and development of ClinicalTrials.gov and the PRS and will meet the directive of the NIH Clinical Trial Diversity Act of 2022 which aims to enhance the diversity of participants in clinical trials.

Understanding the available tools and tactics that could be applied to ClinicalTrials.gov's outreach initiatives has also been informed by existing research on diversifying clinical trials, conducted by organizations such as the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard and the Milken Institute.

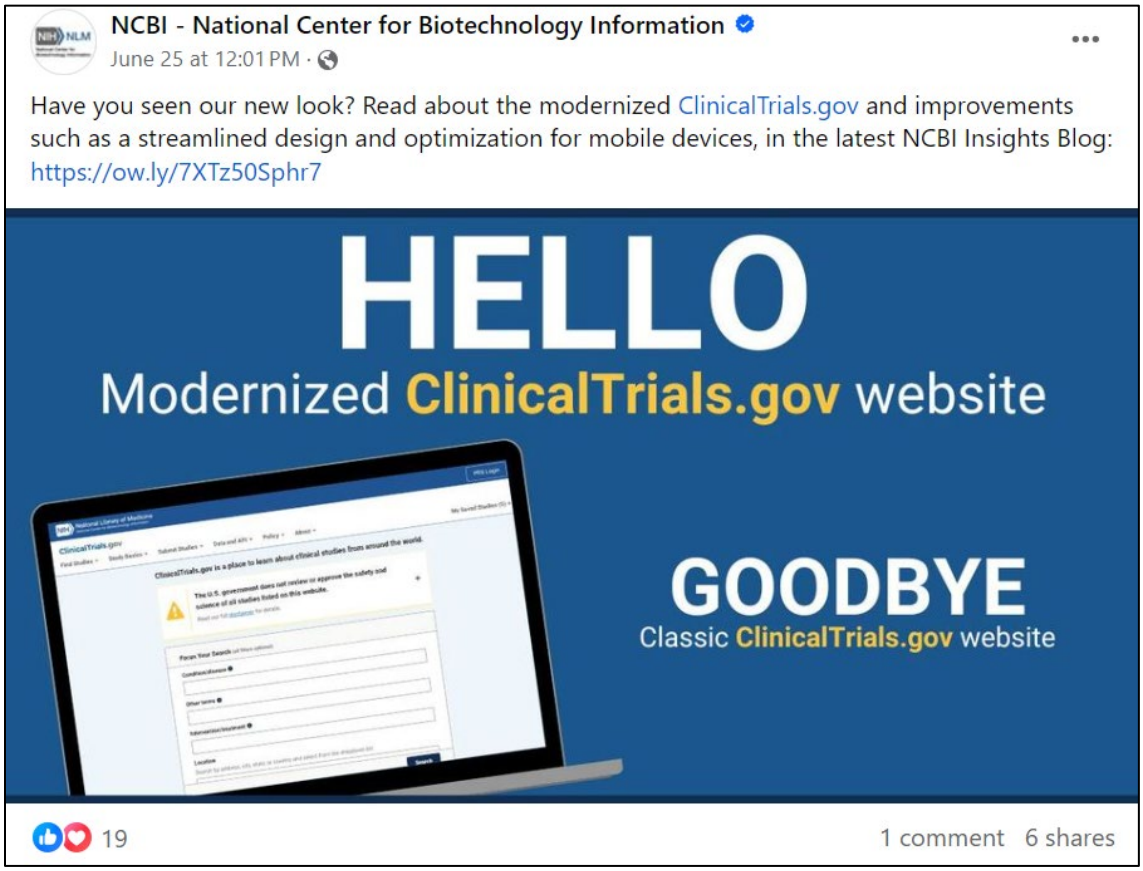
Approach to the Retirement of the Classic ClinicalTrials.gov Website

During the lead-up to the retirement of the classic ClinicalTrials.gov on June 25, 2024, the ClinicalTrials.gov team employed an educational communications campaign that focused on the benefits and features of the modernized website. The team worked with NCBI and NLM to share updates with the public in the months prior to this milestone, including the following blog posts and articles:

