

National Library of Medicine



2024 Modernized ClinicalTrials.gov Update Webinar

June 6, 2024 | 1–1:45 p.m. ET

| Housekeeping Items



The webinar is being recorded, and the recording will be made available with the slides on our website within 30 days; participants can download a PDF of the slides from the chat.



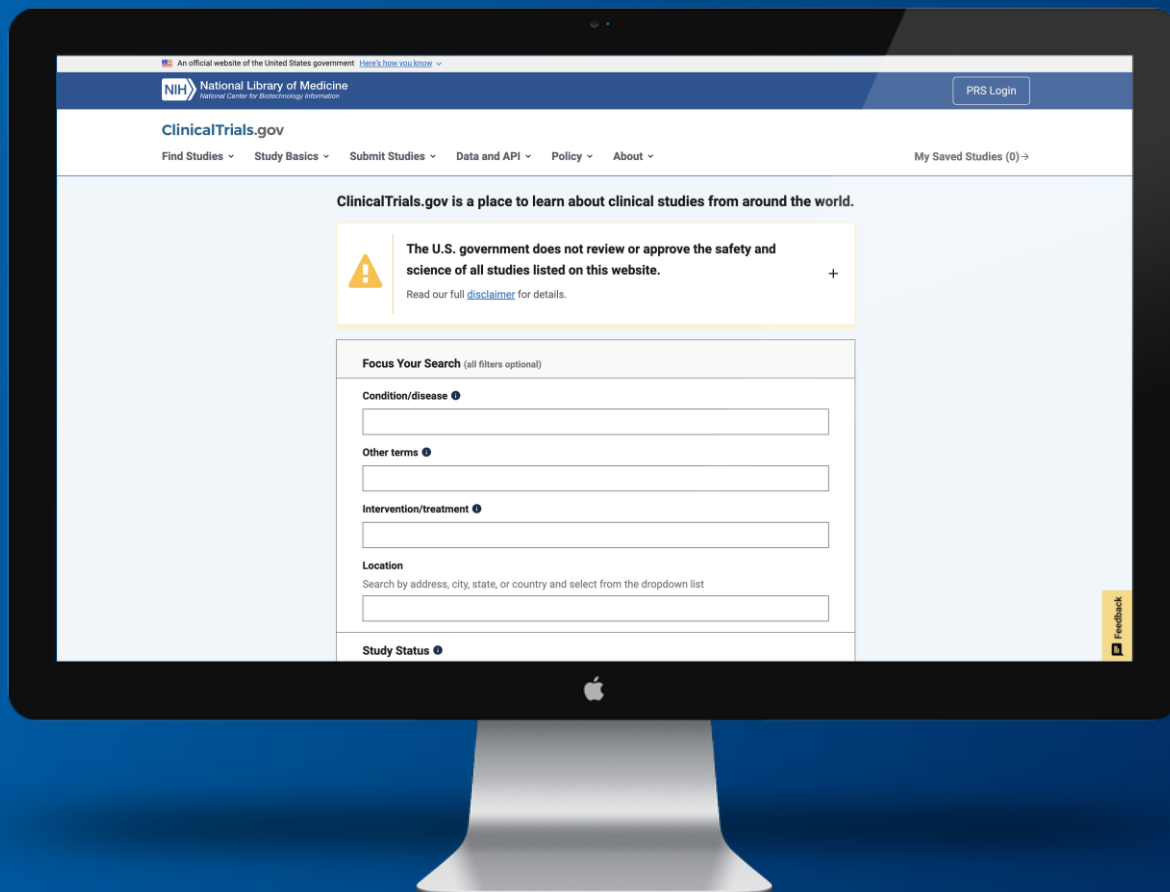
All participants will be muted and will have the opportunity to interact via a poll and the moderated question-and-answer (Q&A) session.



If you have technical issues during the webinar, please contact technical support via the Q&A box.

2024 Modernized ClinicalTrials.gov Update Webinar: Agenda

Time	Description	Presenter
1–1:35 p.m.	ClinicalTrials.gov Modernization Effort	Anna M. Fine
	Modernized ClinicalTrials.gov	Christina Robinson
1:35–1:45 p.m.	Moderated Q&A	Anna M. Fine and Christina Robinson



ClinicalTrials.gov Modernization Effort



Anna M. Fine

ClinicalTrials.gov Acting
Program Head

| Two Aims of ClinicalTrials.gov



ClinicalTrials.gov

PRS Protocol Registration
& Results System

- 1 Collect and disseminate** complete, accurate, and timely information about clinical studies submitted by study sponsors and principal investigators.



ClinicalTrials.gov

- 2 Facilitate information use** to help patients, clinicians, and researchers find studies of interest for participation or research.

ClinicalTrials.gov Primary Users



Sponsors and Investigators

Submit their study information

Keep the study record up to date, which may include adding results after the study ends



