Report on the ClinicalTrials.gov Modernization Effort

Summary of Progress: 2022–23

November 2023

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 470,000 clinical trials, observational studies, and expanded access programs. More than 100,000 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 2000 to 2023
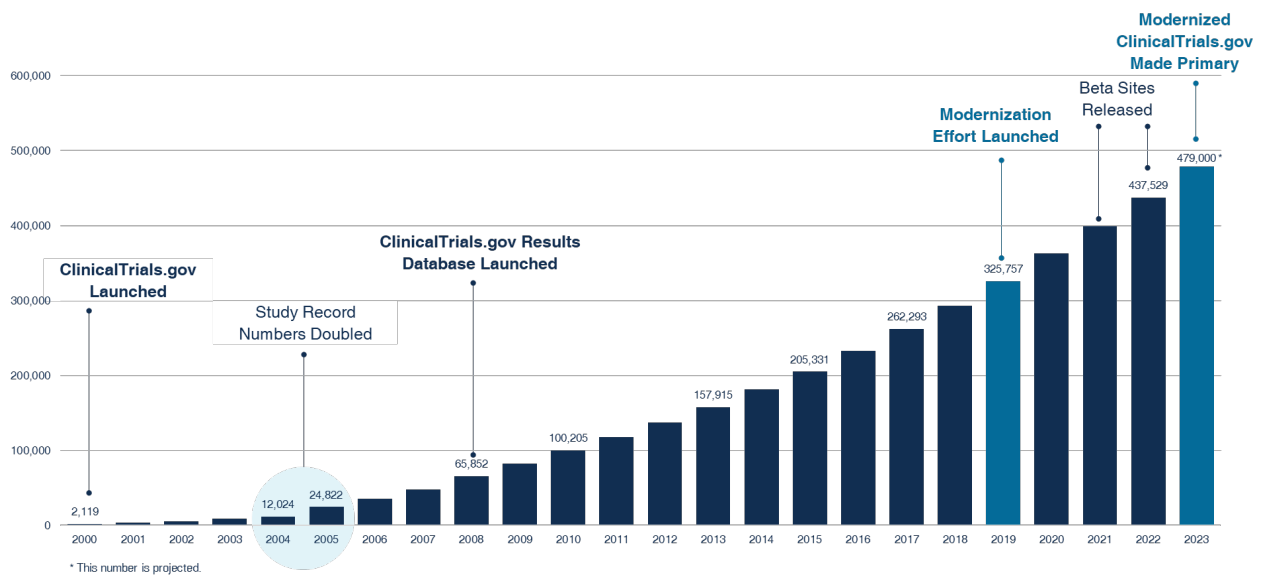
In August 2019 NLM initiated an effort to modernize the ClinicalTrials.gov public website and components of the Protocol Registration and Results System (PRS) to ensure that ClinicalTrials.gov continues to be a trusted premier public health resource that provides maximum value to the public well into 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 2022–23 Modernization Summary Report

This report, the third in the series, provides a summary of the ClinicalTrials.gov modernization effort from October 2022 to September 2023. It presents an update on the modernized ClinicalTrials.gov public website, which became the primary site in June 2023;
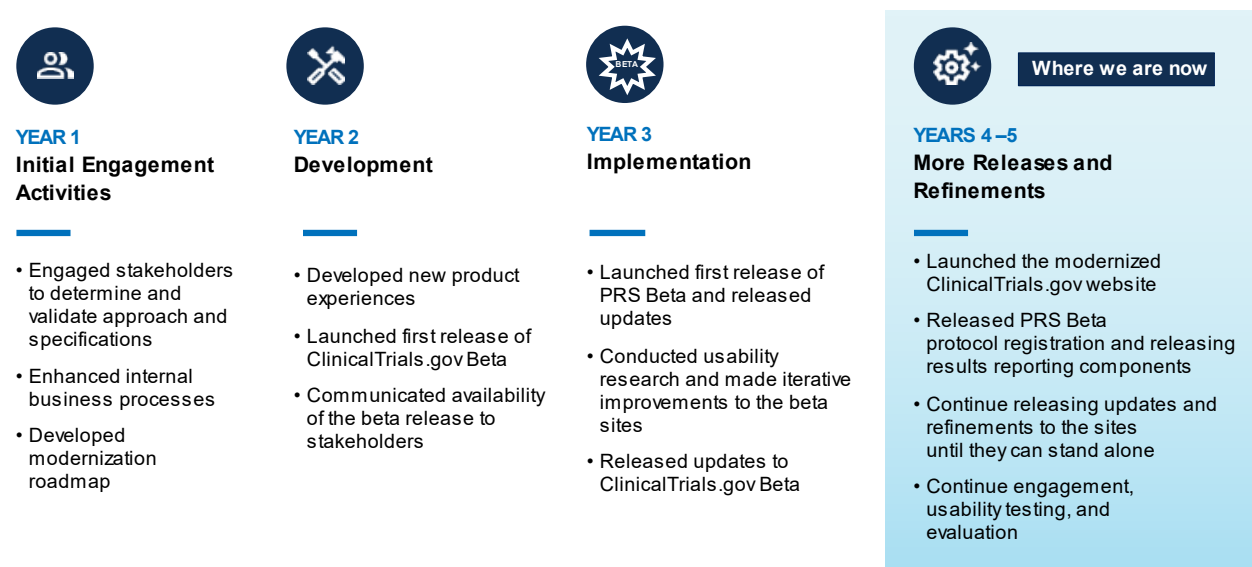
development of PRS Beta; progress on modernization's strategic goals; stakeholder input received during the reporting period; the modernization communication strategy; research undertaken to support the modernization effort; and future modernization activities.

During this reporting period, the NLM Board of Regents (BOR) Public Service Working Group on ClinicalTrials.gov Modernization (Working Group) continued to be an important source of input on modernization; the group's charge, roster, and member biographies are provided in appendix A, and the group's meeting schedule for the period is provided in appendix B. The Working Group supported the adoption of the three strategic goals that organize the desired outcomes, or effects, of the modernization effort: (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 help structure the efforts of the ClinicalTrials.gov team members involved in modernization, who are listed in appendix C. The abbreviations used in this report are listed in appendix D. More detailed information about the history of ClinicalTrials.gov and the first three years of the modernization effort can be found in the previous modernization summary reports.

Current Phase of the Modernization Effort

The modernization of ClinicalTrials.gov is a multiyear effort that began in 2019 and will continue through 2024 (figure 2).

Figure 2. ClinicalTrials.gov modernization overview, by year

YEAR 1
Initial Engagement Activities

• Engaged stakeholders to determine and validate approach and specifications

• Enhanced internal business processes

• Developed modernization roadmap

YEAR 2
Development

• Developed new product experiences

• Launched first release of ClinicalTrials.gov Beta

• Communicated availability of the beta release to stakeholders

YEAR 3
Implementation

• Launched first release of PRS Beta and released updates

• Conducted usability research and made iterative improvements to the beta sites

• Released updates to ClinicalTrials.gov Beta

Where we are now

YEARS 4–5
More Releases and Refinements

• Launched the modernized ClinicalTrials.gov website

• Released PRS Beta protocol registration and releasing results reporting components

• Continue releasing updates and refinements to the sites until they can stand alone

• Continue engagement, usability testing, and evaluation

In years 1 and 2, NLM prioritized engagement and development, conducting broad stakeholder engagement activities and focused usability 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 usability research activities and updates to the technical infrastructure continued. All the engagement 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. (Users will still be able to access the classic ClinicalTrials.gov website until it is retired in 2024.) The main achievements of year 4 were nine releases of updates to the modernized ClinicalTrials.gov and eight releases of updates to PRS Beta (see section 2). Also in year 4, the Working Group continued to provide input, validate our approach, and support public communications about modernization. Year 5 will focus on more releases and refinements, further usability testing and stakeholder engagement, and the transition to PRS Beta being the primary PRS site.

Modernization work for this reporting period, and through 2024, 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). The stakeholder engagement component of the modernization effort is shown in figure 3.

Figure 3. Stakeholder engagement component of ClinicalTrials.gov modernization
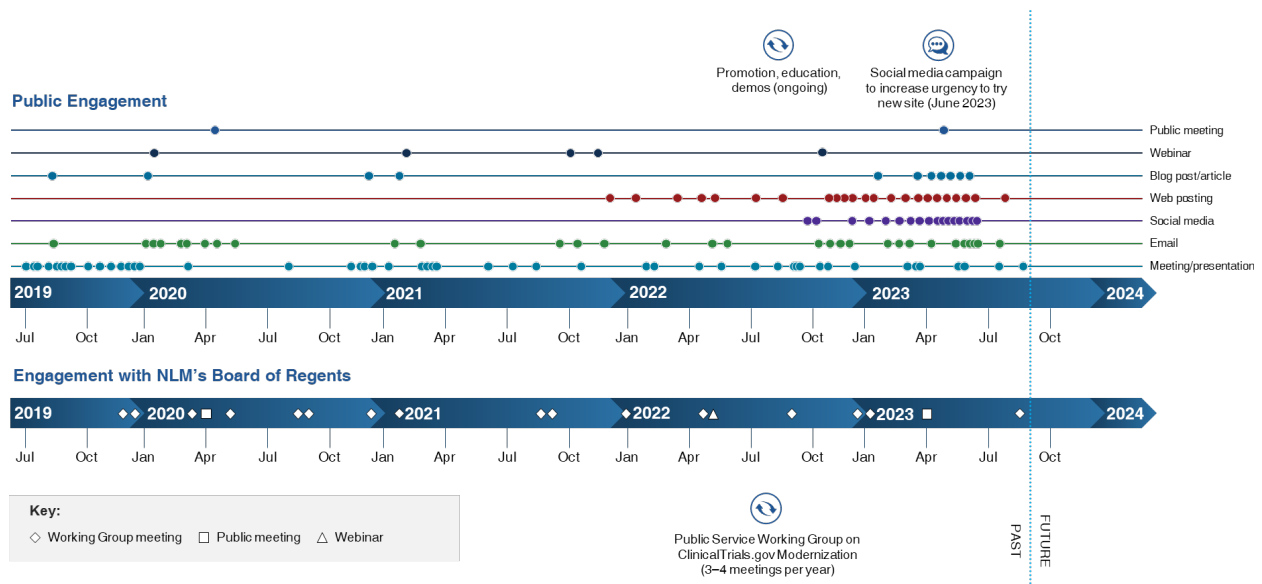
As demonstrated throughout this report, users have been, and remain, central to the ClinicalTrials.gov team's approach to modernization. How users see changes to the beta sites and how their feedback helps inform further improvements are key considerations (figure 4).