- NLM Announcement, "The Modernized ClinicalTrials.gov Will Become the Singular Website Experience," May 30, 2024 (1,133 views)
- *Musings from the Mezzanine* blog post, "Marking a Milestone: The Modernized ClinicalTrials.gov Becomes the Singular Website Experience," June 5, 2024 (1,700 views)
- NCBI Insights blog post, "A Modern ClinicalTrials.gov Website," June 25, 2024 (2,083 views)
- *NLM Technical Bulletin* article, "A Modern ClinicalTrials.gov Website," June 25, 2024 (176 views). Note: This article is a reprint of the NCBI Insights post.

Social media communications about the retirement of the classic site began in March and increased in frequency in the weeks immediately prior to June 25, appearing on the NCBI and NLM Facebook, LinkedIn, and X accounts. An example is shown in figure 10.

Figure 10. Example of social media post on the day the classic ClinicalTrials.gov website was retired

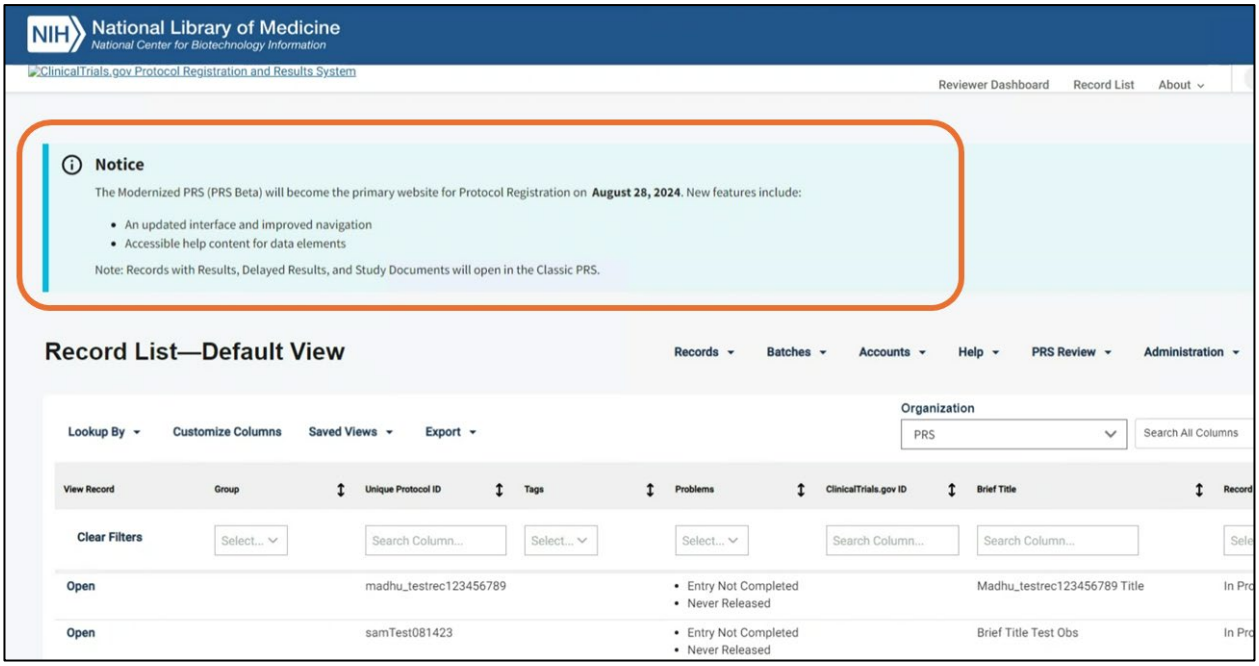


Approach to the Launch of the Modernized PRS Protocol Registration

The PRS is a password-restricted website principally used by researchers and research administrators to register clinical studies and submit summary results for posting on the public ClinicalTrials.gov website. Because of this, the communications strategy for the transition to the Modernized PRS centers on this specialized audience, rather than the general public. The ClinicalTrials.gov team worked with NLM to notify PRS users about the Modernized PRS becoming primary for protocol registration. This outreach included:

- Emails to Internal NIH stakeholders (e.g., NIH Office of Legislative Policy and Analysis, NIH Office of Extramural Research, NIH Office of Data and Science Strategy)
- Emails to stakeholders (e.g., NLM Board of Regents)
- Article in NLM Technical Bulletin
- Banners on the Modernized PRS and PRS Test (Figure 11)
- Hot off the PRS! e-bulletin
- Post in NLM Announcements
- Development of additional Fast Forward educational videos

Figure 11. Screenshot of banner alert on Modernized PRS



Plans for 2024–25

The ClinicalTrials.gov team will continue to communicate with users about the release of updated features and functionality to ClinicalTrials.gov and the Modernized PRS via emails to internal NIH and NLM audiences and external users, banners and modals on the websites, public events, the Hot off the PRS! e-newsletter, and social media. These well-established approaches also provide the opportunity to share further information about the overall modernization effort.

Specific planned communications activities for the coming year include the development of additional Fast Forward from ClinicalTrials.gov demonstration videos, ongoing updates to the Modernization Transition Top Questions webpage, and public webinar(s).

5. Research in Support of the Modernization Effort

During this reporting period, ClinicalTrials.gov staff undertook a variety of research activities in support of the modernization effort. Findings of interest to a broader audience have been published to both inform and engage the research community as well as to demonstrate how ClinicalTrials.gov information can be used as a resource.

Use of AI

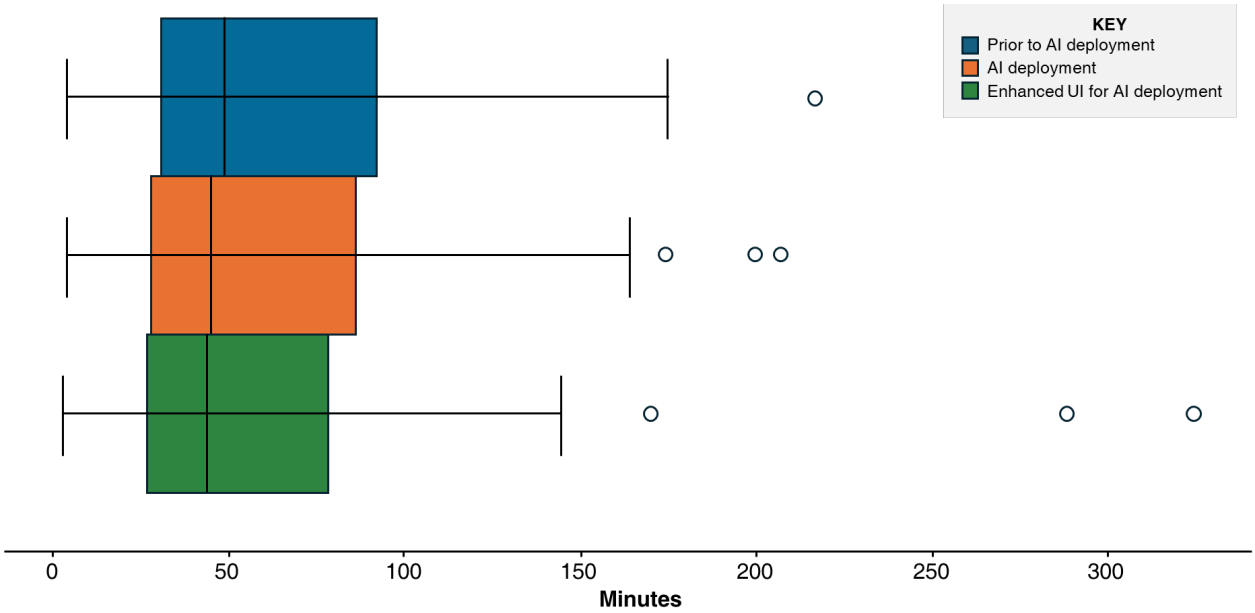
The PRS Automation Support team continued to conduct research to assess the effect of integrating AI technology into the PRS to support the manual QC review of clinical trial results information. This effort is exploring the possibility that integrating AI technology into the QC reviewers' native work environment, in combination with a useful UI, could supplement reviewers' processes and, potentially, reduce the time required to manually review each study record.