Patients and Health Care Professionals

Find studies that patients may be able to join

Learn about clinical research

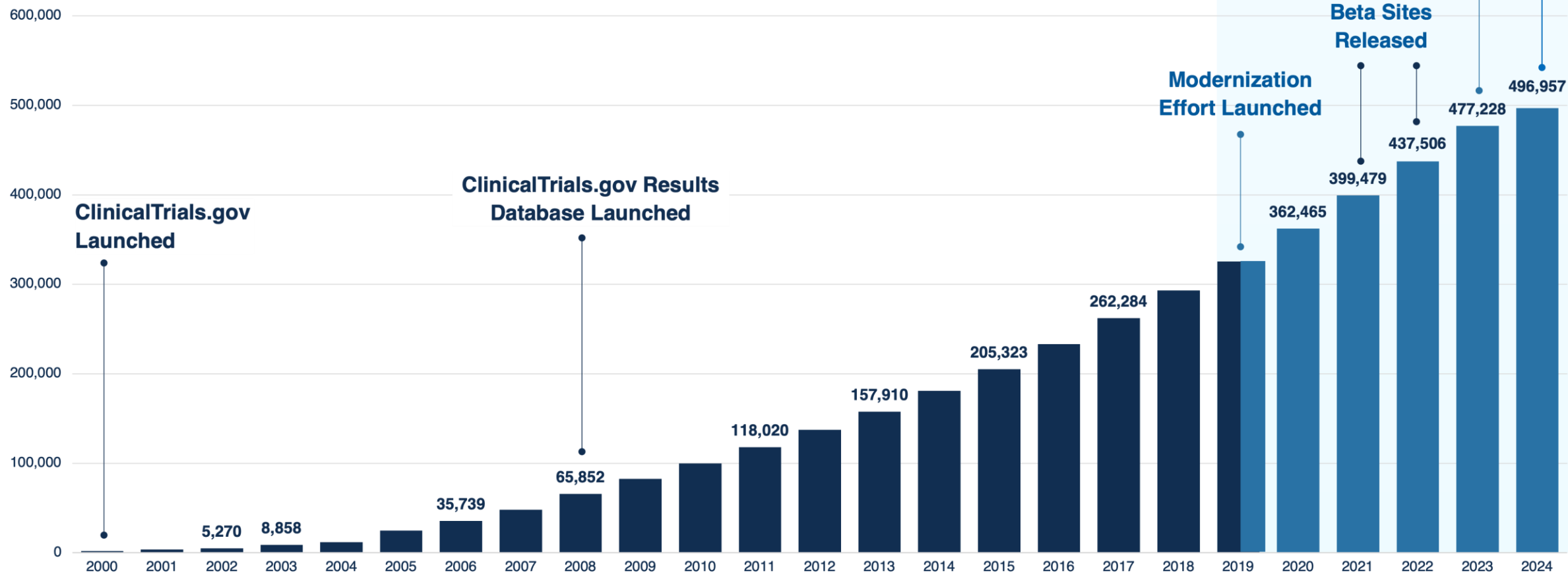


Researchers

Look for studies on a specific topic

Identify unmet research and medical needs

ClinicalTrials.gov Timeline



Updated 6.4.24

ClinicalTrials.gov Modernization Vision and Goals

VISION

To ensure that **ClinicalTrials.gov** continues to be a trusted and premier public health resource that provides maximum value to the public and serves its mission well into the future

STRATEGIC GOALS



Improve the user experience.



Upgrade the technical infrastructure and processes to enhance sustainability.



Support the existing legal, regulatory, and policy framework.

ClinicalTrials.gov Modernization Overview



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
- Made ClinicalTrials.gov Beta available
- Communicated availability of the beta release to stakeholders



YEAR 3 Implementation

- Made Protocol Registration and Results System (PRS) Beta available
- Conducted usability research, and made iterative improvements to the beta sites



YEAR 4 More Releases and Refinements

- Launched the modernized ClinicalTrials.gov website
- Released PRS Beta protocol registration and quality-assurance (QA)/quality-control (QC) functionality

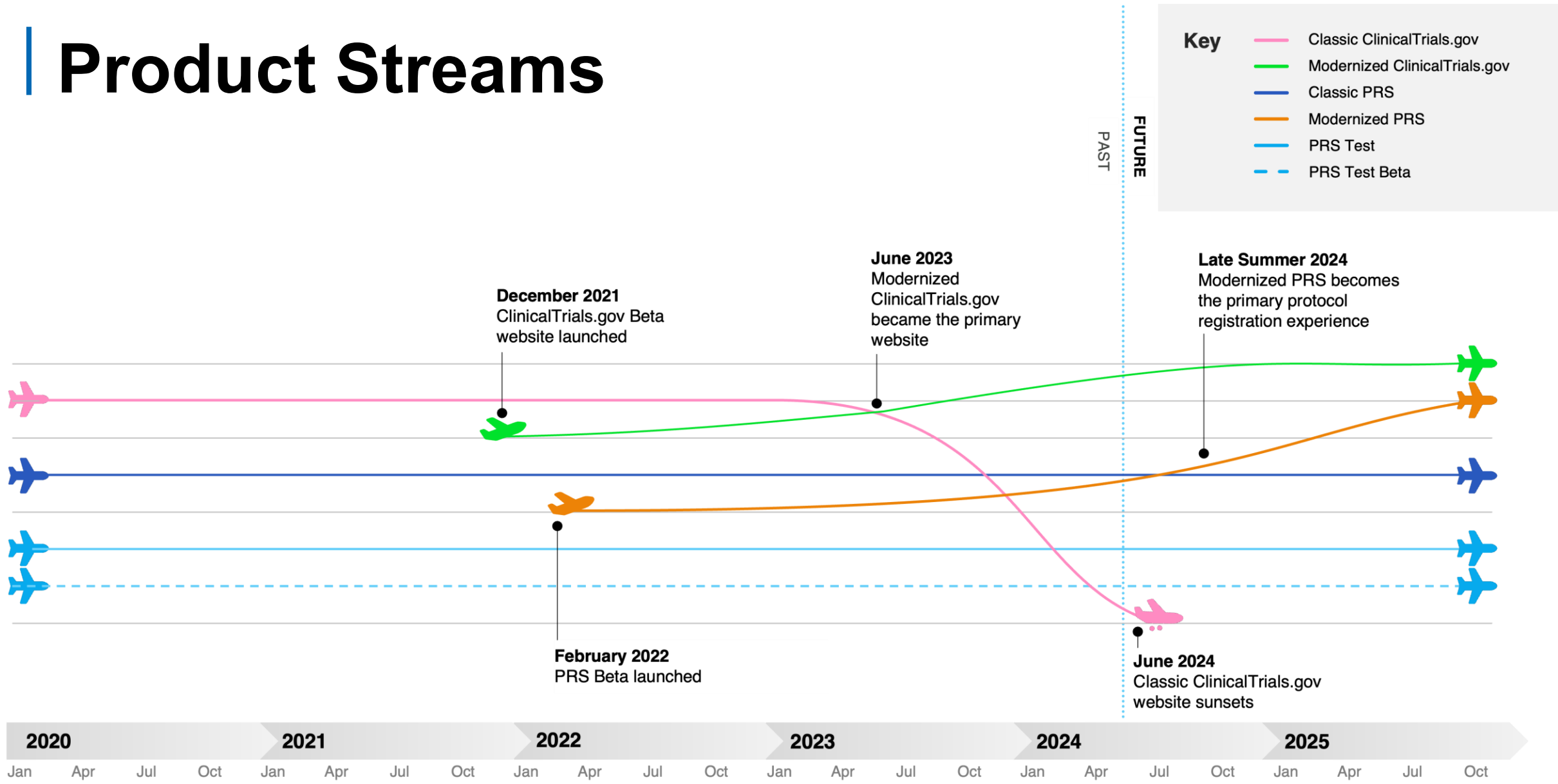


Where we are now

YEAR 5 More Launches and Landings

- Continue updates and refinements
- Retire the classic ClinicalTrials.gov on June 25, 2024
- Launch the modernized PRS protocol registration section
- Release the PRS Beta results submission section