Figure 4. How users see changes to the beta sites

Beta site	Add features to beta site	Beta site is primary	New site
Available in parallel to the current site	Improve until all needed features are included	Current site still available as the secondary site	Beta site is the only site; current site retired
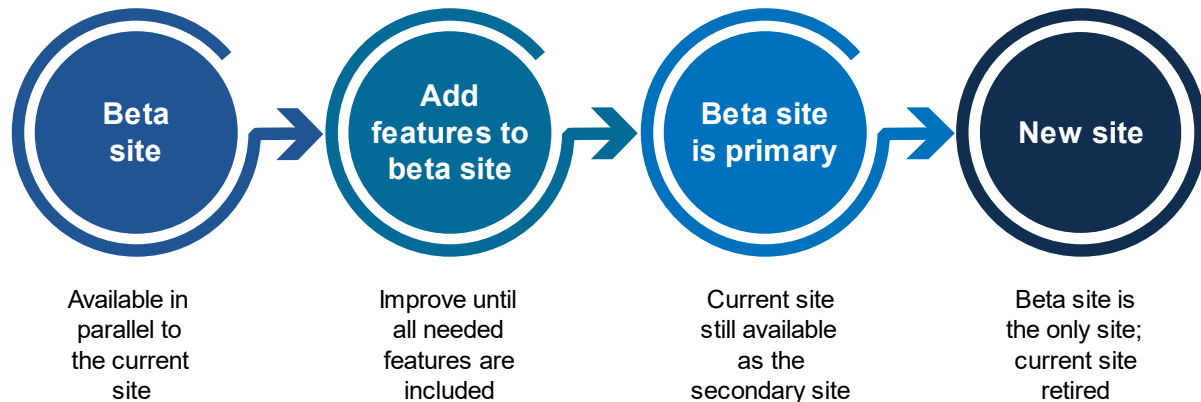
Activities and Achievements

NLM BOR Working Group Meetings

The Working Group met three times during the October 2022–September 2023 reporting period (see appendix B). Highlights from the meetings are provided in section 4 of this report.

Fall 2022 Webinar

During the ClinicalTrials.gov Modernization and Beta Sites Progress public webinar held on October 27, 2022, NLM provided an update on the progress of the modernization effort, an overview of the modernized ClinicalTrials.gov website and PRS Beta, and a live question-and-answer session for almost 400 attendees.

Spring 2023 Virtual Public Meeting

NLM hosted a virtual public meeting on April 25, 2023, to present an overview of the ClinicalTrials.gov modernization effort, share information about the modernized ClinicalTrials.gov website and PRS Beta, and provide an opportunity for users and stakeholders to ask questions and give feedback. The nearly 500 attendees represented a wide range of perspectives, including those of academic, industry, and government data submitters; information specialists and librarians; regulatory and regulatory affairs staff; data researchers; and patients and their advocates. The Director of NLM and the Working Group Chair each briefly described the Working Group, its charge, and the activities to date that had fulfilled that charge. The Acting Director of ClinicalTrials.gov and Working Group Executive Secretary provided an overview of the modernization effort.

ClinicalTrials.gov modernization team members summarized the user-centered process for the design and development of the modernized ClinicalTrials.gov website, including how input and feedback had been gathered and used to address user and stakeholder needs and iteratively enhance the site. Working Group member Jennie Lucca of The Children's Inn at NIH provided an example of this process, sharing how The Inn's team and guest families have worked with NLM to offer feedback on the ClinicalTrials.gov website that has informed modernization.

An overview of the modernized ClinicalTrials.gov website covered its launch in December 2021 through plans for 2024, when the classic site is scheduled to be retired, and noted that the modernized website was targeted to become the primary site in June 2023. Descriptions of the design and development process, emphasizing the role of user feedback and data analytics, and of several key features of the site and their evolution were shared, along with descriptions of currently available, in-progress, and future features. The progress of efforts to modernize the PRS since the launch of PRS Beta in February 2022, including recent updates, was described. Selected PRS Beta features were presented, and updates planned for the future were previewed. Once PRS Beta includes all the necessary features, it will become the primary website and the classic site will be retired, although it is anticipated that the classic site will be supported until 2025.

Meeting attendees had the option to engage further with modernization staff and Working Group members in one of two breakout rooms, one for the modernized ClinicalTrials.gov and one for PRS Beta. The ClinicalTrials.gov breakout room featured a prerecorded presentation by Working Group member Steven Woloshin of The Dartmouth Institute for Health Policy and Clinical Practice. After the video, the modernized ClinicalTrials.gov website product owner responded to Dr. Woloshin's comments and then took questions from breakout room participants via the chat. The PRS Beta breakout room featured a live presentation by Working Group member Carrie Dykes of the University of Rochester Clinical and Translational Science Institute. After the presentation, the PRS Beta product owner responded to Dr. Dykes' comments. Breakout room participants were polled on the continued inclusion of certain functions in the modernized PRS, and the PRS Beta product owner and Dr. Dykes addressed questions and recommendations from breakout room participants received via the chat.

September 2023 NLM Office Hours

In conjunction with the Network of the National Library of Medicine (NNLM), the ClinicalTrials.gov team participated in a public office hours session with 112 attendees, who were primarily librarians and information professionals, researchers, and data scientists but also included members of the general public, representatives of federal agencies, and community-based organizations. The product owner gave an overview of the modernized ClinicalTrials.gov website along with future plans for continued development, and a panel of team members answered questions from the audience.

Releases

During the reporting period, additional features and enhancements based on usability testing and user feedback were regularly released to the beta websites. The most significant of these releases involved the modernized ClinicalTrials.gov website becoming the primary site. Detailed information about the releases is provided in section 2 of this report, and the releases are also summarized on the modernized ClinicalTrials.gov Release Notes and PRS Beta Release Notes webpages.

2. Product Releases

Modernized ClinicalTrials.gov

2022–23 Releases and Transition to the Primary Website

The modernized ClinicalTrials.gov website became the primary website in June 2023. Between the time that the previous report was issued and this June milestone, there were seven ClinicalTrials.gov Beta releases. After the beta site became the primary website, there were two additional releases. All the releases that occurred during this reporting period are described below.

The November 17, 2022, release focused on the expanded and customizable table view of search results, which includes columns for additional data elements and the ability to customize the order of the columns displayed. Printer-friendly layouts for study records and the card view of search results were added, and navigation from one study to another was improved.

The December 19, 2022, release featured a streamlined home page and the addition of a new Record History tab to the study record. In addition, dates were reformatted to be more consistent with universal standards, and improvements were made to the print functionality and to the search results page.

The January 31, 2023, release included a new draft design of the application programming interface (API), and resources for using the API were added. Error messages were revised to improve clarity, and improvements to the display of study record information were made. In addition, the migration of selected content from the classic site to the modernized site began.

The March 8, 2023, release featured a table view of study details for interventional and observational study records. A "new" label was added to applicable records in the table view on the search results page, and hyperlinks were added to the CSV download. Also, general text and formatting improvements were made for the mobile view.

In the April 11, 2023, release, new features were added to the Record History, including the ability to view the details of a single version of an interventional study, and recruitment status changes were made available on the summary table. Also, "Location terms" was removed as a default search field, based on user feedback, and changes were made to labels on the site menu to improve clarity.

The May 25, 2023, release featured a refreshed home page that included a redesigned disclaimer and a simplified search experience combining the basic and advanced search features of the classic website, improving the functionality of the advanced filters. Also, a new API migration guide was provided to assist API users in transitioning to the new API, "Intervention/Treatment" and "Study Status" were added as default search fields, and a radius slider was included to help users find studies close to a specified address.

In the June 14, 2023, release, a What's New page was added, and the spell-check function for two fields in the default search form—the Conditions or disease and Other terms search fields—was improved to include suggestions for misspelled words. Various bug fixes and general formatting improvements were also made. Preparations to make the modernized ClinicalTrials.gov the primary website continued.

The August 3, 2023, release featured the ability to search by enumerated fields and a new landing page for the About This Site content. General improvements to the formatting, color palette, and text were made across the site. The FHIR®JSON download option for study records was also restored.

The September 28, 2023, release focused on new functionality for saving study records and for creating an RSS feed. A new page, My Saved Studies, was added to allow users to view and manage their saved studies. The study record cards were redesigned, and additional information icons with links to the glossary for terms found in the study were added.

On June 21, 2023, the modernized ClinicalTrials.gov website became the primary site. The modernized site includes the following:

- A new home page with a welcome message
- A simple search, located on the home page, which uses a cloud-based infrastructure with elastic search for lightning-fast response times
- Search results on cards that highlight key information for each study such as overall study and recruitment status, study locations relevant to the user's search, and related terms within the study record
- An improved table view of search results that allows users to customize their experience
- A redesigned study record page with easy navigation, collapsible sections, interactive study results tables for data researchers, and an integrated Google Maps API for viewing study locations
- Updated background information about ClinicalTrials.gov and educational information about clinical research, presented in plain language

Metrics and Evaluation, Including User Feedback

Since the launch of ClinicalTrials.gov Beta in December 2021, the modernization team has solicited user feedback via the site's **Feedback** button, surveys, and usability testing. The team has assessed and analyzed over 2,500 comments from users, including more than 600 comments since the modernized ClinicalTrials.gov became the primary website in June 2023. 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. Examples of these comments are shown in figure 5.

Figure 5. Sample feedback on ClinicalTrials.gov

I conduct searches and then select the ones I'm interested in reviewing. Then those are all compiled in my **saved studies list**. Very handy for me. I can't see a similar option in the new platform. **Downloading the results is not equivalent**.

Is there no longer an option to **subscribe to an RSS feed**? How can I track the status of trials without having to manually search for them?