In the previous reporting year, the team integrated AI technology into the classic PRS that suggests the Units of Measure used for a study's outcome measure data during manual QC review of results submissions. The tool is able to classify 116 Units of Measure based on the information entered in the Outcome Measure Title and Outcome Measure Description data fields and is intended to support results QC reviewers in the identification of Unit of Measure–related major issues (e.g., invalid units, mismatched units, multiple units).

To evaluate the effect of this tool on the time required for manual QC review, the total duration of review, or "touch time," was measured using Google Analytics and AppLog. Data were collected for three time periods: (1) before AI deployment (November 27–December 25, 2022), (2) after AI deployment (October 2–30, 2023), and (3) after enhancing the tool's UI (November 27–December 25, 2023). The first period predated integration of the AI technology into the classic PRS; by the second period, the AI technology had been integrated, along with a UI that was designed to gather feedback on the tool's performance. By the third time period, a new UI designed to streamline commenting on inappropriate or invalid Units of Measure had been implemented.

Figure 12 presents the estimated time spent reviewing study records with major issues by four QC reviewers during the three time periods. The results suggest a possible, but not statistically significant, trend toward less time needed for review following the deployment of the AI technology and changes to the UI. The central box represents the interquartile range, while the line inside the box indicates the median. Circles outside the whiskers denote outliers. Overall differences between time periods were small, but they generally seemed consistent with the rates of occurrence of Unit of Measure–related major issues (e.g., Mismatch Units, Invalid Unit of Measure) in study records. For example, between July 1, 2020, and July 31, 2021, the Mismatch Units, Invalid Unit of Measure, and Multiple Measures major issues occurred in 19%, 11%, and 3%, respectively, of initial study results submissions with major issues.

Figure 12. Estimated time spent reviewing study records with major issues illustrated by box-and-whisker plots.



To measure the effect of the AI technology on the quality of manual QC reviews, quality scores from QA checks of reviews were obtained for the same time periods and reviewers included in the touch-time analysis. Quality scores range from 1 (best) to 4 (worst), with scores of 1 indicating that all issues were identified in the study record and commenting was appropriate for the issues identified. Table 1 presents the quality scores for reviewers with access to the AI technology during the three time periods. The results suggest that the quality of reviews did not decline, remaining high following the deployment of the AI technology and changes to the UI.

Table 1. Quality Scores across Four QC Reviewers during Three Time Periods

	Goal	Actual
	Percentage of records with a quality score of 1 or 2	
Prior to AI deployment	100%	100% (3 of 3 records rated 1 or 2)
AI deployment	100%	100% (3 of 3 records rated 1 or 2)
Enhanced UI for AI deployment	100%	100% (5 of 5 records rated 1 or 2)

Together these results provide a first glimpse into the utility of AI for creating efficiencies in the identification of major issues in study results submissions. The AI technology generally reduced the time required to review results submissions with major issues without negatively impacting the quality of the reviews. It may be reasonable to expect that if implemented at a larger scale, AI-based decision support would have a greater impact on manual QC review, potentially enhancing the overall operational capacity of the results QC review team while maintaining review consistency across study records.