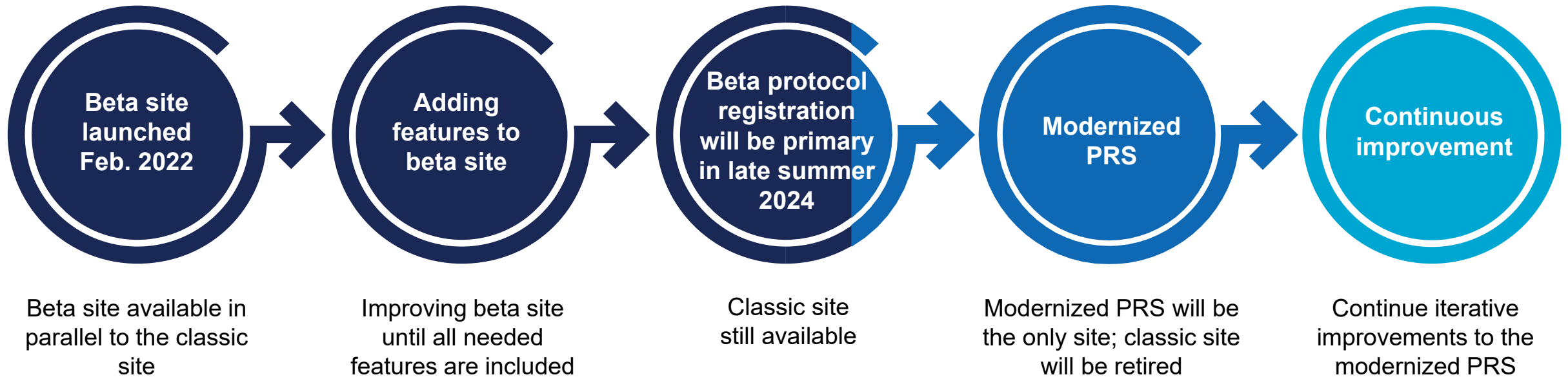
Product Streams



Updated 5.30.24

How Users See Change: Protocol Registration and Results System (PRS)

Continuous Feedback



Updated 5.30.24

How to Access PRS Beta

The PRS Test system is a sandbox (or playground) version of the PRS production system.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](#) Protocol Registration and Results System (PRS).

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password: [Forgot password](#)

Login

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for a PRS account.
See [PRS Guided Tutorials](#) for assistance with entering registration and results information in the PRS.
[Send email to ClinicalTrials.gov PRS](#) Administration.

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services | [HHS Vulnerability Disclosure](#)

PRS Beta resides within the classic version of the PRS production system.

ClinicalTrials.gov PRS
Protocol Registration and Results System

[Contact ClinicalTrials.gov PRS](#)

Org: TestOrg User: ab [Logout](#)

Email: [bergeris@nlm.nih.gov](#) [Update](#)

Help us improve: [PRS Survey](#)

Quick Links

- [New Record](#)
- [Quick Start Guide](#)
- [Problem Resolution Guide](#)

Records ▾ Accounts ▾ Help ▾

Try out the new PRS beta home page, part of the ongoing ClinicalTrials.gov modernization.

[New PRS Beta Home Page](#)

Record List

Showing: 1 record

Show/Hide Columns ▾

Protocol ID ▾	ClinicalTrials.gov ID ▾	Brief Title ▾	Record Status ▾	Last Update ▾	Responsible Party ▾	Problems ▾
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Record List and Record Summary Page Views

The Classic PRS interface shows a Record List on the left with a table of records and a Record Summary on the right. The Record Summary for ID 124 shows the record status as 'In Progress' and lists various fields like Record Owner, Last Update, and Initial Release. The Record List table includes columns for Record ID, Protocol ID, Record Title, Status, Date, and User.

Record Summary (ID: 124)

Record Status: In Progress → Entry Completed → Approved → Released → PRS Review → Public

Next Step: Finish Protocol section (Entry Complete)

Record Owner: ab | Access List: Edit

Last Update: 07/28/2015 07:53 by root | Upload: Allowed Edit

Initial Release: [Not yet released] | PRS Review: [Not yet released]

Public Site: [Not yet registered]

FDA: Unknown (insufficient information entered)

Record List

Record ID	Protocol ID	Record Title	Status	Date	User
ND_Test Create Record 021524			In Progress	12/26/2023 12:30	PRAdminTesting [Sponsor]
ND_TestRecord_Review 003			PRS Review	12/21/2023 17:40	nachiket_admin [Sponsor]
TTTICrossover			Entry Completed	10/05/2023 13:30	PRAdminTesting [Sponsor]
TTTISmart			Approved	09/13/2023 10:56	PRAdminTesting [Sponsor]
fgkfgkfgkfgk			In Progress	07/20/2023 14:29	PRAdminTesting [Sponsor]
Test1_July			In Progress	07/28/2022 15:34	nachiket_admin [Sponsor]
TTTISmartR			Approved	11/16/2021 09:56	Investigator Not Found

Classic PRS

The PRS Beta interface shows a Record List on the left with a table of records and a Record Summary on the right. The Record Summary for ID 124 shows the record status as 'In Progress' and lists various fields like Record Owner, Last Update, and Initial Release. The Record List table includes columns for Record ID, Protocol ID, Record Title, Status, Date, and User.