Please show more columns at one time in the search results page. The old CT.gov displayed much more information at once. Having to scroll within an embedded frame is the worst possible design.

I miss the map view and option to quickly assess the geographies of trials returned in the search. **This map is a vital tool** that helps feasibility professionals assess the landscape quickly. Can this be added to the new clinicaltrials.gov?

It would be nice to be able to click the column title and it **sorts the table results by that column** in descending order. This is standard and expected functionality for tabular search results.

I am very concerned Ñ about the **lack of fields available for download in .txt and XML format** that were available with prior, now Classic system. This information is needed for import to EndNote and other software for many working on systematic reviews. It would be nice to have an .RIS format as well.

As noted previously, users are central to the team's approach to modernization. Figure 6 provides one example of how user feedback was incorporated into the design and development process, resulting in an updated **Search** button on the modernized site.

Figure 6. User feedback in action

BEFORE

AFTER

Many users commented that the color scheme made the **Search** button hard to see and that it was confusing to go back to the top of the form to click on **Search**.

For the next release of the beta site, we increased the contrast between the **Search** button and its background; moved the button to the bottom of the form; and made it "sticky" so that it is always visible on the page, no matter how many search fields are added.

ClinicalTrials.gov

Many of the core features of the classic website are available on the modernized ClinicalTrials.gov, including the search function, study record details, record history, and table view of a study record. However, the team continues to review user feedback to help prioritize the migration of other classic site features to the modernized site.

Future Releases and Features

Future ClinicalTrials.gov releases will be strategic, occurring less frequently than during the beta development phase of modernization. These releases will focus on providing significant functionality to users.

Features under development for the modernized ClinicalTrials.gov include XML download functionality and version 2 of the API; the data ingest process, which pulls data from the PRS and populates the study records on the public site, is also being rewritten. Work on developing version 4 of the study record history, migrating content from the classic site to the modernized site, developing version 3 of the table view of search results, and providing information about next steps to join a study is ongoing.

PRS Beta

2022–23 Releases

During this reporting period, there were 11 PRS Beta releases, which are described below.

The October 24, 2022, release included bug fixes on the Record List page. Many of these fixes were made in response to user feedback.

In the November 10, 2022, release, updates to PRS Beta, made in the PRS Test system, allow users to create a new record as well as edit two Protocol Section modules. This release also featured on-demand help tips and guidance to make the data elements more understandable. More direct access to data element definitions, through slide-out drawers, and a left-hand navigation rail were added as well.

In the December 15, 2022, release, the Study Status, IPD Sharing Statement, and Conditions modules were added to the Protocol Section in the PRS Test system. These modules include new or updated onscreen guidance. The ability to view validation errors at the top of all modules and a single text box for adding conditions and keywords were also added.

In the January 26, 2023, release, the Study Design, Eligibility, and References modules were added to the Protocol Section in the PRS Test system, along with new and updated help content available onscreen and in slide-out drawers. Detailed guidance on gender-based eligibility was also provided, and the format for adding citations was simplified.

In the February 9, 2023, release, an additional module was added to the Protocol Section in the PRS Test system, along with updated onscreen guidance and new error-message displays. Various bug fixes were also implemented.

In the March 29, 2023, release, two additional modules, with new help content, were added to the Protocol Section in the PRS Test system. An auto-suggest feature for adding collaborators and the investigator affiliation was also added, and new page designs for the Arms and Interventions and Outcome Measures modules were implemented.

In the April 13, 2023, release, the Contacts and Locations module was updated in the Protocol Section in the PRS Test system. A cross-references table was added to the Arms

and Interventions module, and the design of and navigation to the Contacts and Locations module was updated. Bug fixes to resolve general content and formatting issues were also implemented.

In the May 4, 2023, release, updates to PRS Beta were released to the PRS production system. This release included all of the Protocol Section modules, each with a new design, improved navigation, and updated help content. Information icons linking to slide-out drawers with additional help content and direct access to data element definitions were added, and an updated color scheme, larger fonts, and clearly identifiable tabs and section labels were implemented.

In the June 22, 2023, release, updates to PRS Beta, made in the PRS Test system, included the framework for the Record Summary and Protocol Summary pages and the display of error and warning messages at the data element level. Improvements to the Protocol Section modules also continued.

In the July 13, 2023, release, additional functionality was added to the Protocol Summary and Record Summary pages in the PRS Test system, along with new and updated onscreen guidance and slide-out drawers containing additional information. A record status bar to help track the study record's progress from creation through posting on ClinicalTrials.gov was also added, as well as a menu with options for identifying and interacting with people involved with the study record.

In the August 8, 2023, release, updates to PRS Beta were released to the PRS production system. This release included the Record Summary and Protocol Summary pages, each with a new design and new and updated help content. Menus for various record actions were added. Also, a study record can now be copied, deleted, downloaded, or uploaded using the Actions menu. In addition, the Protocol Summary page displays a summary of all the information for all the Protocol Section modules, along with a collapsible list of validation messages.

Metrics and Evaluation, Including User Feedback

The modernization team has documented user feedback on PRS Beta 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. For example, the team has employed user feedback to refine the Record List and the record summary, among other features. A summary of recent user comments on PRS Beta is provided in figure 7.

Figure 7. Summary of recent feedback on PRS Beta

Based on PRS Beta general comment card responses, the most significant feature updates that users would like to see are:

- Add username and full name to make the modifier immediately identifiable
- Make error messages more recognizable by using the red box around
- Allow editing of whole record rather than making the user select **Edit** on every module
- Improve functionality issue with XML conversion of characters/symbols
- Add the PI to the access list and allow users to auto-generate an email to not just the Record Owner, but to some or all users in the Access List
- Add autosave to data entry screens

Percentage of Comments
May 5–August 9, 2023 (44)
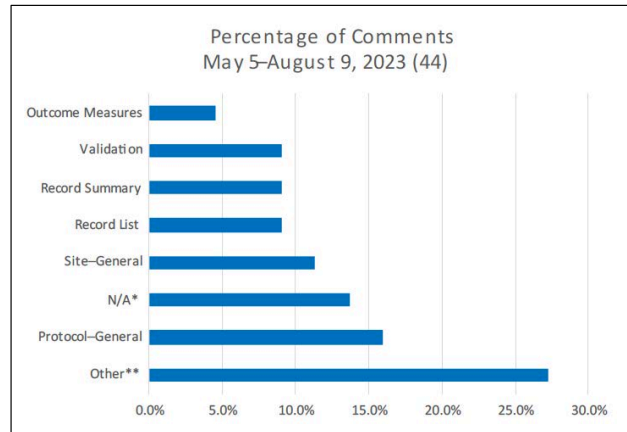
* 14% of comments labeled N/A concerned features that had not yet been built, such as the results modules, or provided other noncontextual feedback.

** 27% of comments aggregated under the Other category provided minimal comments related to the protocol modules, including Arms and Interventions, Study Design, Study ID, Tools and Education, and Download, among others.

Future Releases and Features

Features under development for PRS Beta in 2023–24 include the record-submission workflow, the protocol registration quality-assurance (QA)/quality-control (QC) processes, results submission, and the results QA/QC processes. The database design is also being optimized.

3. Progress on the Modernization Strategic Goals

Features included in the modernized ClinicalTrials.gov and PRS Beta releases in 2022–23 that align with the modernization priorities established by the Working Group are described in the sections that follow, grouped by strategic 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
    - Tabs were added to group the study record information so that it is easier to view and understand (e.g., creation of a record summary that is separate from the Protocol Section and other parts of the record).
    - A left-hand navigation rail was added to allow direct access to a summary of the Protocol Section and all the modules it contains. Once users have created a record, they can use this navigation option to add information to the record in any order they choose.
    - The color scheme was updated; the font size was increased; and features that make data easier to access, enter, and delete were added.
    - Information that summarizes the record was reorganized on the Record Summary tab; related fields (e.g., record dates, status indicators, information about users with access to the record, record-processing options) were grouped to make them easier to find and to provide context.
    - Explanations of the differences between various record functions, such as upload and download options, were added, and email addresses were added to the access list to facilitate communication among members of an organization.
- Enhancing content that encourages correct use of data element fields
    - Onscreen content was revised and expanded, and information icons that link to slide-out drawer content were added to data element names. The drawers enable direct access to the data element definitions as well as brief descriptions and additional information in plain language to support greater understanding. Examples of targeted guidance include the following:
        - Descriptive information was added for the Gender Based data element to ensure that relevant and appropriate details are included in this field.
        - Stronger wording was added to encourage the reporting of U.S. federal government grant or contract numbers as Secondary IDs for studies funded by federal agencies, since this information is required, if applicable, but is often missing.
        - Context-sensitive onscreen and slide-out drawer content, based on the study type selected (interventional, observational, or expanded access), was added.

- Improving automated, just-in-time PRS support and resources to reduce the need for one-on-one assistance, particularly during the QC review process
  - Validation messages were placed in a central location that provides direct access to the modules that need attention, to both emphasize the issues and make them easier to resolve. These messages notify data submitters of errors that must be addressed and warnings that should be addressed, if possible, before a record is submitted for QC review.
  - Notes to data submitters, which do not need to be addressed and typically remain visible, were replaced with information onscreen and in slide-out drawers as much as possible.

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 ClinicalTrials.gov search experience
  - Modernized ClinicalTrials.gov: The home page user interface was streamlined by moving the action bar to the bottom of the search form, adjusting the fields included in the default search form, and making advanced filter functionality more intuitive based on user feedback, usability testing, and a heuristic review of the website.
  - PRS Beta: Help content was added that encourages data submitters to include information that will make searching for clinical trials easier for patients, caregivers, patient advocates, and health care providers. This support includes targeted onscreen content and links to plain language resources (i.e., a checklist and template) for the Brief Summary data element.
- Enhancing the functionality and features of ClinicalTrials.gov based on user feedback—For example, users can now reorder the columns in the table view of search results and have a table view of study details that focuses on data of interest to researchers. A record history tab was added to the study record during this period, and users have both My Saved Studies and RSS feeds to manage studies of interest over time.