User Research and Input

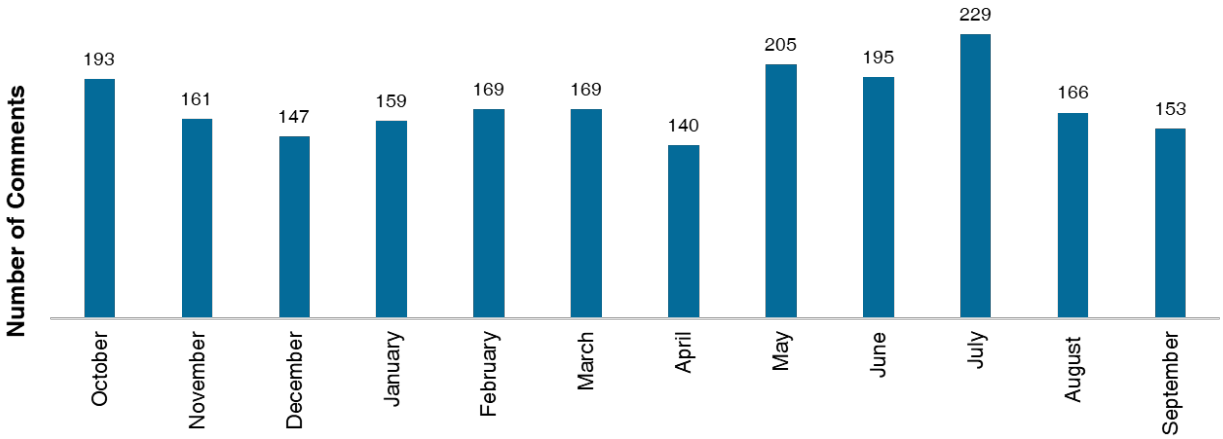
The ClinicalTrials.gov team has integrated a user-centered testing and evaluation process for the modernized ClinicalTrials.gov and PRS. This collaborative approach employs various methodologies to gather insights from users to enhance the discoverability of information and improve site navigation for all user groups.

Between October 2023 and July 2024, the modernization teams conducted more than 35 usability testing and user interview sessions to gather feedback on the API for the modernized ClinicalTrials.gov website, the protocol registration and record summary portions of the PRS, and a PRS workflow for basic experimental studies involving humans (BESH), as well as deployed more than 30 surveys to gather input on the download experience and the expert search feature on ClinicalTrials.gov. The teams also hosted user experience workshops to help align the goals of usability testing; brainstorm and seek alignment on new features, such as the Patients' Next Steps feature of ClinicalTrials.gov; and collaborate to prioritize user feedback for feature improvement.

The ClinicalTrials.gov team also collected input on the user experience by hosting a public webinar and attending professional meetings such as a meeting of the NLM Associate Fellows. All these activities have informed the design and development of the modernized ClinicalTrials.gov and PRS.

Furthermore, the team continued to analyze the user feedback collected by the NCBI comment card and provide recommendations based on that feedback. Between October 2023 and July 2024, more than 1,700 comments, received from both new and returning ClinicalTrials.gov and PRS Beta users, were reviewed, and the team continues to assess and analyze all comments received. A snapshot of the volume of feedback about the modernized ClinicalTrials.gov is provided in figure 13.

Figure 13. Number of NCBI comment card responses on the modernized ClinicalTrials.gov website, October 2023–September 2024



In addition, the team continued to use the more than 1,400 modernization request for information responses and feedback from the more than 70 interviews that the team conducted in 2020 to support the modernization of both ClinicalTrials.gov and the PRS.

6. Modernization Next Steps and Future Activities

Plans for 2024–25

Modernized ClinicalTrials.gov

The modernized ClinicalTrials.gov team plans to prioritize users' need for outstanding features that were previously available on the classic ClinicalTrials.gov, such as searching for studies on a map, searching for studies by topic, and expert search. Work to rewrite the data-ingest process, which pulls data from the PRS and populates the study records on the public website, is also continuing. Alongside these efforts, the team will continue to review user feedback and address issues and concerns, as appropriate.

Modernized PRS

The Modernized PRS team plans to complete the results submission modules, results QA/QC processes, and the Study Documents section. Development of the BESH alternate summary results reporting workflow in the PRS is also underway. The team will continue to make improvements to previously released features and address user feedback.

Automation Support

The PRS Automation Support team is using research to assess the utility and value of adopting AI at ClinicalTrials.gov in the future.

More Information

The following resources provide additional information about the modernization effort:

- Report on the ClinicalTrials.gov Modernization Effort, Summary of Progress: 2019-21
- Report on the ClinicalTrials.gov Modernization Effort, Summary of Progress: 2021-22
- Report on the ClinicalTrials.gov Modernization Effort, Summary of Progress: 2022–23
- Recordings and presentation slides of public webinars and demonstrations
- ClinicalTrials.gov Modernization webpage
- ClinicalTrials.gov News and Updates webpage
- Fast Forward from ClinicalTrials.gov demonstration video series
- Modernized ClinicalTrials.gov website
- ClinicalTrials.gov Release Notes webpage
- PRS Beta Release Notes webpage

Appendices

Appendix A: ClinicalTrials.gov Modernization Team Members: October 2023–September 2024

Thank you to NCBI leadership and the many team members who have continued to support the ClinicalTrials.gov modernization effort, including:

- Renny Akintunji, Modernized PRS QA Tester (contractor)
- Stacey Arnold, ClinicalTrials.gov Results Subject Matter Expert (SME)
- Ben Babics, Modernized PRS Engineering Lead (contractor)
- Eric Babin, Modernized PRS Back-End Team Lead (contractor)
- Richard Ballew, ClinicalTrials.gov Business/Data Analyst (contractor)
- Zahraa Ballout, ClinicalTrials.gov User Experience (UX) Researcher (contractor)
- Jayaram (Ram) Basava, Modernized ClinicalTrials.gov Website Developer (contractor; former team member)
- Gunnar Baskin, Modernized PRS Business Analyst (contractor)
- Steven Bedrick, PRS Automation Support Developer (contractor)
- Annice Bergeris, ClinicalTrials.gov Acting Deputy Director, Information Research Specialist, and Operations Team Product Owner
- Isabelle Bonke, ClinicalTrials.gov Communications Coordinator (contractor)
- Landon Bressler, Modernized PRS Business Analyst (contractor)
- Elissa Bush, ClinicalTrials.gov Technical Information Specialist
- Qiao Chang, ClinicalTrials.gov Technical Information Specialist
- Padmini Chilappagari, Modernized ClinicalTrials.gov Website Developer (contractor)
- Monica Corley, Modernized PRS Business Analyst (contractor)
- Vinod Danam, Modernized PRS Developer (contractor)
- Mandy Davis, ClinicalTrials.gov UX Researcher (contractor; former team member)
- Stormi Dettmann, Modernized PRS Developer (contractor)
- Austin Devereux, Modernized PRS Database Engineer (contractor)
- Nachiket Dharker, ClinicalTrials.gov Lead Results Analyst and Modernized PRS Product Owner
- Sergey Dikunov, Modernized ClinicalTrials.gov Website Technical Lead (contractor)
- Sarah DiPasquale, ClinicalTrials.gov UX Researcher (contractor)
- Anna M. Fine, ClinicalTrials.gov Acting Program Head
- Kim Fugel, Modernized PRS Business Analyst (contractor)
- Madhurima Gade, Modernized ClinicalTrials.gov Website Developer (contractor)
- Robert Gale, PRS Automation Support Developer (contractor)

- Rithika Ganni, Modernized PRS QA Engineer (contractor; former team member)
- Jennifer Glas, Modernized PRS UX Designer (contractor)
- Elisa Golfinopoulos, ClinicalTrials.gov Policy Analyst and PRS Automation Support Team Product Owner
- Slava Gorelenkov, ClinicalTrials.gov Technical Program Manager
- Eugene Gribov, ClinicalTrials.gov Developer (contractor)
- Karen Hanson, ClinicalTrials.gov Technical Writer (contractor)
- Wendy Harman, ClinicalTrials.gov UX Task Lead (contractor; former team member)
- Jimithy Hawkins, Modernized ClinicalTrials.gov Website Business Analyst/Product Strategist (contractor)
- Brad Henry, Modernized PRS Developer (contractor)
- Samrat Hirapara, Modernized PRS Developer (contractor)
- Rafis Ismagilov, Modernized ClinicalTrials.gov Website Developer (contractor)
- Catherine Kihara, ClinicalTrials.gov UX Research Lead (contractor)
- Olga Komina, Modernized PRS QA Tester (contractor)
- Chris Konizer, Modernized PRS Product Manager/Strategist (contractor)
- Carl Leubsdorf, Consultant (contractor)
- John Lopez, ClinicalTrials.gov Technical Lead (contractor)
- Irina Lupu, Modernized PRS QA Tester (contractor)
- Jesus Mendiola, Modernized ClinicalTrials.gov Website Test Automation Engineer (contractor)
- Damon Miller, Modernized ClinicalTrials.gov and PRS QA Tester (contractor)
- Annie Morris, Modernized PRS Website UX Designer (contractor; former team member)
- Hibah Nazir, ClinicalTrials.gov Product Manager (contractor)
- Ngoc Nguyen, ClinicalTrials.gov Developer (contractor)
- Kenneth Ni, Modernized ClinicalTrials.gov Website and PRS UI Designer (contractor)
- Maria Ochoa-Vargas, Modernized PRS UX Designer (contractor)
- Hardik Parekh, Modernized PRS Front-End Team Lead (contractor)
- Chris Pemberton, Modernized PRS Developer (contractor)
- Haneef Pervez, Modernized PRS Developer (contractor)
- Alison Powell, ClinicalTrials.gov Communications Specialist (contractor)
- Rupinder Randhawa, ClinicalTrials.gov Modernization Project Manager (contractor)
- Christina Robinson, ClinicalTrials.gov Web Content and Outreach Coordinator and Modernized ClinicalTrials.gov Website Product Owner
- Mary Sanders, ClinicalTrials.gov Project Director (contractor)
- Michael San Gabriel, Modernized PRS Developer (contractor)

- Gurdeep Sayal, ClinicalTrials.gov Technical Consultant (contractor)
- Max Shestopalov, ClinicalTrials.gov Scrum Master (contractor)
- Stephen Shoemaker, Modernized ClinicalTrials.gov Website and PRS Information Architect and Content Strategist (contractor)
- Shweta Shrivastava, Modernized PRS Developer (contractor)
- Colin Small, Modernized ClinicalTrials.gov Website UX Lead and Modernized PRS UX Designer (contractor)
- Scott Smith, Modernized PRS Product Manager (contractor)
- Zachary Sommers, Modernized PRS Developer (contractor)
- Maureen Strange, ClinicalTrials.gov SME (contractor)
- Tony Tse, ClinicalTrials.gov Analyst
- Diane Webb, ClinicalTrials.gov Health Literacy SME (contractor)
- Susan Wimmer, ClinicalTrials.gov Editor (contractor)
- Tirsit Wondemu, Modernized PRS Developer (contractor; former team member)
- Allison Yu, Modernized ClinicalTrials.gov Website Developer (contractor)
- Rici Yu, ClinicalTrials.gov Developer (contractor)
- Chris Ziegler, Modernized PRS UX Lead (contractor)
- Maya Zuhl, PRS Automation Support Technical Lead (contractor)

Appendix B: Abbreviations

An alphabetical list of the abbreviations used in this report is provided below.

- AI: artificial intelligence
- API: application programming interface
- BESH: basic experimental studies involving humans
- NCBI: National Center for Biotechnology Information
- NIH: National Institutes of Health
- NLM: National Library of Medicine
- PRS: Protocol Registration and Results System
- QA: quality assurance
- QC: quality control
- SME: subject matter expert
- UI: user interface
- UX: user experience