Record Summary (ID: 124)

Record Status: In Progress → Entry Completed → Approved → Released → PRS Review → Public

Next Step: Finish Protocol section (Entry Complete)

Record Owner: ab | Access List: Edit

Last Update: 07/28/2015 07:53 by root | Upload: Allowed Edit

Initial Release: [Not yet released] | PRS Review: [Not yet released]

Public Site: [Not yet registered]

FDA: Unknown (insufficient information entered)

Record List

Record ID	Protocol ID	Record Title	Status	Date	User
ND_Test Create 021524			In Progress	12/26/2023 12:30	PRAdminTesting [Sponsor]
ND_TestRecord_Review 003			PRS Review	12/21/2023 17:40	nachiket_admin [Sponsor]
TTTICrossover			Entry Completed	10/05/2023 13:30	PRAdminTesting [Sponsor]
TTTISmart			Approved	09/13/2023 10:56	PRAdminTesting [Sponsor]
fgkfgkfgkfgk			In Progress	07/20/2023 14:29	PRAdminTesting [Sponsor]
Test1_July			In Progress	07/28/2022 15:34	nachiket_admin [Sponsor]
TTTISmartR			Approved	11/16/2021 09:56	Investigator Not Found

PRS Beta

Modernized PRS Features

	Record and Account Management Experience	Data Submission and Review Experience	Technology Modernization
AVAILABLE	<ul style="list-style-type: none">Intuitive Record ListSearch, filter, and sort functionalityCustomizable columns and views	<ul style="list-style-type: none">Protocol registration submissionProtocol QA/QCRecord Summary and ActionsEasy navigationImproved error handlingJust-in-time help	<ul style="list-style-type: none">Migration to National Center for Biotechnology Information (NCBI) secure platformHelpful pop-up content
IN PROGRESS	<ul style="list-style-type: none">Secure log-in	<ul style="list-style-type: none">Results reporting	<ul style="list-style-type: none">Move to cloudImproved system architectureOptimized database performance and data integrity
FUTURE	<ul style="list-style-type: none">Account creation and modificationManagement of groups and permissionsNotificationsDashboards	<ul style="list-style-type: none">Study document uploadResults QA/QCDelayed resultsXML upload	<ul style="list-style-type: none">Optimized database design

ClinicalTrials.gov Products

ClinicalTrials.gov

PRS Protocol Registration
& Results System

ClinicalTrials.gov

Classic ClinicalTrials.gov Website

Will be retired on June 25, 2024





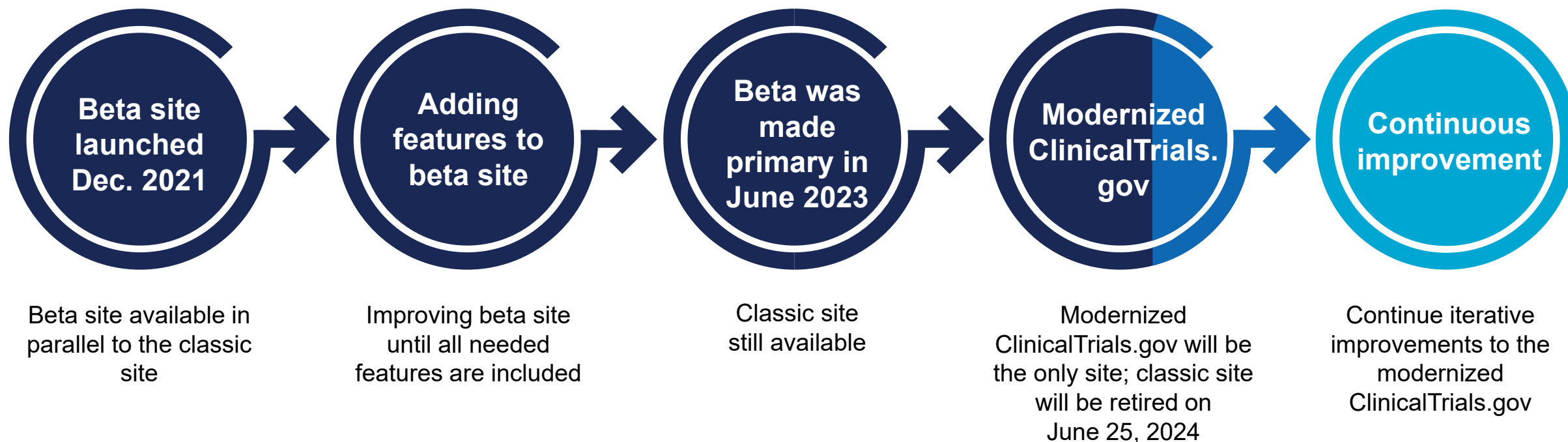
Christina Robinson

ClinicalTrials.gov Product Owner

Modernized ClinicalTrials.gov Website

How Users See Change: ClinicalTrials.gov Website

Continuous Feedback



Updated 5.13.24

Modernized ClinicalTrials.gov Features

	Search Experience	Study Record Experience	Easy-to-Find and Easy-to-Use Content
AVAILABLE	<ul style="list-style-type: none">Enhanced searchIntegrated Search and Search ResultsDownload (JSON, CSV, RIS)Card view of search resultsModifiable table view of search resultsPrint view of search resultsSave studies of interestSave search/get search updates (RSS)Application programming interface (API)	<ul style="list-style-type: none">Compiled study record dataOn-page navigationPrint view of study registrationStudy details view of study recordResearcher view of study recordFast Healthcare Interoperability Resources (FHIR) API pilotIntegrated record history	<ul style="list-style-type: none">API documentationData about ClinicalTrials.govSupport materials for searchingStreamlined information architectureCompiled policy/regulatory contentAbout ClinicalTrials.gov pageLearn About Studies pageLearn About FHIR page
FUTURE	<ul style="list-style-type: none">Rewritten ingestExpert search capabilitiesBrowse studies by topic	<ul style="list-style-type: none">Next steps for patients	

Updated 6.3.24

Benefits of the Modernized ClinicalTrials.gov

An official website of the United States government [Here's how you know](#) ▼

NIH National Library of Medicine
National Center for Biotechnology Information


PRS Login

ClinicalTrials.gov

Find Studies ▼ Study Basics ▼ Submit Studies ▼ Data and API ▼ Policy ▼ About ▼

My Saved Studies (0) →

ClinicalTrials.gov is a place to learn about clinical studies from around the world.