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 and enhanced API service to support data reuse by third parties, including patient-oriented organizations and researchers who conduct analyses of the clinical research enterprise or the clinical research landscape

- o Along with technical documentation, a new draft API for additional access to data on the modernized ClinicalTrials.gov website was released.
- o An API migration guide was added to assist users in transitioning from the classic to the modernized ClinicalTrials.gov.
- Supporting interoperability of clinical trial information via Fast Healthcare Interoperability Resources (FHIR)
  - o The FHIR®JSON download option for study records was restored.
  - o The "Learn About HL7® FHIR® Standard" page was restored.
- Researching opportunities and developing tools based on advanced computational techniques, such as artificial intelligence (AI), to improve aspects of the QC review workflow for submitted clinical trial registration and results information
  - o A tool that suggests units of measures for outcome measures during QC review in the reviewer's native work environment was implemented. The tool uses advanced computational techniques to determine units of measure based on information in the outcome measure title and description and, currently, can classify more than 100 different units. If the tool cannot determine a relevant unit from its options, it will not display a suggestion; otherwise, a suggestion will be displayed in the vicinity of the entered unit.

4. Working Group Input on Modernization

The NLM Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization was formed in September 2019 to provide oversight of and input on the modernization effort. The Working Group included individuals who represented the three key external stakeholder groups: (1) data submitters, (2) patients and their advocates, and (3) data researchers. Working Group members were initially asked to serve for 1–2 years; of the 14 members from 2022–23, 12 participated since the initial 2019–20 period. During the 2022–23 reporting period, one new member was added, with a background in research informatics.

The Working Group met three times during this reporting period. Working Group Chair Lourdes Baezconde-Garbanati reported on the group's activities during the subsequent full NLM BOR meetings in February and May and Working Group member Omolola Ogunyemi reported during the full BOR meeting in September.

Working Group Meetings

Highlights from the Working Group meetings during this reporting period are provided below.

December 19, 2022, Meeting

The purpose of this meeting was to summarize for Working Group members the progress made during 2022 on the modernized ClinicalTrials.gov and PRS Beta as well as gather input from the group on communication plans for 2023. The discussion of those plans focused on a virtual public meeting on modernization proposed for April and Working Group members' interest in participating in that meeting.

Increased user outreach in the latter part of 2022, undertaken in response to earlier Working Group feedback on stakeholder engagement, was highlighted. Outreach activities included hosting an October 27, 2022, virtual public webinar and question-and-answer session on the progress of the modernization effort with almost 400 participants; conducting more stakeholder conversations and making more presentations at conferences and similar events; and releasing the Report on the ClinicalTrials.gov Modernization Effort, Summary of Progress: 2021–22.

The modernization effort's 2022 milestones, specifically, the ClinicalTrials.gov and PRS beta launches and subsequent releases, were reviewed. It was noted that modernization of the PRS was on a timeline separate from modernization of the ClinicalTrials.gov public website. The PRS Beta and ClinicalTrials.gov Beta product owners provided brief updates and previewed plans for 2023. For PRS Beta, recent efforts had concentrated on the protocol registration, which will be released in its entirety to the PRS Beta production system in spring 2023. The release of data-entry forms for results reporting and enhanced QA/QC processes for internal team members are planned for 2023–24. For the modernized

ClinicalTrials.gov, user research activities were described. It was noted that updates will be released more frequently in 2023, in support of making the modernized ClinicalTrials.gov the primary website. The team's response to feedback from the Working Group regarding the need to drive traffic to the modernized site was also discussed. Related changes included updating the banner on the classic site that takes users to the modernized site and adding a link from study records on the classic site to the corresponding records on the modernized site. An increase in visitors to the modernized website followed each of those updates.

Specific Working Group activities planned for 2023 were discussed, including Working Group and NLM BOR meetings and an April public meeting. The modernization effort began with focus on public input and included a public meeting in 2020. As the modernization effort entered its concluding phase, the team planned to host a public meeting to gain input on progress made so far and the activities that remain. Attendees briefly discussed the preliminary plans and draft agenda for the public meeting, which would include Working Group members, who are the voices of their communities, speaking and sharing insights on selected beta site features. The team also proposed hosting breakout sessions on the public website and the PRS during the meeting to allow for deeper discussion. The public meeting would be discussed in detail during the next Working Group meeting, in January, and members were asked to consider what public meeting attendees might find helpful, how to hold their attention for 2–3 hours, and what they would be most interested in hearing about.

January 13, 2023, Meeting

During this meeting, the April modernization public meeting and other work planned for spring were discussed. Feedback was solicited from the Working Group on one new item, data monitoring committee (DMC) charters, and follow-up was provided on another item discussed previously, the modernized ClinicalTrials.gov disclaimer text. The group also welcomed new NLM BOR and Working Group member Nancy Smider, of Epic.

A proposal by a stakeholder to create dedicated space on ClinicalTrials.gov to post DMC charters or links to those documents was presented. DMCs play a critical role in the conduct of clinical trials by independently assessing the risks and benefits of interventions to participants during trials, and their responsibilities are defined by a charter for each clinical trial they monitor. Attendees discussed the benefits and challenges of making DMC charters publicly available via ClinicalTrials.gov and reviewed possible options for the voluntary reporting of DMC charter information to ClinicalTrials.gov.

The team provided an update on the modernized ClinicalTrials.gov website's disclaimer text, noting that it had been almost a year since the Working Group provided valuable feedback on this item during a usability session. In addition to the usability session with the Working Group, the team also conducted a workshop to gather input from staff and others at The Children's Inn at NIH; this was made possible by Working Group member Jennie Lucca of The Inn. Images of the recent design prototype, intended to update the

functionality of the disclaimer and make it interactive, were shared, along with plans for usability testing.

The discussion of Working Group activities anticipated for 2023 centered on the modernization public meeting. In the coming months, the ClinicalTrials.gov team will work with group members individually to prepare for the public meeting in April. The group was reminded that the team planned to make the modernized ClinicalTrials.gov website the primary public site by June. Regarding PRS Beta, selected protocol registration modules had been made available in the PRS Test system, and the team was planning to make all the protocol registration modules available in the PRS production system in the spring. It was noted that when there were beta site releases, the team announced them through various channels, such as blogs, the *NLM Technical Bulletin*, public webinars, and educational videos.

The draft agenda for the public meeting was reviewed, and the Working Group's feedback was solicited. The public meeting will begin with a 25-minute welcome and introductory segment, which will acknowledge the Working Group and its contributions, provide a brief history of the multiyear modernization effort, discuss the current status of modernization, and describe milestones achieved this year in particular and the communications announcing them. Efforts by Working Group members, such as Carrie Dykes of the University of Rochester Clinical and Translational Science Institute, to communicate with their communities about modernization were also noted.

The team will then provide an overview of usability research conducted for the modernization effort, focusing on the fact that modernization has been a user-centered process. The types and amounts of feedback received will be described, and the fact that the team reads all comments and tries to incorporate them into the design and development process will be emphasized. There will be a review of how the team reached this point in the effort, from research to insight to product vision to concept to design, and how the team works together before and after each release to iteratively design, develop, and improve the sites. How the needs of the three external user groups (data submitters, patients and their advocates, and data researchers) have been balanced will also be illustrated.

Next on the public meeting agenda were two "getting to know you" presentations, one on the modernized ClinicalTrials.gov and one on PRS Beta, which the team hoped would include Working Group members demonstrating how they use a particular beta site feature. These two presentations would highlight new site features and improvements; orient attendees to what is currently available on the beta sites, particularly the updates made since the October 2022 public webinar; and describe what is planned for the future. There will also be two breakout sessions to address the public site and the PRS in greater detail, and the team noted that this was where Working Group member input was most needed.

During the meeting, Working Group members made various suggestions, both general and specific, and some members confirmed that they were willing to participate in the public meeting.

Progress on the modernization effort and plans for the April public meeting were reported to the full NLM BOR during the February 7, 2023, meeting.

August 25, 2023, Meeting

The final meeting of the Working Group opened with a summary of the accomplishments of the ClinicalTrials.gov modernization effort to date and the critical role played by Working Group members, including participation in 16 meetings and several public activities and events. Two progress reports describing the modernization effort, including the valuable input received from the Working Group, had been released, and a third report was in progress. Planned activities for years 4 and 5 of modernization were also described. The modernized ClinicalTrials.gov website will continue to be refined through additional releases and updates. Development of PRS Beta will continue, with new features released during the rest of 2023 and into 2024. Usability testing, evaluation, and engagement with stakeholders were ongoing. The need to increase engagement among diverse groups of patients who are underrepresented in clinical research, as well as their advocates, was noted, and Working Group members were asked for their suggestions.

Summaries of the latest progress on PRS Beta, PRS Automation Support Team activities, and the modernized ClinicalTrials.gov were provided. Features introduced in recent releases of PRS Beta, such as the Record Summary page and new just-in-time help and field-level error messages in the Protocol Section were highlighted, and next steps for PRS modernization, including the protocol QA/QC review pages, results submission modules, results QA/QC review pages, and account management pages, were presented. The difference between PRS Test, where users can try out new PRS Beta features, and the PRS production system, where the new features are deployed and go live, was also explained. A Working Group member recommended developing a simple infographic that shows how to access PRS Beta from the classic site and highlights the differences between the PRS test and production environments.

An update on providing access to DMC charters through ClinicalTrials.gov was shared as a follow-up to a previous Working Group discussion. As recommended by the Working Group, NLM planned to update an existing optional data element to allow standardized labeling of links within ClinicalTrials.gov to DMC charter documents posted on other websites. This plan addressed the needs described in a May 2023 commentary by DeMets et al. in *Clinical Trials*, and implementation was anticipated for 2025, following completion of the modernization effort. Working Group members were asked to engage with their communities to promote the use of this new DMC charter–linking capability once it became available.

Efforts by the PRS Automation Support Team to automate aspects of the QC review process using machine learning and deep learning classifiers were also described. The classifiers had been trained to identify the three most common major issues identified by reviewers in registration records, and the results were summarized for the group. Future

efforts will explore the utility and value of integrating the classifiers into the QC review team's native work environment.