The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full [disclaimer](#) for details.

Focus Your Search (all filters optional)

Condition/disease ⓘ

Other terms ⓘ

Intervention/treatment ⓘ

Location
Search by address, city, state, or country and select from the dropdown list

Study Status ⓘ

☒ All studies
☐ Recruiting and not yet recruiting studies

More Filters +

Search


Feedback

An official website of the United States government [Here's how you know](#) ▼

NIH National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov Menu

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Focus Your Search (all filters optional)

Condition/disease ⓘ

Other terms ⓘ

Intervention/treatment ⓘ

Location
Search by address, city, state, or country and select from the dropdown list

Search

Feedback

Sample Improvements to the Search Results

Focus Your Search
(all filters optional)

Hide

Condition/disease ⓘ

Stage II Breast Cancer

Other terms ⓘ

Intervention/treatment ⓘ

Location

Search by address, city, state, or country and select from the dropdown list

Study Status ⓘ

Looking for participants

☐ Not yet recruiting (7)

☐ Recruiting (57)

No longer looking for participants

☐ Active, not recruiting (69)

☐ Completed (502)

☐ Terminated (107)

Other

Clear Filters (2)

Apply Filters

Search Results

Viewing 1-10 out of 794 studies

Showing results for: Stage II Breast Cancer | Funded by NIH

+ Synonyms of conditions or disease (54)

None Selected

RSS

☐ COMPLETED

NCT01431196

Trial With Autologous Dendritic Cell Vaccination in Patients With Stage II-III HER2 Negative Breast Cancer

Conditions

Stage II Breast Cancer

Stage III Breast Cancer

Locations

Pamplona, Navarra, Spain

☐ RECRUITING

NCT04720209

Taking AIM at Breast Cancer

Conditions

Breast Cancer Stage II

Breast Cancer

Breast Cancer Stage I

Breast Cancer Stage III

Locations

Boston, Massachusetts, United States (2)

Search Results

Viewing 1-10 out of 794 studies

Showing results for: Stage II Breast Cancer | Funded by NIH

+ Synonyms of conditions or disease (54)

Focus Your Search (2)

None Selected

RSS

☐ COMPLETED

NCT01431196

Trial With Autologous Dendritic Cell Vaccination in Patients With Stage II-III HER2 Negative Breast Cancer

Conditions

Stage II Breast Cancer

Stage III Breast Cancer

Locations

Pamplona, Navarra, ...

☐ RECRUITING

NCT04720209

Taking AIM at Breast Cancer

Conditions

Breast Cancer Stage II

Breast Cancer

Breast Cancer Stage I

Breast Cancer Stage III

Feedback

Sample Improvements to the Study Record

RECRUITING ⓘ



Phase I/II Study of the Anti-Programmed Death Ligand-1 Durvalumab Antibody (MEDI4736) in Combination With Olaparib and/or Cediranib for Advanced Solid Tumors and Advanced or Recurrent Ovarian, Triple Negative Breast, Lung, Prostate and Colorectal Can...

ClinicalTrials.gov ID ⓘ NCT02484404

Sponsor ⓘ National Cancer Institute (NCI)

Information provided by ⓘ National Institutes of Health Clinical Center (CC) (National Cancer Institute (NCI)) (Responsible Party)

Last Update Posted ⓘ 2024-02-28

  | + Expand all content — Collapse all content

Study Details | Researcher View | No Results Posted | Record History

On this page

- Study Overview
- Contacts and Locations
- Participation Criteria
- Study Plan
- Collaborators and Investigators
- Publications
- Study Record Dates
- More Information

Study Overview

Brief Summary

Background:

- Durvalumab is a drug that may help people s immune systems respond to and kill cancer cells. Olaparib is a drug that may inhibit repairing DNA damage of cancer cells. Cediranib is a drug that may stop the blood vessel growth of cancer cells. This study has two components. In the phase 1 component of the study, researchers want to investigate how well participants tolerate the combination of these drugs in treating advanced solid tumors, and in the phase 2 part of this study, researchers want to study if the

[+ Show more](#)

Detailed Description

Background:

Disruption of the immune checkpoint PD-1/PD-L1 pathway yielded clinical activity in subsets of advanced solid tumors, such as melanoma and lung cancer.

Study Start (Actual) ⓘ
2015-06-29

Primary Completion (Estimated) ⓘ
2024-12-30

Study Completion (Estimated) ⓘ
2025-12-30

Enrollment (Estimated) ⓘ
384

Study Type ⓘ
Interventional

RECRUITING ⓘ



Phase I/II Study of the Anti-Programmed Death Ligand-1 Durvalumab Antibody (MEDI4736) in Combination With Olaparib and/or Cediranib for Advanced Solid Tumors and Advanced or Recurrent Ovarian, Triple Negative Breast, Lung, Prostate and Colorectal Can...

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Last Update Posted ⓘ 2024-02-28

  | More

Study Details | Researcher View | No Results Posted | Record History

Study Overview

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- Durvalumab is a drug that may help people s immune systems respond to and kill cancer cells. Olaparib is a drug that may inhibit repairing DNA damage of cancer cells. Cediranib is a drug that may stop the blood vessel growth of cancer cells.

[+ Show more](#)

Detailed Description

Feedback

On this page

Background:

- Durvalumab is a drug that may help people s immune systems respond to and kill cancer cells. Olaparib is a drug that may inhibit repairing DNA damage of cancer cells. Cediranib is a drug that may stop the blood vessel growth of cancer cells.

[+ Show more](#)

Detailed Description

Background:

Disruption of the immune checkpoint PD-1/PD-L1 pathway yielded clinical activity in subsets of advanced solid tumors, such as melanoma and lung cancer.

Olaparib (O), a PARP inhibitor (PARPi), has
[+ Show more](#)

Official Title

Phase I/II Study of the Anti-Programmed Death Ligand-1 Antibody Durvalumab (MEDI4736) in Combination With Olaparib and/or Cediranib for Advanced Solid Tumors and Advanced or Recurrent Ovarian, Triple Negative Breast, Lung, Prostate and Colorectal Cancers

Conditions ⓘ
Colorectal Neoplasms | **Breast Neoplasms**

Intervention / Treatment ⓘ

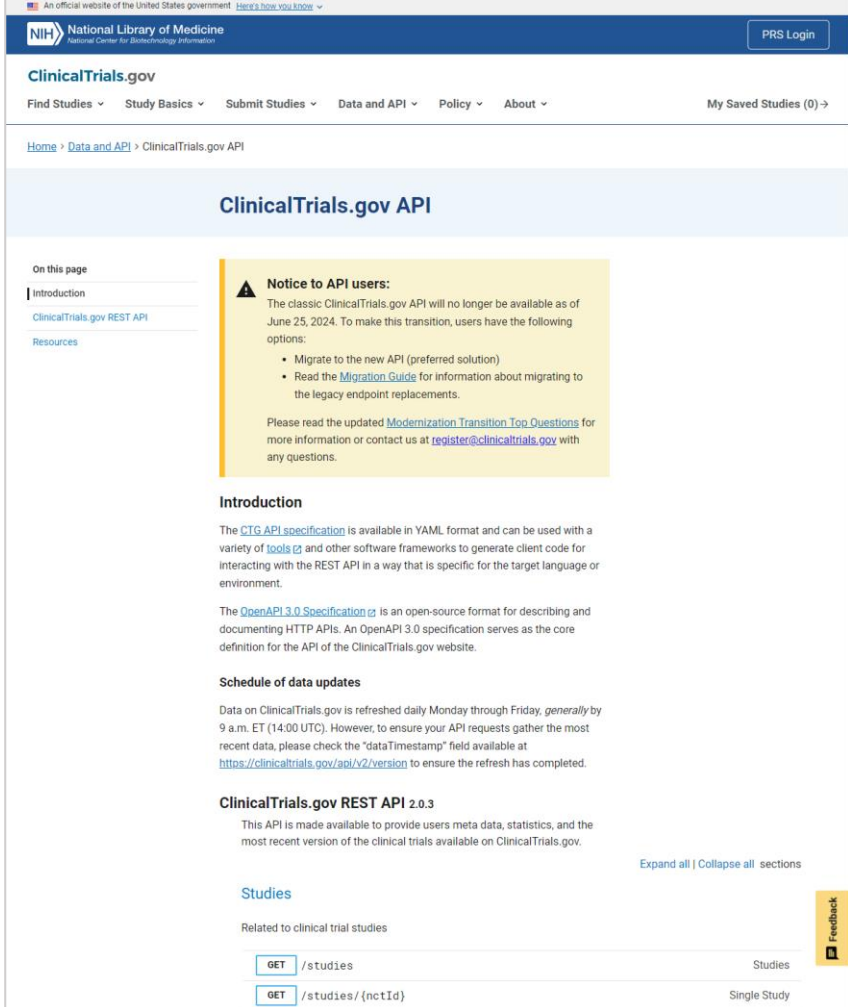
- Drug: Olaparib
- Drug: Cediranib
- Drug: Durvalumab

Feedback

Application Programming Interface

The modernized API:

- Uses OpenAPI Specification version 3.0
- Exists within the main website
- Supports XML legacy endpoints



The screenshot shows the ClinicalTrials.gov website with the API section highlighted. The page includes a navigation bar with links like 'Find Studies', 'Study Basics', 'Submit Studies', 'Data and API', 'Policy', and 'About'. A 'PRS Login' button is in the top right. The main content area is titled 'ClinicalTrials.gov API' and features a 'Notice to API users' box with a warning icon, stating that the classic API will be discontinued by June 25, 2024, and providing migration options. Below the notice, there is an 'Introduction' section explaining the CTG API specification and its use with tools like Swagger. A 'Schedule of data updates' section mentions daily refreshes from Monday to Friday. The 'ClinicalTrials.gov REST API 2.0.3' section describes the API's purpose. At the bottom, there is a 'Studies' section with a table of API endpoints, including 'GET /studies' and 'GET /studies/{nctId}'. A 'Feedback' button is located in the bottom right corner.

On this page

- Introduction
- ClinicalTrials.gov REST API
- Resources

Notice to API users:

The classic ClinicalTrials.gov API will no longer be available as of June 25, 2024. To make this transition, users have the following options:

- Migrate to the new API (preferred solution)
- Read the [Migration Guide](#) for information about migrating to the legacy endpoint replacements.

Please read the updated [Modernization Transition Top Questions](#) for more information or contact us at register@clinicaltrials.gov with any questions.

Introduction

The [CTG API specification](#) is available in YAML format and can be used with a variety of [tools](#) and other software frameworks to generate client code for interacting with the REST API in a way that is specific for the target language or environment.

The [OpenAPI 3.0 Specification](#) is an open-source format for describing and documenting HTTP APIs. An OpenAPI 3.0 specification serves as the core definition for the API of the ClinicalTrials.gov website.

Schedule of data updates

Data on ClinicalTrials.gov is refreshed daily Monday through Friday, generally by 9 a.m. ET (14:00 UTC). However, to ensure your API requests gather the most recent data, please check the "dataTimestamp" field available at <https://clinicaltrials.gov/api/v2/version> to ensure the refresh has completed.

ClinicalTrials.gov REST API 2.0.3

This API is made available to provide users meta data, statistics, and the most recent version of the clinical trials available on ClinicalTrials.gov.