Recent usage trends, user feedback, and usability testing activities for the modernized ClinicalTrials.gov website were presented. Since the modernized ClinicalTrials.gov became the primary website in June, the team had monitored traffic to the classic and modernized sites and had collected user feedback to guide further improvements. Usability testing was ongoing, and before the classic site is retired in 2024, content migration will be completed, an XML download option will be integrated, the ClinicalTrials.gov API will be finalized, and the data ingest from the PRS will be rewritten. Recent additions to the modernized site were demonstrated, and Working Group members were asked to continue to promote the modernized ClinicalTrials.gov to their networks and to convey user feedback to the modernization team.

ICF user experience researchers facilitated a landscape analysis activity that assessed Working Group members' experience with two features of the classic ClinicalTrials.gov website that allow users to find studies by topic or on a map; the activity also gathered feedback on those features. Working Group members agreed that it would be good or important, but not critical, to have both features available on the modernized website by the time the classic site is retired, and the Finding Studies by Topic feature was ranked as more important than the Finding Studies on a Map feature.

The Director of NLM, the Acting Director of NIH, the Acting NIH Associate Director for Science Policy, and the Acting Director of ClinicalTrials.gov all provided closing remarks in which they thanked Working Group members for their nearly four years of service in support of the modernization effort. Working Group Chair Lourdes Baezconde–Garbanati and the modernization team were also thanked for their work. Working Group members were encouraged to continue reaching out to the team to share their feedback.

Progress on the modernization effort was reported to the full NLM BOR during the September 12–13, 2023, meeting.

5. Public Communications Related to Modernization and the Product Releases

Overall Approach

The ClinicalTrials.gov team has approached public communications about modernization with an eye to informing and educating stakeholders and the general public. The team has focused not only on ensuring that people such as data submitters, patients and their advocates, and data researchers (including journal editors) have the basic information they need about the current state of the modernization effort but also on generating excitement about what is to come. This dual focus is accomplished by showcasing the modernized ClinicalTrials.gov and PRS Beta 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 supporting reporting to the full NLM BOR during its regularly scheduled meetings
- Hosting public meetings and webinars
- Attending and presenting at conferences, industry meetings, and other events

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

- [Hot Off the PRS! e-bulletin](#) (more than 10,000 subscribers)
- [News and Updates](#) and [ClinicalTrials.gov Modernization](#) pages of the modernized ClinicalTrials.gov website
- ClinicalTrials.gov [Release Notes](#) and PRS Beta [Release Notes](#) pages, where summaries of all releases are publicly available

During this reporting period, the October 2022 public webinar and the April 2023 public meeting were two high-profile venues for sharing the latest modernization news with a wide audience and engaging with stakeholder communities.

Approach to the Modernized ClinicalTrials.gov Becoming the Primary Website

The team employed a strategy focused on education during the lead-up to the modernized ClinicalTrials.gov becoming the primary website on June 21, 2023. The team worked with NCBI and NLM to share social media updates in the months prior to this milestone, including a variety of blog posts and articles:

- *Musings from the Mezzanine* post on [March 29, 2023](#) (500,000 subscribers)

- *NCBI Insights Blog* post on June 6, 2023 (16,712 subscribers)
- *NLM Technical Bulletin* article on June 21, 2023 (47,000 subscribers)

The official launch of the modernized ClinicalTrials.gov was also covered by the CenterWatch website in a June 26, 2023, article, "Modernized ClinicalTrials.Gov Website Goes Live." The site reaches 200,000 clinical trial executives.

Social media communications about this milestone occurred from April to June 2023, with more frequent postings in the week leading up to June 21. Coverage appeared in posts on NLM and NCBI social media channels (Facebook, LinkedIn, and Twitter (now known as X)) on June 12, 20 and 21. Social media posts that linked to the *NLM Technical Bulletin* article and *NCBI Insights Blog* post received more than 14,000 impressions and more than 100 reactions (such as "like" and "celebrate"). An example of these social media posts is shown in figure 8.

Figure 8. Example of NLM social media post on the day the modernized ClinicalTrials.gov website became the primary site

A debriefing meeting was held in August 2023 with NCBI and NLM communications staff to review what went well during this campaign and discuss what could be done to communicate major modernization events and activities in the future.

Plans for 2023–24

Possible communication activities for the coming year include conducting targeted outreach to patients and other diverse audiences and educational sessions with interested groups who want to learn more about the modernized ClinicalTrials.gov, speaking at industry events and conferences, and creating prerecorded videos that demonstrate how to use the modernized site. Other forms of stakeholder outreach and engagement, such as hosting public webinars, will also be considered.

6. Research in Support of the Modernization Effort

Over the past few years, ClinicalTrials.gov staff have undertaken 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 conducted research to assess the feasibility of using AI, such as natural language processing, machine learning, and deep learning, to identify problematic entries (i.e., major issues) in outcome measures in protocol registration records.

As shown in table 1, the top three major issues occurring in more than one third of initial study registrations with major issues between 2020 and 2021 were the Multiple Measures, Vague Time Frame, and Unclear Measure major issues. The term "multiple measures" refers to entries that list more than one outcome measure with different units of measure (e.g., height and weight). Because only one unit of measure can be accommodated in each outcome measure data table, multiple measures with different units of measure must be separated into different tables or information needs to be provided to clarify that the intent is to combine the different measures as a single measure (e.g., body mass index). "Vague time frame" describes entries that do not provide sufficient information to understand the specific time point at which a participant will be assessed or the duration of data collection. Not only do these major issues occur frequently across protocol registration submissions, but they can also occur more than once within a submission. For example, from July 1, 2020, through July 31, 2021, the Vague Time Frame major issue occurred three times per submission, on average. Finally, "unclear measure" refers to entries that do not provide sufficient information to understand what, specifically, will be measured and summarized in the outcome measure data table (e.g., the measure is listed as "Safety" without sufficient details about how safety will be assessed). This historical data set is well suited for training a classifier, since it is already labeled with the type and location of the major issue and is comprised of a variety of different instances of the same type of major issue. Using this data set, the team explored the feasibility of applying AI to classify the occurrence of these major issues automatically in protocol registration submissions.

Table 1. Top three most common major issues in registrations across all organizations among 25,431 initial submissions with major issues from July 1, 2020, through July 31, 2021

Standard Major Issue Comment	Number (Percentage) of Submissions with Major Issues	Mean (SD) Issues per Submission
Multiple Measures More than one outcome measure appears to be described.	10,718 (42%)	1.7 (1.16)
Vague Time Frame The Time Frame does not appear specific or in the correct format.	9,816 (39%)	3.0 (2.90)
Unclear Measure The measure does not appear to include sufficient information to understand what will be assessed.	10,394 (41%)	1.8 (1.38)

Different machine-learning algorithms and a deep-learning algorithm were trained to determine whether major issues were present in the outcome measures in the Protocol Sections of study records. Recall (also known as sensitivity) and precision (also known as positive predictive value) were among the metrics used to evaluate classifier performance. A perfect classifier has a recall and precision of 1, meaning, in this case, that the classifier does not miss any measures identified by reviewers as having the major issue and does not incorrectly label a measure as having the major issue when it was not labeled by reviewers as having the major issue.

For all three major issues associated with outcome measures in the Protocol Section, the deep learning classifier outperformed the machine learning classifiers. Performance of the deep learning classifier is presented in table 2. The model correctly classified 93% of outcome measures identified by reviewers as having the Multiple Measure major issue, and 13% of outcome measures identified by the classifier as having the major issue were not labeled by reviewers as having the major issue. These results demonstrate that the model was able to perform at a high level for this classification problem. However, training and testing was performed using artificially balanced data sets, in which outcome measures labeled as having the major issue and those without that label were equally represented. This level of performance may therefore not be generalizable to a more realistic data set in which the major issue occurs less frequently.

Performance was assessed using a test data set that simulated a more realistic major issue prevalence for the Vague Time Frame major issue using 100 resampled test sets. The median precision and recall for the deep learning classifier were 0.88 and 0.96, respectively, indicating that the classifier was able to retain a high level of performance even for a more realistic distribution of the major issue in the data.

For the Unclear Measure major issue, classifiers were trained and tested using the more realistic major issue prevalence. The deep learning classifier correctly classified 81% of outcome measures identified by reviewers as having the major issue. At the same time,

36% of outcome measures identified by the classifier as having the major issue were not labeled by reviewers as having the major issue. These results suggest that classifying measures as unclear is a much more challenging problem. Outcome measures may lack clarity for many different reasons, some of which may be due to information outside the outcome measure, which was not given to the classifier.

Table 2. Deep learning classifier performance. Performance for the Multiple Measures and Unclear Measure major issues corresponded to a balanced and a more natural, unbalanced test set, respectively. Performance on a decreased major issue prevalence was simulated for the Vague Time Frame major issue using 100 resampled test sets.

Major Issue	Test Set MI Prevalence	Recall	Precision
Multiple Measures	50% MI Prevalence	0.93	0.87
Vague Time Frame	Simulated 20% MI Prevalence	Median: 0.96	Median: 0.88
Unclear Measure	20% MI Prevalence	0.81	0.64

MI = major issue

This research provides a first glimpse into the feasibility of applying AI to identify major issues in protocol registration submissions. The deep learning classifier identified a large majority of outcome measures with the major issues. At the same time, it also labeled certain outcome measures as having an issue when reviewers had not labeled the measure as having that issue. If such a tool were incorporated into the QC review process, reviewers would not be able to simply accept the predictions of the classifier without additional consideration. This research did not assess reviewers' tolerance for error or the impact of error on reviewer productivity. However, it is likely easier to review an outcome measure that is erroneously classified as having a major issue than to find a major issue that has been missed by the classifier. These results suggest that incorporating AI into the QC review process has the potential to create efficiencies and support more standardized application of the major issue comments.

User Research and Input

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

The modernized ClinicalTrials.gov team conducted more than 40 usability testing and user interview sessions to evaluate the site's search feature and evaluate prototypes for the Saved Studies feature. During the past year, the PRS modernization team hosted user experience workshops to help determine a schedule for, the goals of, and priorities related to testing. Moderated sessions with data submitters were also conducted to gather feedback on the How to Create and Modify a Record feature, the Conditions module, the record status bar, and the version of the PRS released on May 4.