Studies

Related to clinical trial studies

GET	/studies	Studies
GET	/studies/{nctId}	Single Study

Expand all | Collapse all sections

Feedback

Hidden Benefits of Modernization

The modernized public website:

- Was built using Angular
- Lives in the cloud
- Uses Elasticsearch

The screenshot displays the ClinicalTrials.gov website. At the top, there is a blue header with the NIH logo and the text "National Library of Medicine National Center for Biotechnology Information". A "PRS Login" button is in the top right. Below the header, a navigation bar includes links for "Find Studies", "Study Basics", "Submit Studies", "Data and API", "Policy", and "About", along with a link to "My Saved Studies (0)". The main content area features a disclaimer: "ClinicalTrials.gov is a place to learn about clinical studies from around the world. The U.S. government does not review or approve the safety and science of all studies listed on this website. Read our full disclaimer for details." Below this is a search section titled "Focus Your Search (all filters optional)". It contains input fields for "Condition/disease", "Other terms", and "Intervention/treatment", and a "Location" section with a dropdown list. There are also radio buttons for "Study Status" (All studies, Recruiting and not yet recruiting studies) and a "More Filters" section. A "Search" button is at the bottom right of the search section. A "Feedback" button is in the bottom right corner.

| Future Features of ClinicalTrials.gov



- Rewritten Ingest
- Expert Search Capabilities
- Browse Studies by Topic
- Next Steps for Patients

Pol Question

**Education Help from ClinicalTrials.gov:
What topic would be most helpful with
using the new ClinicalTrials.gov
website?**

- A. Locating policies or reporting requirements for clinical trials
- B. How to save studies
- C. How to download citations of clinical trials
- D. Difference between CSV and API
- E. Search tips

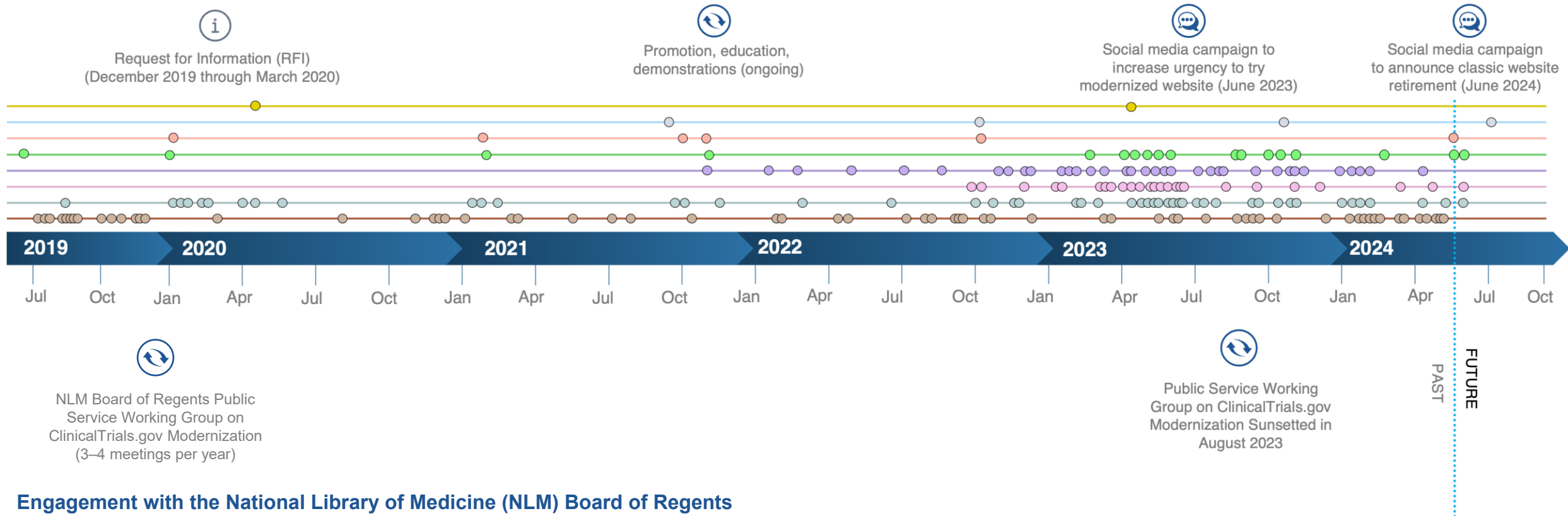


Stakeholder Engagement

Key:

- Public meeting
- Summary report
- Webinar
- Blog post/article
- Web posting
- Social media
- Email
- Meeting/presentation
- Working Group meeting

Public Engagement

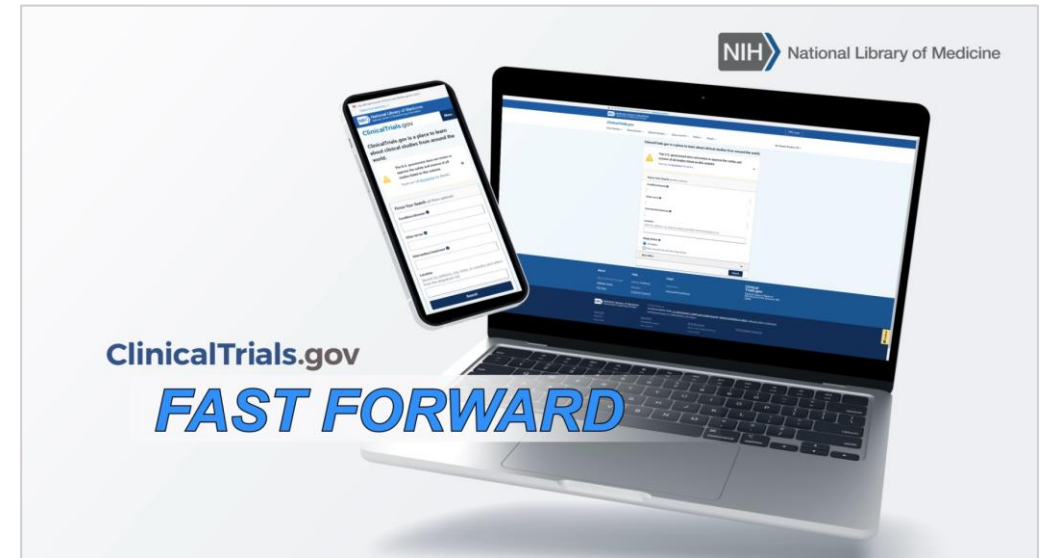


Updated 5.8.24

Fast Forward from ClinicalTrials.gov: Demonstration

“Tip” videos for using the modernized website

- How to find the total number of studies in ClinicalTrials.gov
- How to search for studies that may interest you
- How to learn if a study may be recruiting and find contact information



[Demo Videos](#)

Issued Three Summary-of-Progress Reports

2019–21 report

- Modernization overview and updates on year 2 effort
- NLM Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization and stakeholder input
- ClinicalTrials.gov Beta launched

2021–22 report

- PRS Beta launched

2022–23 report

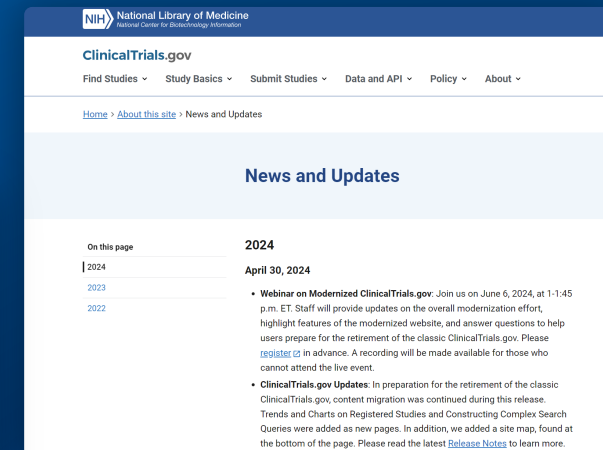
- Modernized ClinicalTrials.gov launched



Communications

We will continue to keep you updated via a variety of tools:

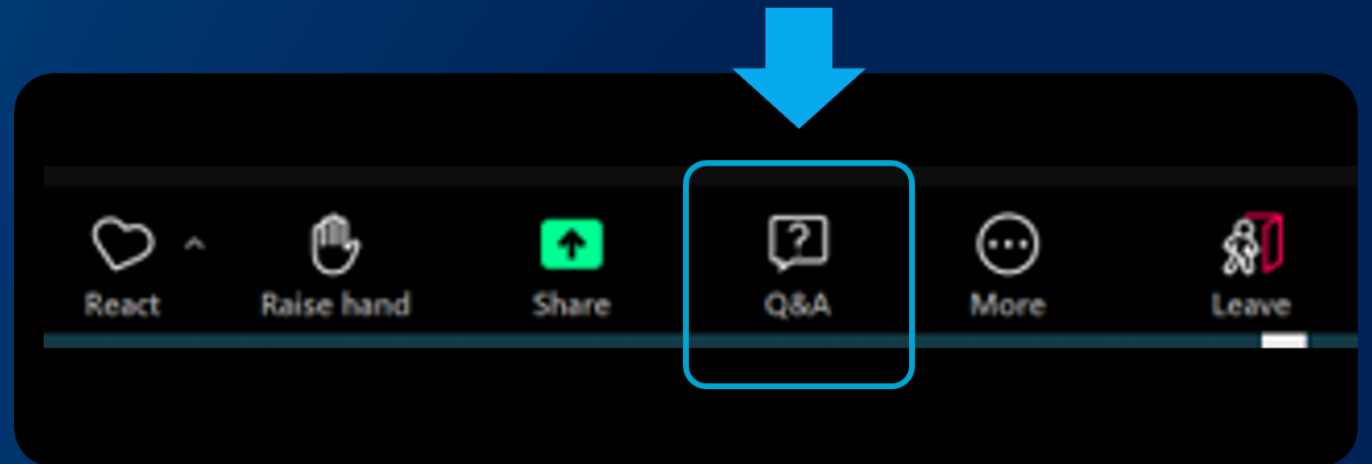
- *NLM Technical Bulletin* articles
- Social media posts
- Web updates (News and Updates and ClinicalTrials.gov Modernization pages, release notes, and website banners)
- Hot Off the PRS! e-bulletin sent to over 17,000 subscribers
- Presentations at conferences
- Public webinars and prerecorded demonstrations



Moderated Q&A Instructions

We welcome your questions for our presenters.

To bring up the Question-and-Answer box, click on the Q&A icon in your Zoom menu bar.





Anna M. Fine

ClinicalTrials.gov Acting Program Head



Christina Robinson

ClinicalTrials.gov Product Owner

Moderated Q&A

| Next Steps

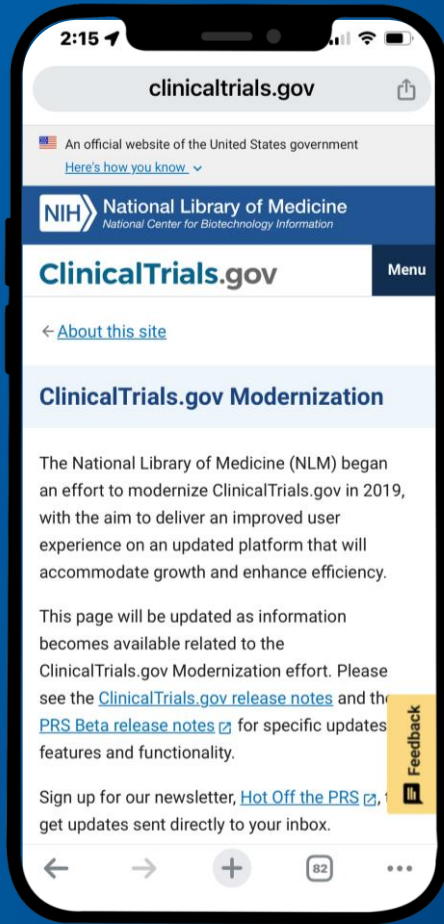
NLM will:

- Announce in Hot Off the PRS! when the meeting recording and slides are available
 - Announce when the modernized PRS protocol registration becomes primary
-

Attendees will:

- Continue to provide their feedback on the modernized ClinicalTrials.gov website and PRS

Thank You.



Learn More:



Find out about the modernization effort

<https://clinicaltrials.gov/about-site/modernization>



Stay up to date with the Hot Off the PRS! e-bulletin

<https://bit.ly/33qcZBb>



Contact us

register@clinicaltrials.gov