The ClinicalTrials.gov modernization team also collected input on the user experience by polling 96 Clinical Trials Registration and Results Reporting Taskforce attendees to gather feedback on use of the RSS feed feature, conducting a landscape analysis with the Working Group to evaluate their experience with finding studies by topic and on a map using those features on the classic ClinicalTrials.gov website, surveying PRS users to gather input on the Protocol Section, and polling the Working Group to assess their understanding of the various PRS environments, among other activities. All these activities have informed the design and development of the modernized ClinicalTrials.gov and PRS Beta.

In addition, the team developed a process for analyzing user feedback collected by the NCBI comment card. As of August 2023, the team has analyzed more than 2,500 comments, received from both new and returning ClinicalTrials.gov and PRS Beta users, and provided recommendations based on that feedback, and the team continues to assess and analyze all comments received. A snapshot of the volume of feedback received on the modernized ClinicalTrials.gov is provided in figure 9.

Figure 9. Number of NCBI comment card responses on the modernized ClinicalTrials.gov website, January 3–August 14, 2023
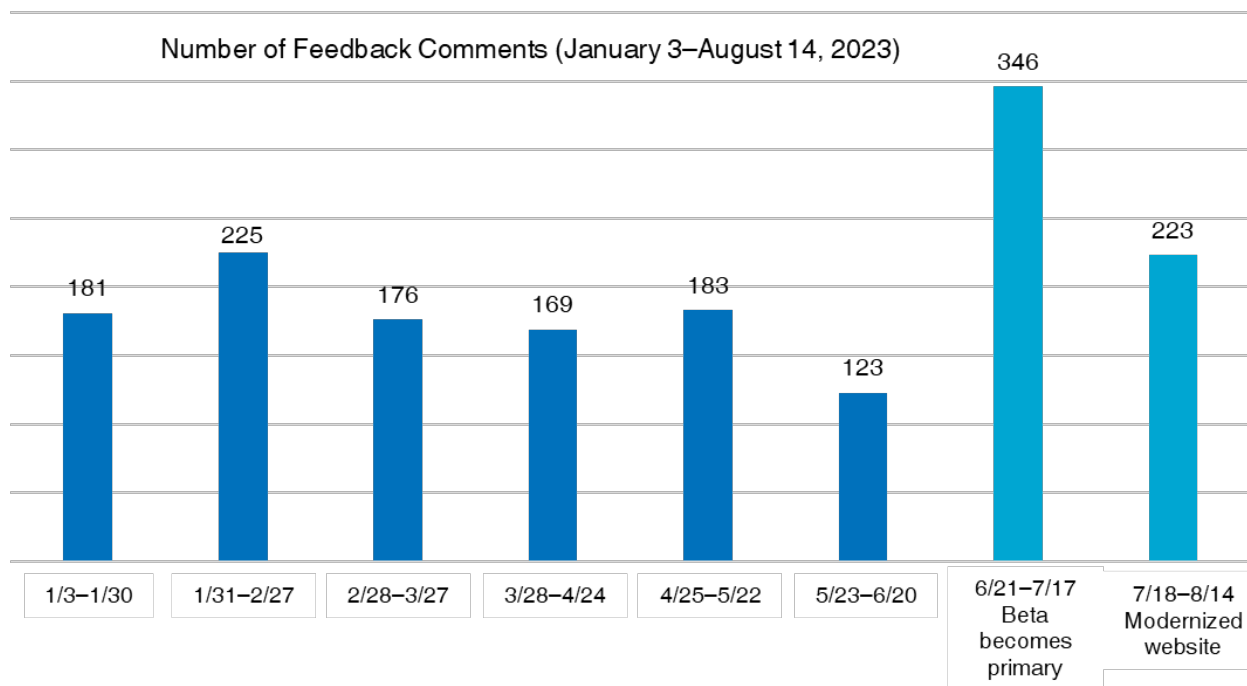
In addition, the team continues to use the more than 1,400 modernization request for information responses and feedback from the more than 70 interviews the team conducted in 2020 to support the modernization of both ClinicalTrials.gov and the PRS.

7. Modernization Next Steps and Future Activities

Plans for 2023–24

Modernized ClinicalTrials.gov

In the remaining year of modernization for ClinicalTrials.gov, the team plans to complete outstanding features such as the remaining functionality for study record history, finalize the API with direct input from API users with varying levels of familiarity with clinical trial data, and finish content migration. Communications around retirement of the classic website will begin in earnest in early 2024 so that users are aware and have time to complete the transition to the modernized website. The classic ClinicalTrials.gov will be sunset in the summer of 2024.

PRS Beta

The PRS Beta team is planning to complete the protocol registration QA/QC processes, results submission, and the results QA/QC processes. The team also plans to address user feedback on the Record List and the Protocol Registration section.

Automation Support

The PRS Automation Support Team demonstrated the feasibility of using AI technology for classifying outcome measure major issues through the development of several prototypes. This work involved offline data extraction and was developed in local environments with optimized data but proved highly successful on the classification tasks. Based on these findings, in the remaining year of modernization, the PRS Automation Support Team is planning to develop processes and tools for making the AI technology operational within the PRS to assess the effectiveness of the technology to support manual QC review of clinical trial registration and results information in reviewers' native work environment. Ultimately, the goal of this next initiative is to build a decision support tool that could reduce the time needed for manual QC review while maintaining consistent application of major issue comments across study records.

More Information

The following resources provide additional information about the ClinicalTrials.gov 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](#)
- [Recordings and presentation slides of public webinars and demonstrations](#)
- Modernized [ClinicalTrials.gov website](#)
- ClinicalTrials.gov [Release Notes webpage](#)
- ClinicalTrials.gov [News and Updates webpage](#)
- [ClinicalTrials.gov Modernization webpage](#)
- PRS Beta [Release Notes webpage](#)

Appendices

Appendix A: NLM Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization: Charge, Roster, and Biographies

NLM Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization

CHARGE

The NLM Board of Regents (BOR) Working Group on ClinicalTrials.gov Modernization is charged to explore topics such as, but not limited to, ways NIH can:

- Maintain the integrity of ClinicalTrials.gov as a trusted resource, particularly among an ever-expanding research enterprise
- Maximize the utility of the growing corpus of information, including through submission practices and user-focused technical functionalities
- Connect with stakeholders through engagement to ensure that their evolving needs are understood and considered in iterative design enhancements

The Working Group is expected to meet at least three times a year in conjunction with the BOR meeting and report regularly in open session to the full BOR on issues essential to the ClinicalTrials.gov modernization process, keeping pace with changes in the external environment and user expectations of key functionalities. All analyses and findings will take into consideration the existing legal and policy requirements.

ROSTER

Chair: Lourdes Baezconde-Garbanati, PhD, MPH, University of Southern California

Executive Secretary: Anna M. Fine, PharmD, MS, NLM, NIH

Board of Regents Members:

- Jennifer (Jennie) S. Lucca, MSW, The Children's Inn at NIH
- Omolola (Lola) Ogunyemi, PhD, FACMI, Charles R. Drew University of Medicine and Science
- Nancy Smider, PhD, Epic

Ex Officio NIH Members:

- Lyric A. Jorgenson, PhD, Office of Science Policy
- Pamela Reed Kearney, MD, Office of Extramural Research

External Members:

- Carrie Dykes, PhD, University of Rochester Clinical and Translational Science Institute
- Alissa T. Gentile, MSN, RN, Dana-Farber Cancer Institute
- Sally A. Gore, MS, MS LIS, University of Massachusetts Medical School
- Barbara Kress, BSN, RN, Merck
- Seth A. Morgan, MD, National Multiple Sclerosis Society
- Stephen J. Rosenfeld, MD, MBA, North Star Review Board and Freeport Research Systems
- Joseph S. Ross, MD, MHS, Yale School of Medicine
- Steven Woloshin, MD, The Dartmouth Institute for Health Policy and Clinical Practice

Former Members:

- Kent J. DeZee, MD, MPH, MACP, COL, MC, Defense Health Agency
- Carlos R. Jaén, MD, PhD, University of Texas Health Science Center at San Antonio (former BOR member and Working Group chair)
- Lauren A. Maggio, PhD, Uniformed Services University of the Health Sciences
- Gary A. Puckrein, PhD, National Minority Quality Forum
- Rebecca (Becky) J. Williams, PharmD, MPH, Essex, an Emmes Company (former Working Group executive secretary)

BIOGRAPHIES

Chair: Lourdes Baezconde–Garbanati

Lourdes Baezconde–Garbanati, PhD, MPH, is Associate Dean for Community Initiatives at the Keck School of Medicine and Associate Director for Community Outreach and Engagement at the Norris Comprehensive Cancer Center at the University of Southern California (USC). She is a tenured Professor of Population and Public Health Sciences and Associate Director for the Center for Health Equity in the Americas.

Dr. Baezconde–Garbanati is an expert in researching cancer disparities in diverse populations, developing effective culturally specific cancer–prevention interventions, and engaging at-risk populations in community–based participatory research. She has been a key member of six NIH–funded research centers. Currently she is one of the key investigators at the Tobacco Center for Regulatory Sciences at USC.

Dr. Baezconde–Garbanati speaks multiple languages and holds five academic degrees. She has a PhD and an MPH in public health from the University of California, Los Angeles, where she focused on community health sciences and social epidemiology. She has a master's degree from the Université catholique de Louvain in Belgium and received dual degrees in industrial and clinical psychology from the Universidad Nacional Pedro Henríquez Ureña in the Dominican Republic.

Executive Secretary: Anna M. Fine

Anna M. Fine, PharmD, MS, is Acting Director of ClinicalTrials.gov, an international registry and results database of clinical research, at the National Center for Biotechnology Information, National Library of Medicine, NIH. As Acting Director, she is responsible for technical, scientific, policy, regulatory, and outreach activities related to the operation of ClinicalTrials.gov. Dr. Fine assumed this role in 2021, after having served as deputy director since 2018. Her previous experience includes over a decade of service in stakeholder engagement, adverse drug event reporting, and supervisory roles at the U.S. Food and Drug Administration. Prior to that, she was Chief of Pharmacy Services at Hanscom Air Force Base in Massachusetts.

Dr. Fine has a PharmD from Northeastern University and an MS in psychopharmacology from William James College. She completed a postgraduate year two drug information residency at Stanford Hospital.

Board of Regents Member: Jennifer S. Lucca

Jennifer (Jennie) S. Lucca, MSW, is Chief Executive Officer of The Children's Inn at NIH. A seasoned human service professional, Ms. Lucca has more than 20 years of experience in the nonprofit sector. She previously served as The Inn's Chief Program and Services Officer, overseeing the daily management of resident services, family programs, and facility operations.

Ms. Lucca's career began in Anchorage, Alaska, where she worked for The Arc of Anchorage, an organization dedicated to serving individuals with disabilities. Since that time, she has focused primarily on developing and managing family support programs in community and health care settings. Passionate about supporting families during times of significant stress, Ms. Lucca has been acknowledged for her compassion, dedication, and strategic leadership.

Ms. Lucca has a bachelor's degree in child psychology from the University of Minnesota and an MSW with a focus on policy, planning, and administration from The Catholic University of America.

Board of Regents Member: Omolola Ogunyemi

Omolola (Lola) Ogunyemi, PhD, FACMI, is Director of the Center for Biomedical Informatics (CBI) and a professor in the Department of Preventive and Social Medicine at Charles R. Drew University of Medicine and Science. She is also a co-chair of the UCLA Clinical and Translational Science Institute's biomedical informatics program and adjunct Professor of Radiological Sciences at the David Geffen School of Medicine at UCLA, with the Medical and Imaging Informatics group. Her research at CBI focuses on novel biomedical informatics solutions for problems that affect medically underserved communities, and her research interests include computerized medical-decision support, reasoning under uncertainty, 3D graphics and visualization, and machine learning. Before becoming Director of CBI, Dr. Ogunyemi was a biomedical informatics faculty member in the Department of Radiology

at Brigham and Women's Hospital and Harvard Medical School, among other teaching positions.

Dr. Ogunyemi is currently an editorial board member for the *Journal of Biomedical Informatics* and was an editorial board member for *Computers in Biology and Medicine* from 2007 to 2013. She served on the National Library of Medicine's (NLM) Biomedical Library and Informatics Review Committee study section from 2003 to 2007 and on NLM's Literature Selection and Technical Review Committee from 2010 to 2014, both as a member and as chair. She was a member of the Agency for Healthcare Research and Quality Health Information Technology Research study section from 2016 to 2019 and a member of the American Medical Informatics Association's Doctoral Dissertation Award Committee from 2017 to 2020.

Dr. Ogunyemi has an undergraduate degree in computer science from Barnard College and an MSE and a PhD in computer and information science from the University of Pennsylvania. She is an elected Fellow of the American College of Medical Informatics.

Board of Regents Member: Nancy Smider

Nancy Smider, PhD, is Director of Research Informatics at Epic, where she focuses on Epic's electronic health record system as an enabling and accelerating technology to support the clinical research mission of health care organizations, including the execution of clinical trials. Dr. Smider joined Epic in 2001 and has led Epic's Research Advisory Council for more than 15 years. In addition to her extensive engagement with research leadership and stakeholders across the Epic community, Dr. Smider has been involved in numerous industrywide research work groups, conferences, and initiatives. She currently serves on the Vulcan HL7 FHIR Accelerator Advisory Council, which advocates for standards-based interoperability to facilitate a range of research activities.

Dr. Smider has a PhD in psychology from the University of Wisconsin–Madison. After completing a postdoctorate in health services research, she accepted a position as a research scientist at the University of Wisconsin School of Medicine, where she continued her work as part of a multidisciplinary team examining biopsychosocial models of health and disease.

Ex Officio NIH Member: Lyric A. Jorgenson

Lyric A. Jorgenson, PhD, is Acting Associate Director for Science Policy and Acting Director of the Office of Science Policy at NIH. In this role she provides senior leadership in the development and oversight of cross-cutting biomedical research policies and programs considered to be of high priority to NIH and the U.S. government. Previously she served in many roles across the agency, including Deputy Director of the Office of Science Policy, and she has led the development of numerous high-impact science and policy initiatives, such as the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative and the National Center for Advancing Translational Sciences. Dr. Jorgenson also served as Deputy Executive Director of the White House Cancer Moonshot Task Force in the Office of

the Vice President during the Obama administration, where she directed and coordinated cancer-related activities across the federal government and worked to leverage investments across sectors to dramatically accelerate progress in cancer prevention.

Dr. Jorgenson has a PhD from the Graduate Program for Neuroscience at the University of Minnesota Twin Cities, where she conducted research in neurodevelopment with a focus on learning and memory systems, and a bachelor's degree in psychology from Denison University.

Ex Officio NIH Member: Pamela Reed Kearney

Pamela Reed Kearney, MD, is Director of the Division of Human Subjects Research in the Office of Extramural Research (OER) at NIH. Prior to joining OER, she was the deputy chair of the Combined NeuroScience Institutional Review Board (IRB) in the NIH Intramural Program for approximately a decade. In this capacity she sat on three to four duly constituted IRBs, chairing one and serving as the vice chair of the others.

Dr. Kearney graduated with distinction from The George Washington University School of Medicine and completed an otolaryngology residency at The George Washington University. She was a Neurolaryngology Clinical Fellow for the National Institute of Neurological Disorders and Stroke in the Medical Neurology Branch's Laryngeal and Speech Section, and she later served as the staff clinician of the section. She has conducted clinical work at The George Washington University, Walter Reed Army Medical Hospital, and the NIH Clinical Center.

External Member: Carrie Dykes

Carrie Dykes, PhD, is Director of Research Services at the University of Rochester Clinical and Translational Science Institute (UR CTSI). Her primary role is to strategically plan, develop, implement, and evaluate the research resources and services of UR CTSI, and she provides leadership for the management and oversight of the Research Help Desk, Recruitment Unit, Clinical Research Center, Pilot and Incubator award programs, and Office of Regulatory Support. She also develops and assesses research education materials for a variety of constituencies across the University of Rochester Medical Center. Dr. Dykes serves as the University of Rochester's ClinicalTrials.gov Protocol Registration and Results System Administrator and is on the leadership board of the Clinical Trials Registration and Results Reporting Taskforce.

Dr. Dykes has a PhD from the University of Rochester and worked in the field of HIV drug resistance research for 20 years before joining UR CTSI.

External Member: Alissa T. Gentile

Alissa T. Gentile, MSN, RN, serves as the Dana-Farber Cancer Institute Research Nursing Manager for the Satellites and Collaborative. In this role, she leads the design, implementation, and evaluation of clinical oncology research and services conducted at Dana-Farber satellite and Collaborative locations and is a key facilitator for the oncologists

in the growth and development of the clinical research program across all Dana-Farber sites. Her responsibilities include providing nursing input for the review of prospective clinical trials and for retrospective review protocols; collaborating with study teams and network nurse leaders on hiring, training, and supervising satellite research nurses; and training and supporting Collaborative research nursing staff. She serves as the primary research nursing liaison between the satellite and Collaborative sites and Dana-Farber's main Longwood campus.

Prior to joining Dana-Farber, Ms. Gentile was the director of The Leukemia and Lymphoma Society's Clinical Trial Support Center, leading the efforts of a team of nurse navigators to educate people affected by blood cancers about the treatment option of clinical trials and to assist them in navigating the process of clinical trial enrollment. Previously she held the position of nurse educator at St. Elizabeth's Medical Center in Boston, Massachusetts, and early in her career she worked for many years as a Certified Emergency Department Nurse. Ms. Gentile has a bachelor's degree in nursing from the University of New Hampshire as well as an MSN focused on nursing management and education.

External Member: Sally A. Gore

Sally A. Gore, MS, MS LIS, is Manager of Research and Scholarly Communication Services for the Lamar Soutter Library at the University of Massachusetts Medical School. She oversees the library's collaborative efforts with basic science and clinical researchers on campus, including expanded support and instruction in data services. Her department leads all scholarly communication endeavors for the library, including providing bibliometric analysis; tracking research impacts; ensuring funder-based public-access compliance; promoting open science initiatives; and managing eScholarship@UMMS, the university's open-access institutional repository. Ms. Gore also serves on the Board of Directors of the Medical Library Association and is Associate Editor of the *Journal of eScience Librarianship*.

Prior to assuming her current position, Ms. Gore was the research evaluation analyst for the University of Massachusetts Center for Clinical and Translational Science. She was also a National Library of Medicine grant–funded informationist at the Lamar Soutter Library, a reference and instruction librarian, and a consumer health librarian. Ms. Gore has an MS LIS from Syracuse University.

External Member: Barbara Kress

Barbara Kress, BSN, RN, is Executive Director of Clinical Data Disclosure and Transparency at Merck. She is responsible for registry and results disclosure, redaction operations, data sharing, and the return of plain language summaries to patients. Ms. Kress joined Merck in 1997 as a clinical scientist working on the successful development and submission of several compounds. In 2007 she was asked to assume an additional responsibility that she was told would take up only 5% of her time: ClinicalTrials.gov. Fifteen years and more than 30 staff members later, disclosure requires 100% of her time.

Ms. Kress currently participates in various Pharmaceutical Research and Manufacturers of America, European Federation of Pharmaceutical Industries and Associations, and TransCelerate disclosure work streams. She is also a member of the Executive Committee of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard, participating in the Data Sharing and Return of Results (aggregate and individual) working groups. Ms. Kress began her career as a critical care and emergency room nurse. She has a bachelor's degree in nursing science from Rutgers University.

External Member: Seth A. Morgan

Seth A. Morgan, MD, is a Fellow of the American Academy of Neurology who served as a clinical neurologist for more than 20 years before becoming an advocate for people living with multiple sclerosis (MS) following his own MS diagnosis in 2004. An activist for people with MS and other types of disabilities, Dr. Morgan is a member and the current chair of the National Multiple Sclerosis Society's (NMSS) Maryland Governmental Relations Committee and an NMSS District Activist Leader. He is a commissioner on and the current chair of the Montgomery County, Maryland, Commission on People with Disabilities, the vice chair of the Maryland Alliance of Disability Commissions and Committees, and a commissioner on the Maryland State Disability Commission. Dr. Morgan's other public service activities include serving as a member of the iConquerMS Research Committee, a reviewer for the Patient-Centered Outcomes Research Institute's Clinical Trials Advisory Panel, and a member of the NMSS Activism Advisory Committee. He was also a reviewer for the Congressionally Directed Medical Research Programs from 2014 to 2016.

Dr. Morgan earned his medical degree from The George Washington University School of Medicine and Health Sciences, and he completed a residency in neurology at The George Washington University Medical Center. He is a Fellow of the Stroke Council of the American Heart Association and a Diplomate of the American Academy of Pain Medicine. Dr. Morgan was inducted into the NMSS Advocacy Hall of Fame in 2015.

External Member: Stephen J. Rosenfeld

Stephen J. Rosenfeld, MD, MBA, trained as a hematologist. He spent 19 years at NIH, holding positions at the National Heart, Lung, and Blood Institute (NHLBI) and the NIH Clinical Center related to both basic and clinical research and, later, working in medical informatics and administration, and he ended his time at NIH as Chief Information Officer of the NIH Clinical Center. He subsequently served as Chief Information Officer of MaineHealth, a large, independent delivery network based in Portland, Maine, and as Chief Executive Officer of the Western Institutional Review Board (IRB) in Olympia, Washington. He was also the executive chair of Quorum Review IRB for seven years. Dr. Rosenfeld is a founder of North Star Review Board, the first nonprofit 501(c)(3) independent IRB, and is the president of Freeport Research Systems, a consulting firm focused on the people and systems of biomedical research.

Dr. Rosenfeld earned his medical degree from Cornell University, trained in internal medicine at Dartmouth College, and completed his hematology fellowship at NHLBI. He has an MBA from Georgetown University. Dr. Rosenfeld received the honor of Distinguished Professor of Medicine from Daegu Catholic University Medical Center in Korea in 2013. Also in 2013, he was appointed to the Secretary's Advisory Committee on Human Research Protections at the U.S. Department of Health and Human Services, and he served as chair of the committee from 2017 to 2021. In 2018 he was elected to the Board of Directors of Public Responsibility in Medicine and Research, and in 2019 he joined the Board of Directors of the Association for the Accreditation of Human Research Protection Programs, which he currently chairs.

External Member: Joseph S. Ross

Joseph S. Ross, MD, MHS, is Professor of Medicine (General Medicine) and of Public Health (Health Policy and Management) at the Yale School of Medicine, a member of the Center for Outcomes Research and Evaluation at Yale–New Haven Health System, and Co–Director of the National Clinician Scholars Program at Yale School of Medicine. With expertise in the development of performance measures and the translation of clinical research into practice, Dr. Ross examines the use and delivery of higher–quality care and addresses issues related to pharmaceutical and medical device regulation, evidence development, post–market surveillance, and clinical adoption. Dr. Ross co–directs the Yale University Mayo Clinic Center of Excellence in Regulatory Science and Innovation, the Yale University Open Data Access Project, and the Collaboration for Research Integrity and Transparency at Yale Law School. He has published more than 500 articles in peer–reviewed biomedical journals and is currently the U.S. Outreach and Research Editor at *The BMJ*.

Dr. Ross earned his medical degree from Albert Einstein College of Medicine and an MHS from Yale School of Medicine.

External Member: Steven Woloshin

Steven Woloshin, MD, is a general internist, Professor of Medicine and Community and Family Medicine, and Director of the Center for Medicine and the Media at The Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine at Dartmouth. His research addresses the excessive fear and hope created by exaggerations and selective reporting in medical journals, advertising, and the health news. He has worked to improve the communication of medical evidence to physicians, journalists, policymakers, and the public, so they can make wiser decisions.

With Lisa Schwartz, Dr. Woloshin developed NIH's Medicine in the Media workshop and ran it for more than a decade. He is coauthor of the books *Know Your Chances* (selected for the National Center for Biotechnology Information's Bookshelf) and *Overdiagnosed* (winner of the Prescrire Prize). His essays have appeared in *The New York Times*, *The Washington Post*, and the *Los Angeles Times*. Dr. Woloshin is a founding organizer of the international Preventing Overdiagnosis meetings sponsored by *The BMJ*, The Dartmouth Institute,

Consumers Union, and Oxford and Bond University (Australia). He collaborates frequently with the National Cancer Institute, serves on the editorial boards of *JAMA Internal Medicine* and the Cochrane Library, and is a strategic advisor to Cochrane Sustainable Healthcare. He and Dr. Schwartz were co-winners of the American Medical Writers Association John P. McGovern Award for preeminent contributions to research and enhancing the communication of medical evidence. Dr. Woloshin is also the founder and director of the Lisa Schwartz Foundation for Truth in Medicine.

Dr. Woloshin earned his medical degree from the Boston University School of Medicine, completed internal medicine training at NYU/Bellevue Hospital, and completed a research fellowship at the White River Junction VA Medical Center in Vermont. He has an MS from the Geisel School of Medicine at Dartmouth.

Appendix B: NLM Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization Meeting Schedule: October 2022–September 2023

Date	Type
December 19, 2022	Working Group meeting
January 13, 2023	Working Group meeting
February 7, 2023	NLM Board of Regents meeting
May 9, 2023	NLM Board of Regents meeting
August 25, 2023	Working Group meeting
September 12–13, 2023	NLM Board of Regents meeting

Appendix C: ClinicalTrials.gov Modernization Team Members: October 2022–September 2023

Thank you to National Center for Biotechnology Information leadership and the many team members who have continued to support the ClinicalTrials.gov modernization effort, including:

- Stacey Arnold, ClinicalTrials.gov Results Subject Matter Expert (SME)
- Ben Babics, Protocol Registration and Results System (PRS) Beta Engineering Lead (contractor)
- Eric Babin, PRS Beta Back-End Team Lead (contractor)
- Richard Ballew, ClinicalTrials.gov Business/Data Analyst (contractor)
- Jayaram (Ram) Basava, Modernized ClinicalTrials.gov Website Developer (contractor)
- Gunnar Baskin, PRS Beta 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
- Jackie Bhadange, PRS Beta Cloud Architect (contractor)
- Landon Bressler, PRS Beta Business Analyst (contractor)
- Elissa Bush, ClinicalTrials.gov Technical Information Specialist
- Qiao Chang, ClinicalTrials.gov Technical Information Specialist
- Monica Corley, PRS Beta Business Analyst (contractor)
- Cassiah Cox, ClinicalTrials.gov Executive Director (contractor)
- Vinod Danam, PRS Beta Developer (contractor)
- Mandy Davis, ClinicalTrials.gov User Experience (UX) Researcher (contractor)
- Austin Devereux, PRS Beta Database Engineer (contractor)
- Nachiket Dharker, ClinicalTrials.gov Lead Results Analyst and PRS Beta Product Owner
- Sergey Dikunov, Modernized ClinicalTrials.gov Website Technical Lead (contractor)
- Sarah DiPasquale, ClinicalTrials.gov UX Researcher (contractor)
- Kayode Enwerem, PRS DevOps Engineer (contractor)
- Anna Fine, ClinicalTrials.gov Acting Director and Program Head (former Deputy Director)
- Beth Fordice, ClinicalTrials.gov Technical Information Specialist (former team member)
- Kim Fugel, PRS Beta Business Analyst (contractor)
- Madhurima Gade, Modernized ClinicalTrials.gov Website Developer (contractor)
- Robert Gale, PRS Automation Support Developer (contractor)
- Rithika Ganni, PRS Beta Quality Assurance Engineer (contractor)
- Jennifer Glas, PRS Beta 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)
- Jimithy Hawkins, Modernized ClinicalTrials.gov Website Business Analyst/Product Strategist (contractor)
- Brad Henry, PRS Beta Developer (contractor)
- Samrat Hirapara, PRS Beta Developer (contractor)
- Rafis Ismagilov, Modernized ClinicalTrials.gov Website Developer (contractor)
- Catherine Kihara, ClinicalTrials.gov UX Research Lead (contractor)
- Carl Leubsdorf, Consultant (contractor)
- Janine Lewis, PRS Automation Support Project Manager (contractor, former team member)
- Russell Loane, PRS Automation Support Developer (contractor)
- John Lopez, ClinicalTrials.gov Technical Lead (contractor)
- Jesus Mendiola, Modernized ClinicalTrials.gov Website Test Automation Engineer (contractor)
- Annie Morris, Modernized ClinicalTrials.gov Website UX Designer (contractor)
- Hibah Nazir, ClinicalTrials.gov Product Manager (contractor)
- Ngoc Nguyen, ClinicalTrials.gov Developer (contractor)
- Kenneth Ni, Modernized ClinicalTrials.gov Website User Interface (UI) Designer (contractor)
- Maria Ochoa Vargas, Modernized ClinicalTrials.gov Website UX Designer (contractor, former team member)
- Justin Pallini, PRS Beta UI Designer (contractor, former team member)
- Hardik Parekh, PRS Beta Front-End Team Lead (contractor)
- Chris Pemberton, PRS Beta 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, PRS Beta Developer (contractor)
- Gurdeep Sayal, ClinicalTrials.gov Technical Consultant (contractor)

- Max Shestopalov, ClinicalTrials.gov Scrum Master (contractor)
- Stephen Shoemaker, Modernized ClinicalTrials.gov Website and PRS Beta Information Architect and Content Strategist (contractor)
- Colin Small, Modernized ClinicalTrials.gov Website UX Lead (contractor)
- Scott Smith, PRS Beta Product Manager (contractor)
- Maureen Strange, ClinicalTrials.gov SME (contractor)
- Tony Tse, ClinicalTrials.gov Analyst
- Susan Wimmer, ClinicalTrials.gov Editor (contractor)
- Tirsit Wondemu, PRS Beta Developer (contractor)
- Allison Yu, ClinicalTrials.gov Developer (contractor)
- Rici Yu, ClinicalTrials.gov Developer (contractor)
- Chris Ziegler, PRS Beta UX Lead (contractor)
- Maya Zuhl, PRS Automation Support Technical Lead (contractor)

Appendix D: Abbreviations

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

- AI: artificial intelligence
- API: application programming interface
- BOR: Board of Regents
- DMC: data monitoring committee
- FHIR: Fast Healthcare Interoperability Resources
- 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
- Working Group: NLM Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization