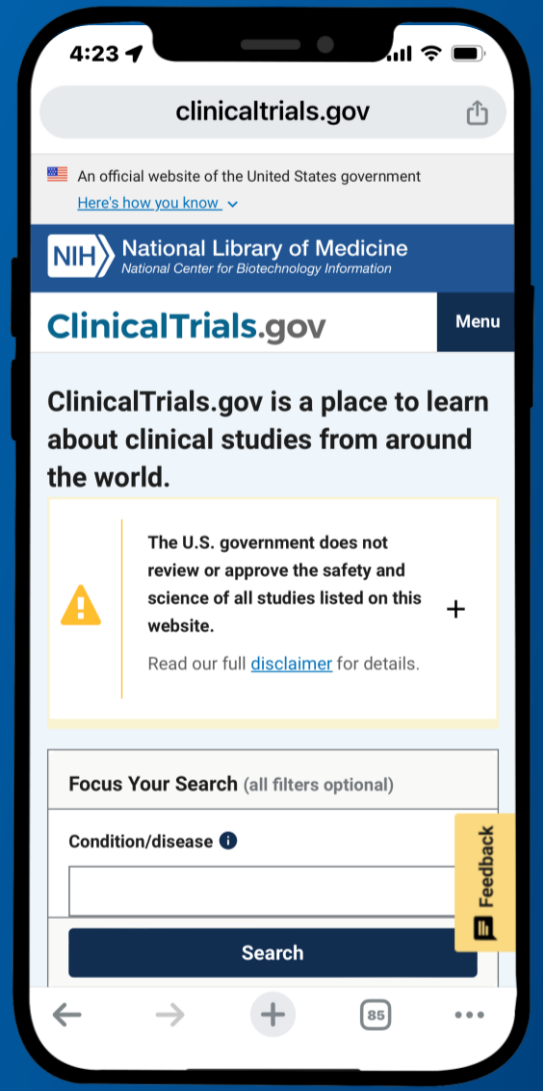


National Library of Medicine

2024 Modernized ClinicalTrials.gov Update Webinar

June 6, 2024 | 1–1:45 p.m. ET

Housekeeping Items

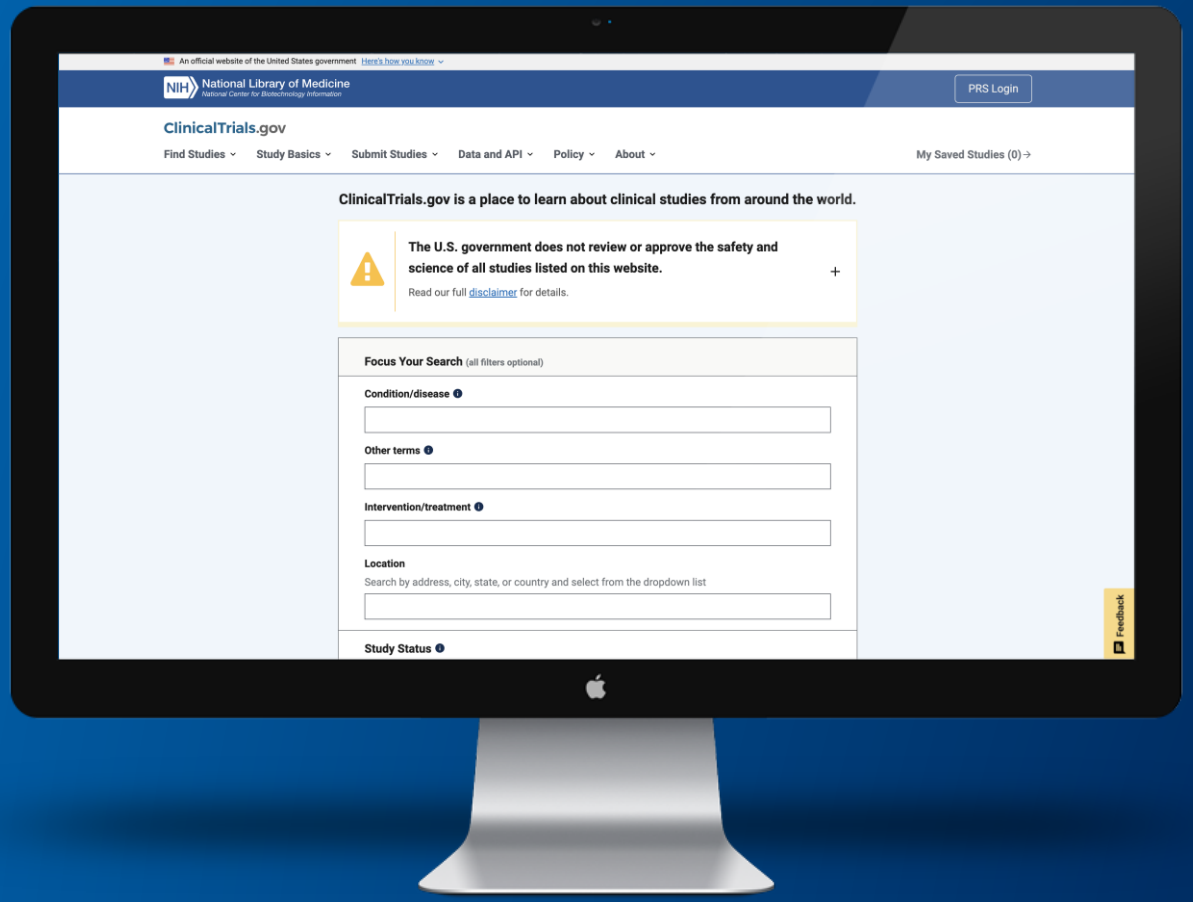
The webinar is being recorded, and the recording will be made available with the slides on our website within 30 days; participants can download a PDF of the slides from the chat.

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

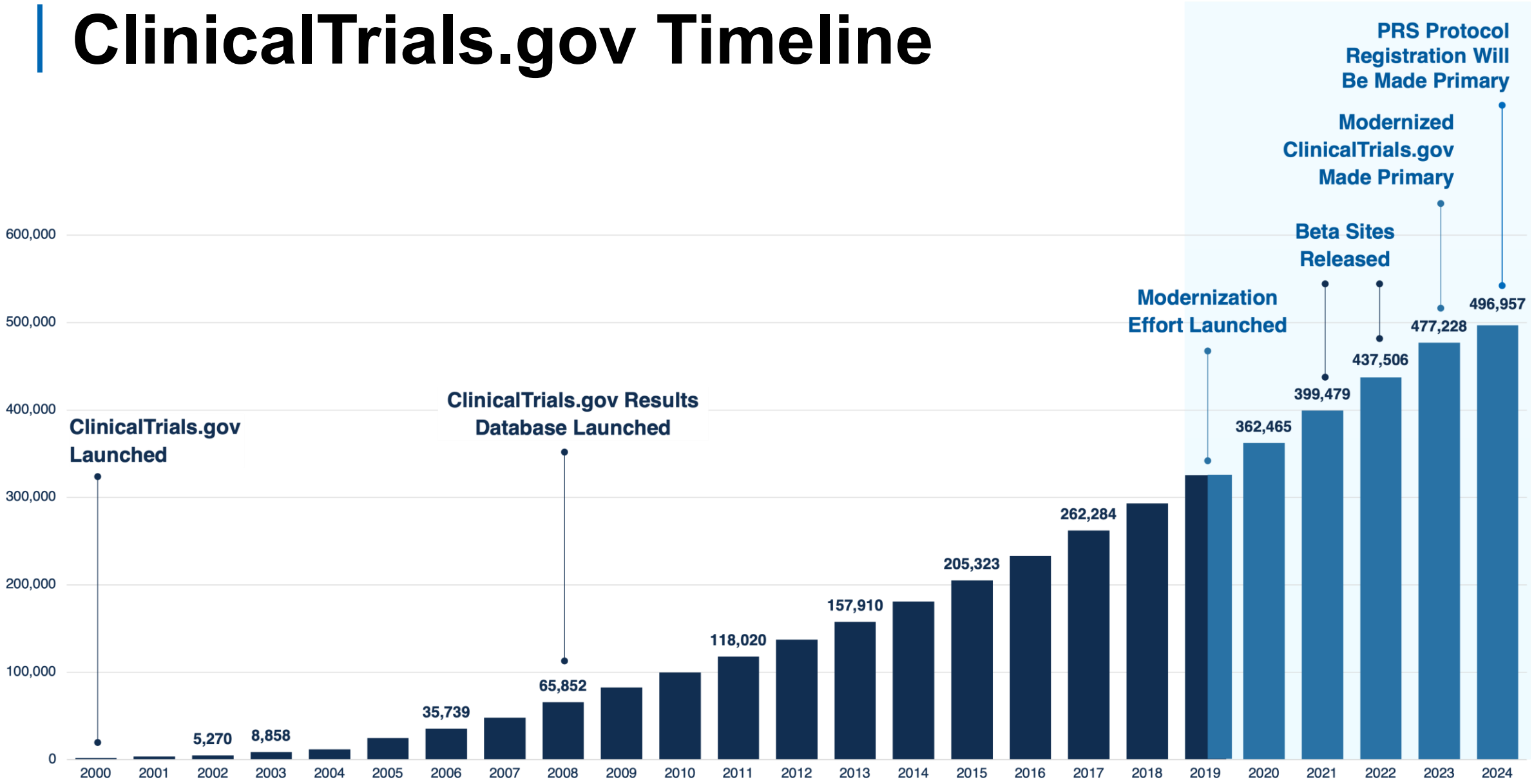
Learn about clinical research

Researchers

Look for studies on a specific topic

Identify unmet research and medical needs

ClinicalTrials.gov Timeline



Updated 6.4.24

NIH National Library of Medicine

ClinicalTrials.gov

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

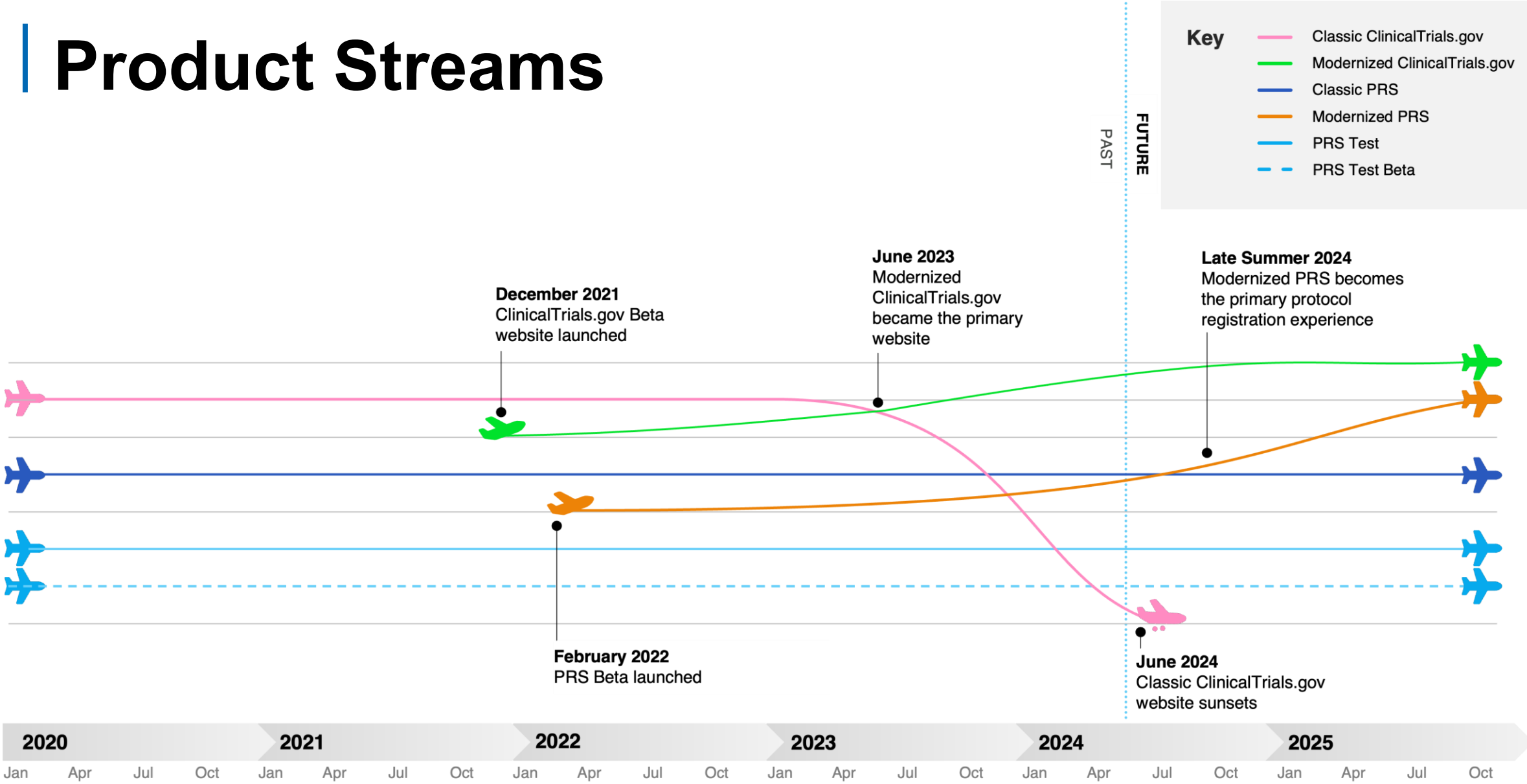
Where we are now

YEAR 5

More Launches and Landings

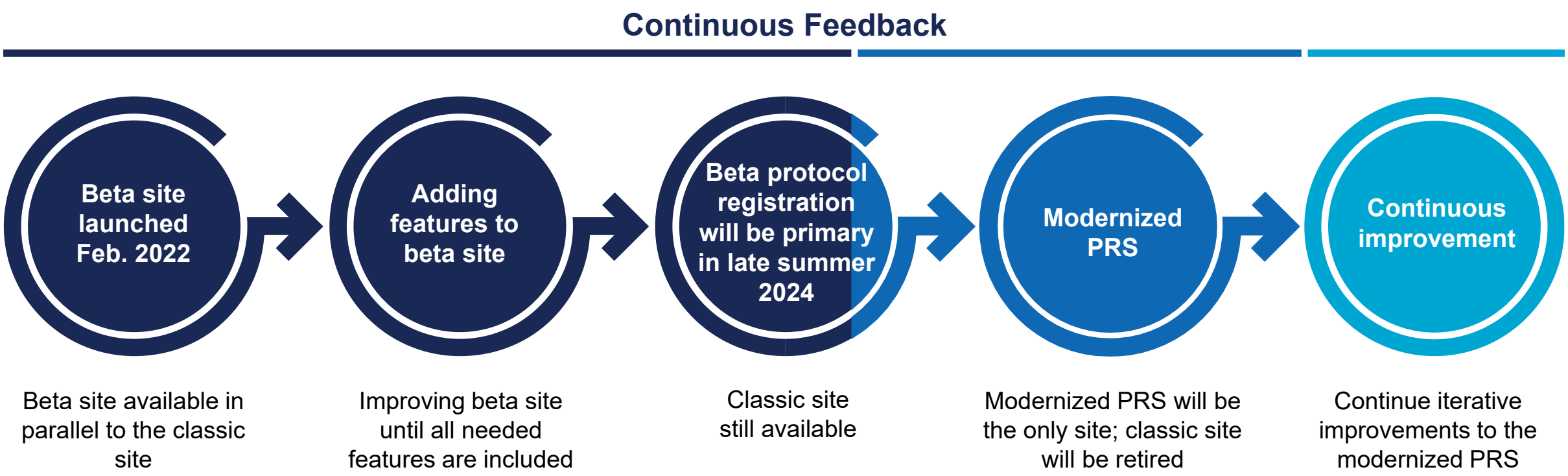
- Continue updates and refinements
- Retire the classic ClinicalTrials.gov on June 25, 2024
- Launch the modernized PRS protocol registration section
- Release the PRS Beta results submission section

Product Streams



Updated 5.30.24

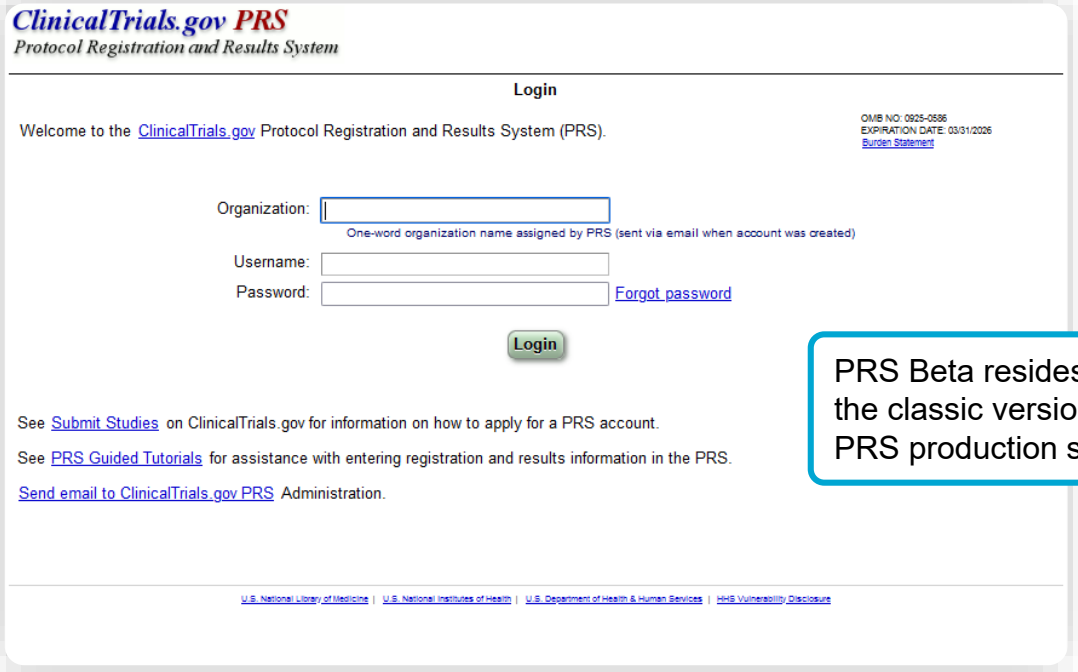
How Users See Change: Protocol Registration and Results System (PRS)



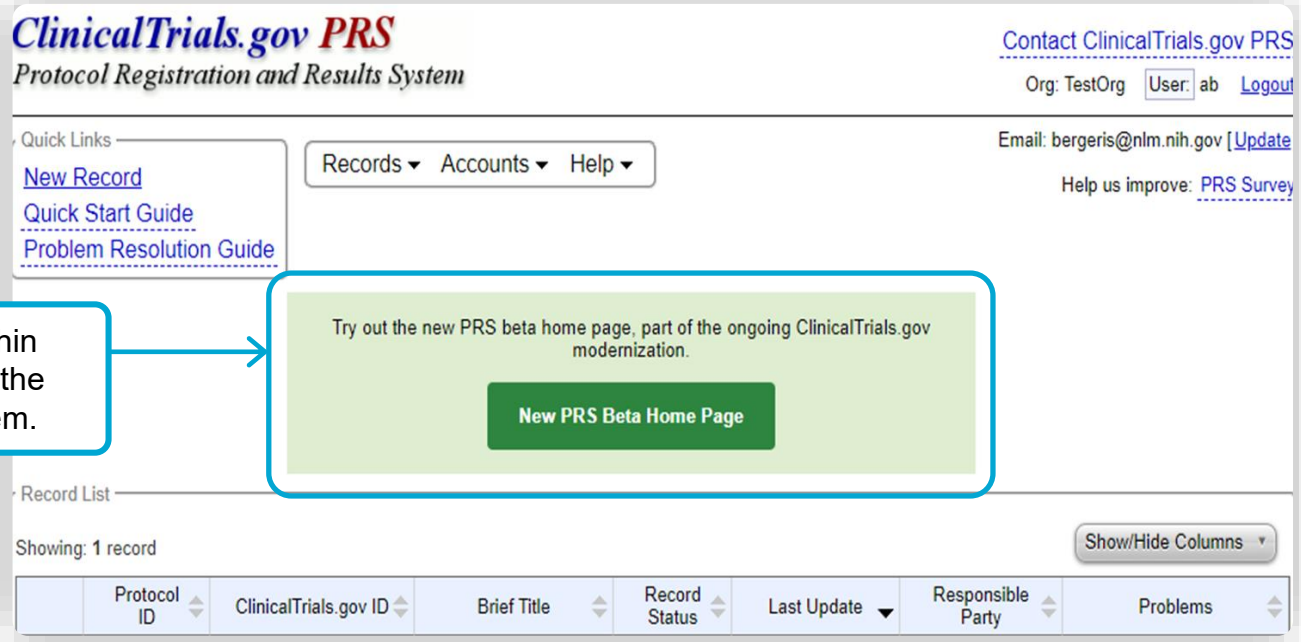
Updated 5.30.24

How to Access PRS Beta

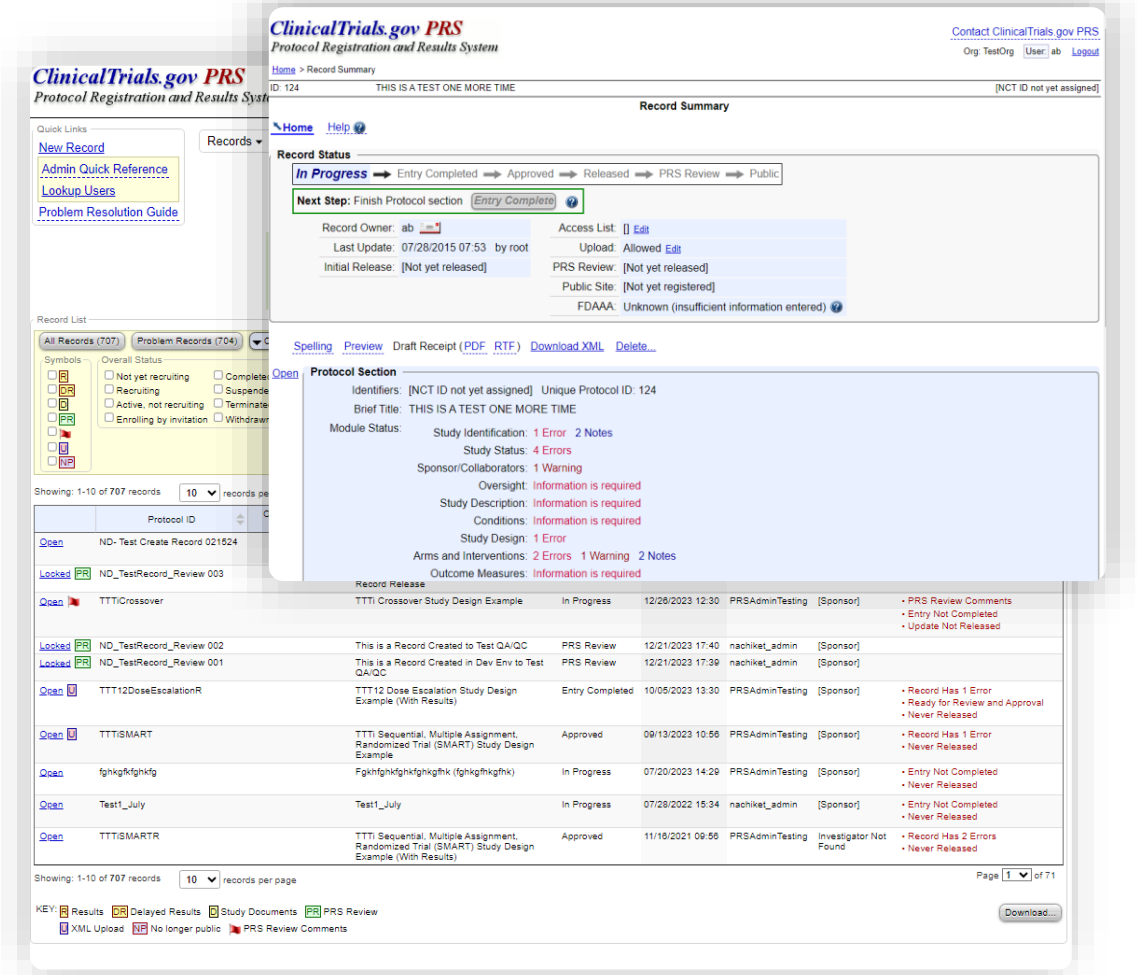
The PRS Test system is a sandbox (or playground) version of the PRS production system.



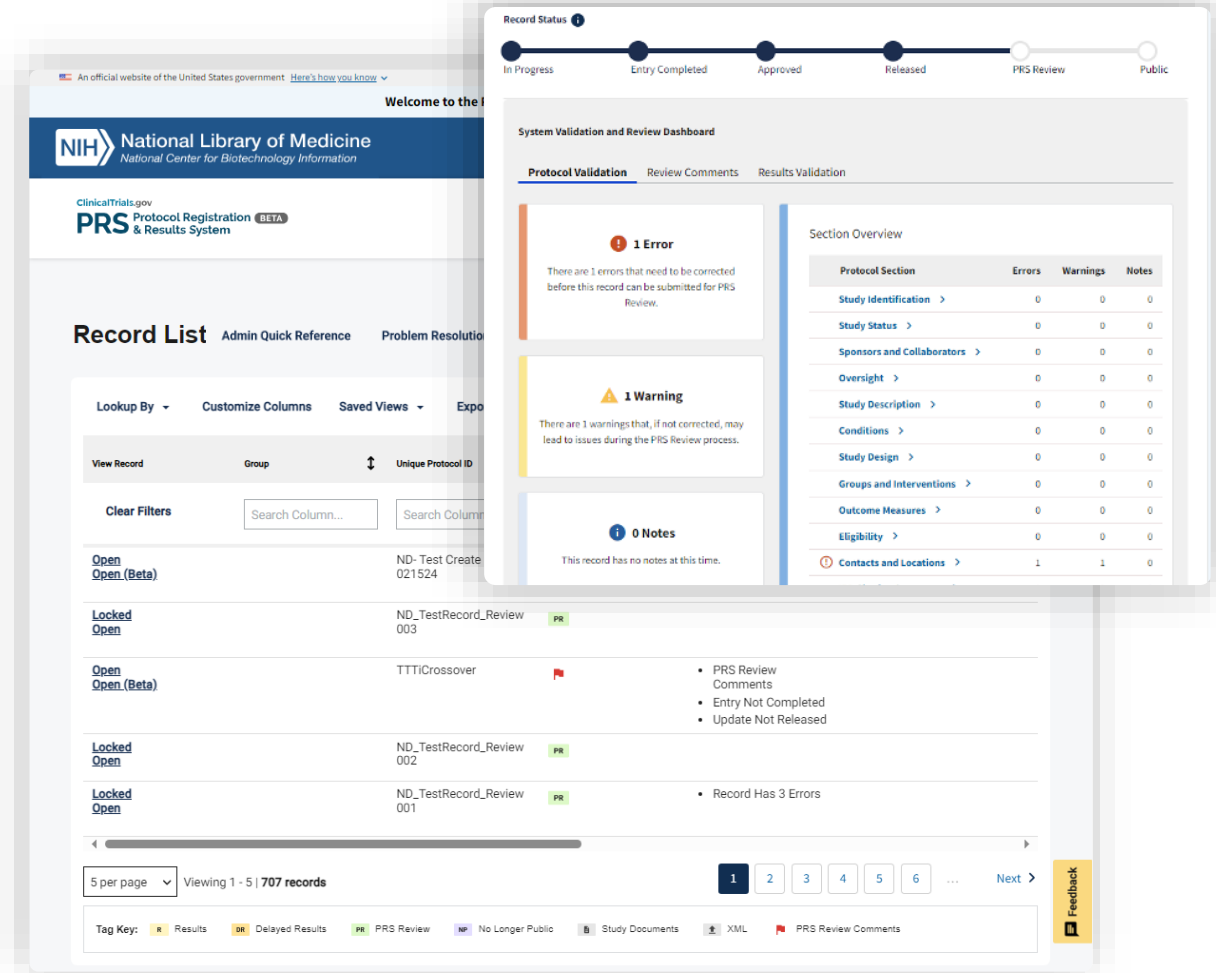
PRS Beta resides within the classic version of the PRS production system.



Record List and Record Summary Page Views



Classic PRS



PRS Beta

Modernized PRS Features

	Record and Account Management Experience	Data Submission and Review Experience	Technology Modernization
AVAILABLE	Intuitive Record List Search, filter, and sort functionality Customizable columns and views	Protocol registration submission Protocol QA/QC Record Summary and Actions Easy navigation Improved error handling Just-in-time help	Migration to National Center for Biotechnology Information (NCBI) secure platform Helpful pop-up content
IN PROGRESS	Secure log-in	Results reporting	Move to cloud Improved system architecture Optimized database performance and data integrity
FUTURE	Account creation and modification Management of groups and permissions Notifications Dashboards	Study document upload Results QA/QC Delayed results XML upload	Optimized database design

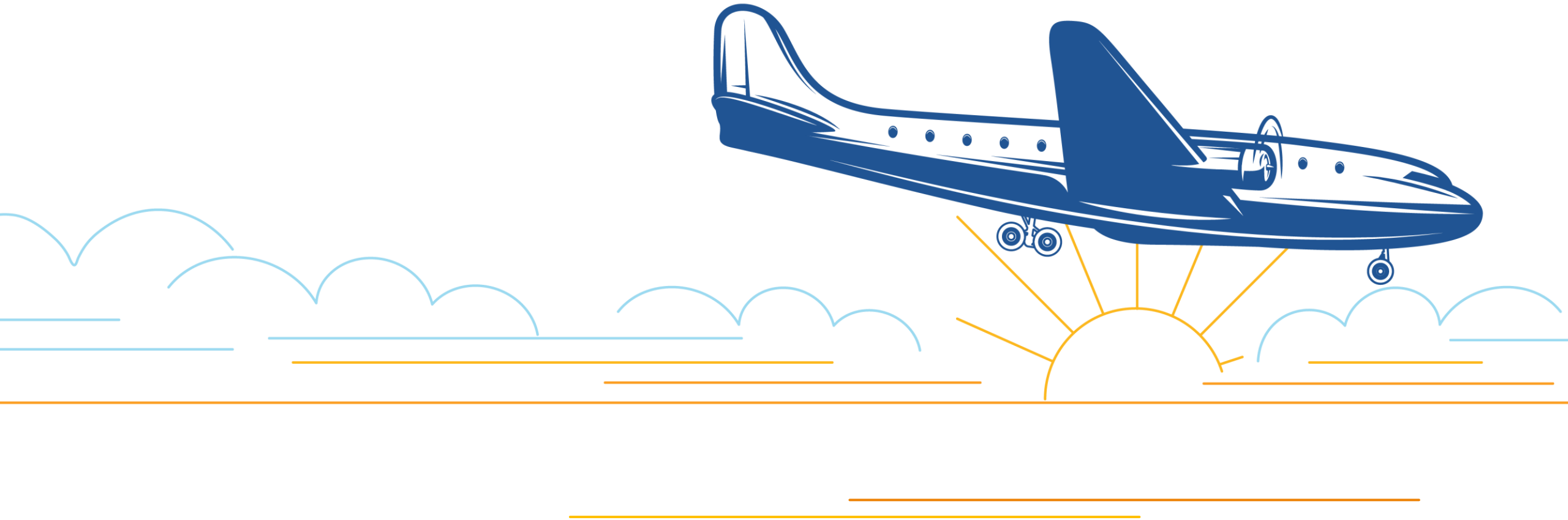
ClinicalTrials.gov Products

ClinicalTrials.gov
PRS Protocol Registration & Results System

ClinicalTrials.gov

Classic ClinicalTrials.gov Website

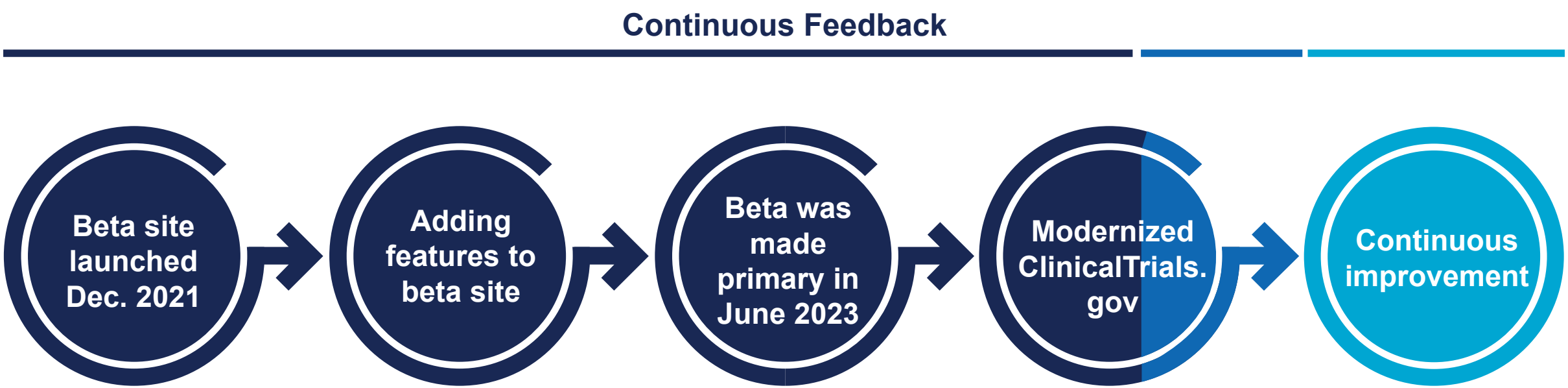
Will be retired on June 25, 2024



Christina Robinson
ClinicalTrials.gov Product Owner

Modernized ClinicalTrials.gov Website

How Users See Change: ClinicalTrials.gov Website



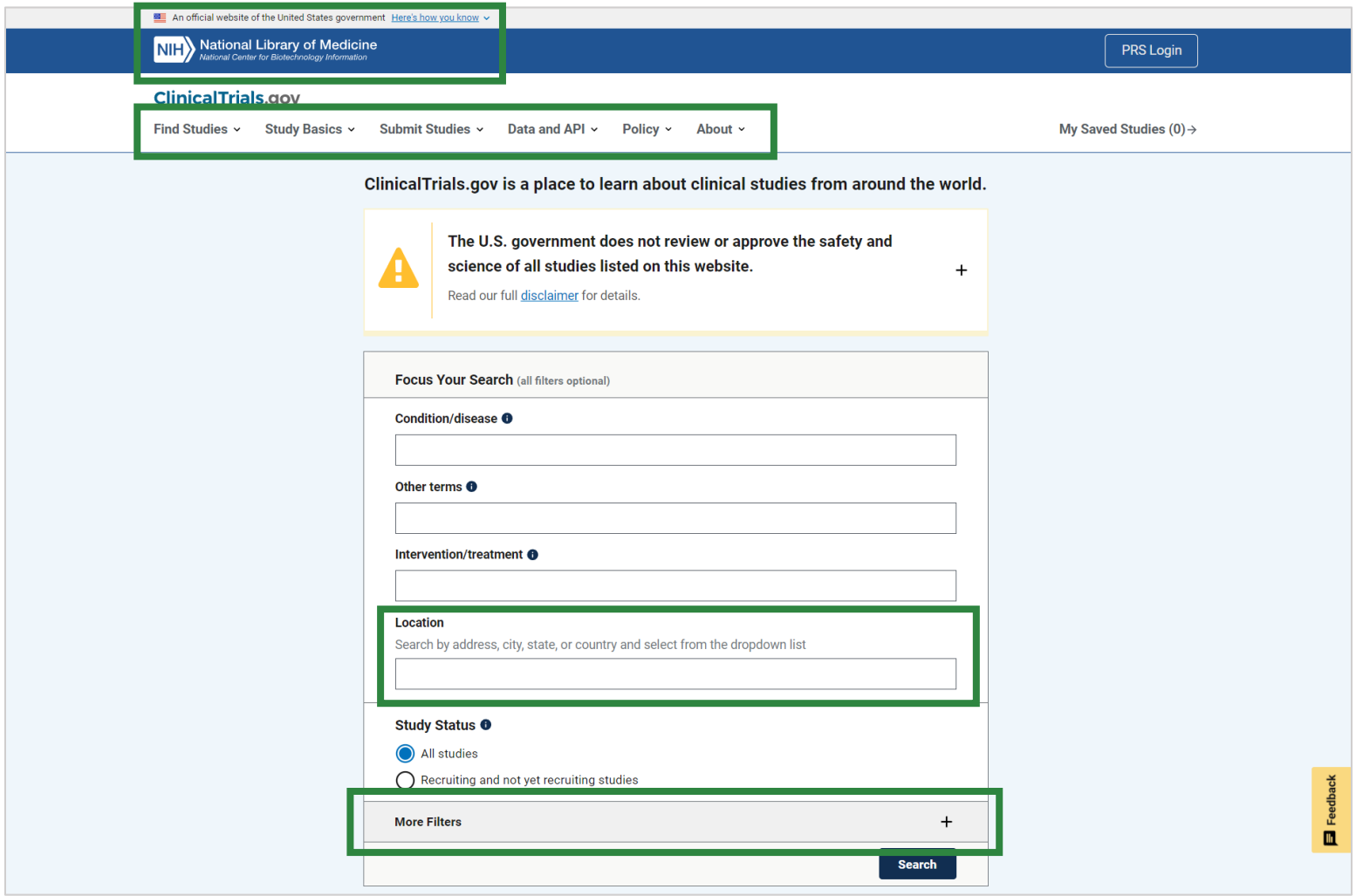
Updated 5.13.24

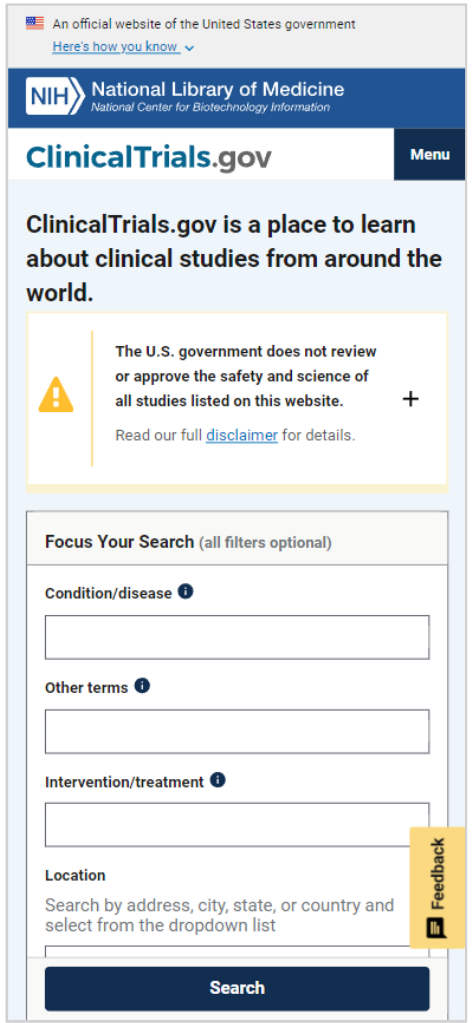
Modernized ClinicalTrials.gov Features

	Search Experience	Study Record Experience	Easy-to-Find and Easy-to-Use Content
AVAILABLE	Enhanced search Integrated Search and Search Results **Download (JSON, CSV, RIS)** Card view of search results **Modifiable table view of search results** Print view of search results Save studies of interest Save search/get search updates (RSS) Application programming interface (API)	Compiled study record data **On-page navigation** Print view of study registration Study details view of study record Researcher view of study record Fast Healthcare Interoperability Resources (FHIR) API pilot **Integrated record history**	API documentation Data about ClinicalTrials.gov Support materials for searching **Streamlined information architecture** Compiled policy/regulatory content About ClinicalTrials.gov page Learn About Studies page Learn About FHIR page
FUTURE	Rewritten ingest Expert search capabilities Browse studies by topic	Next steps for patients	

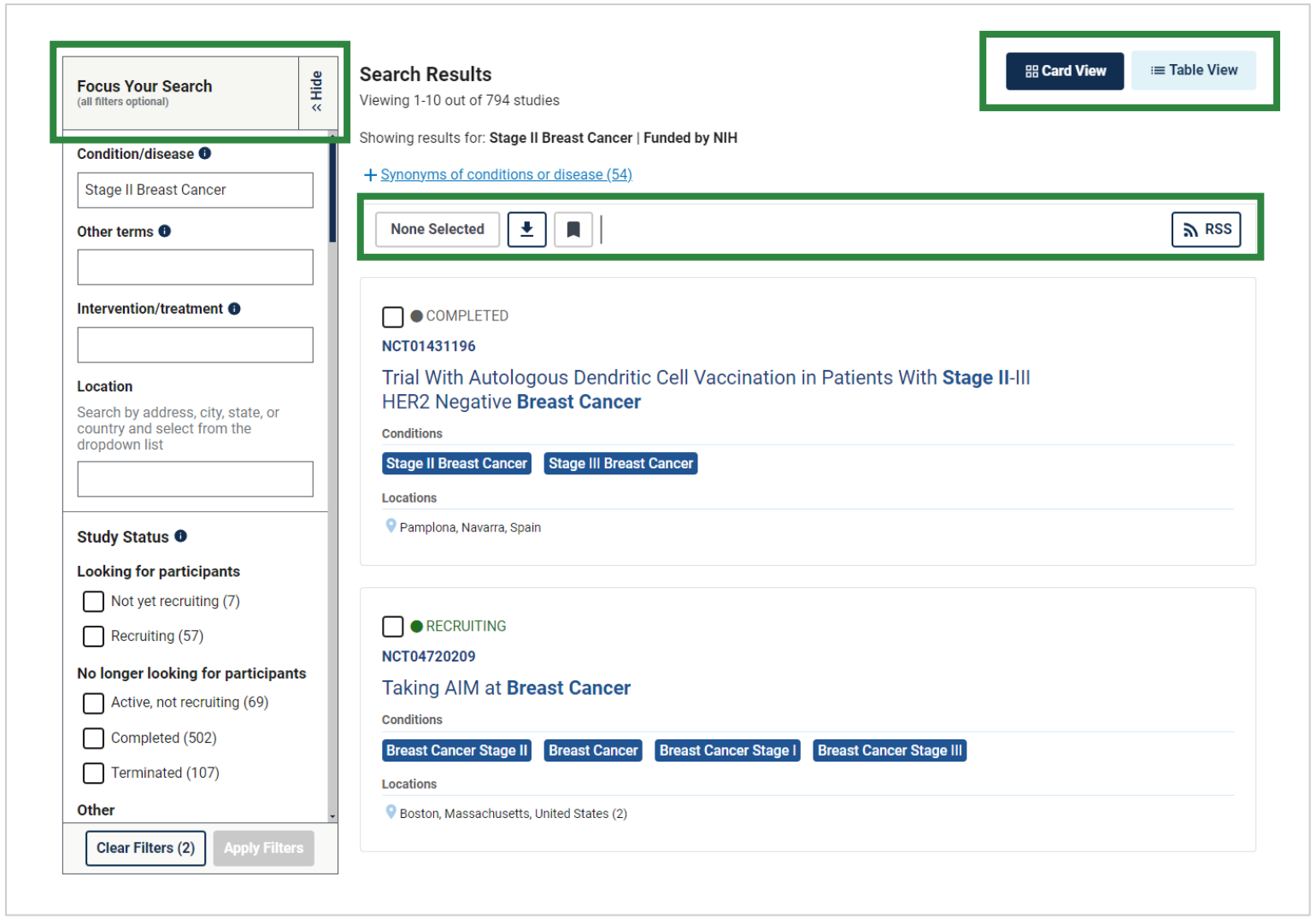
Updated 6.3.24

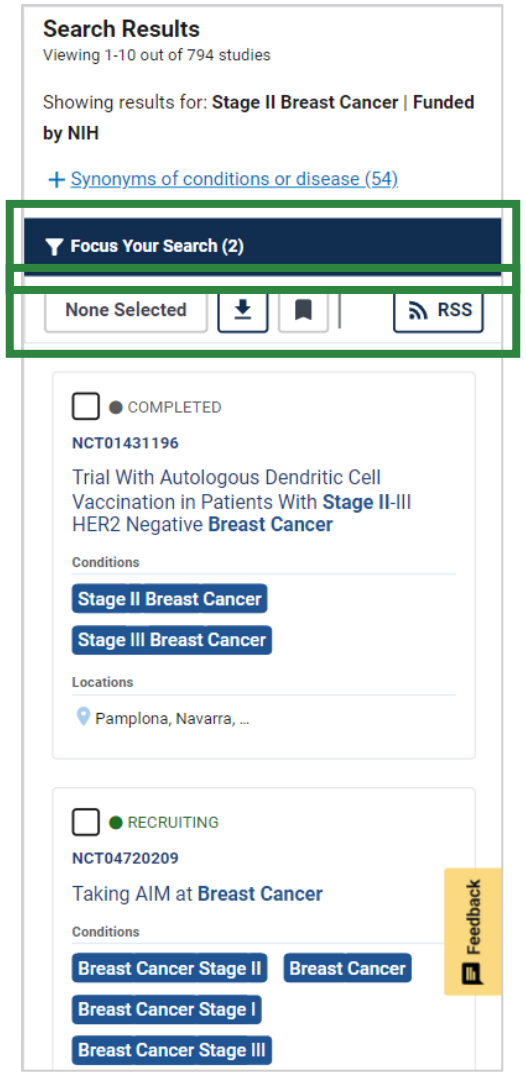
Benefits of the Modernized ClinicalTrials.gov



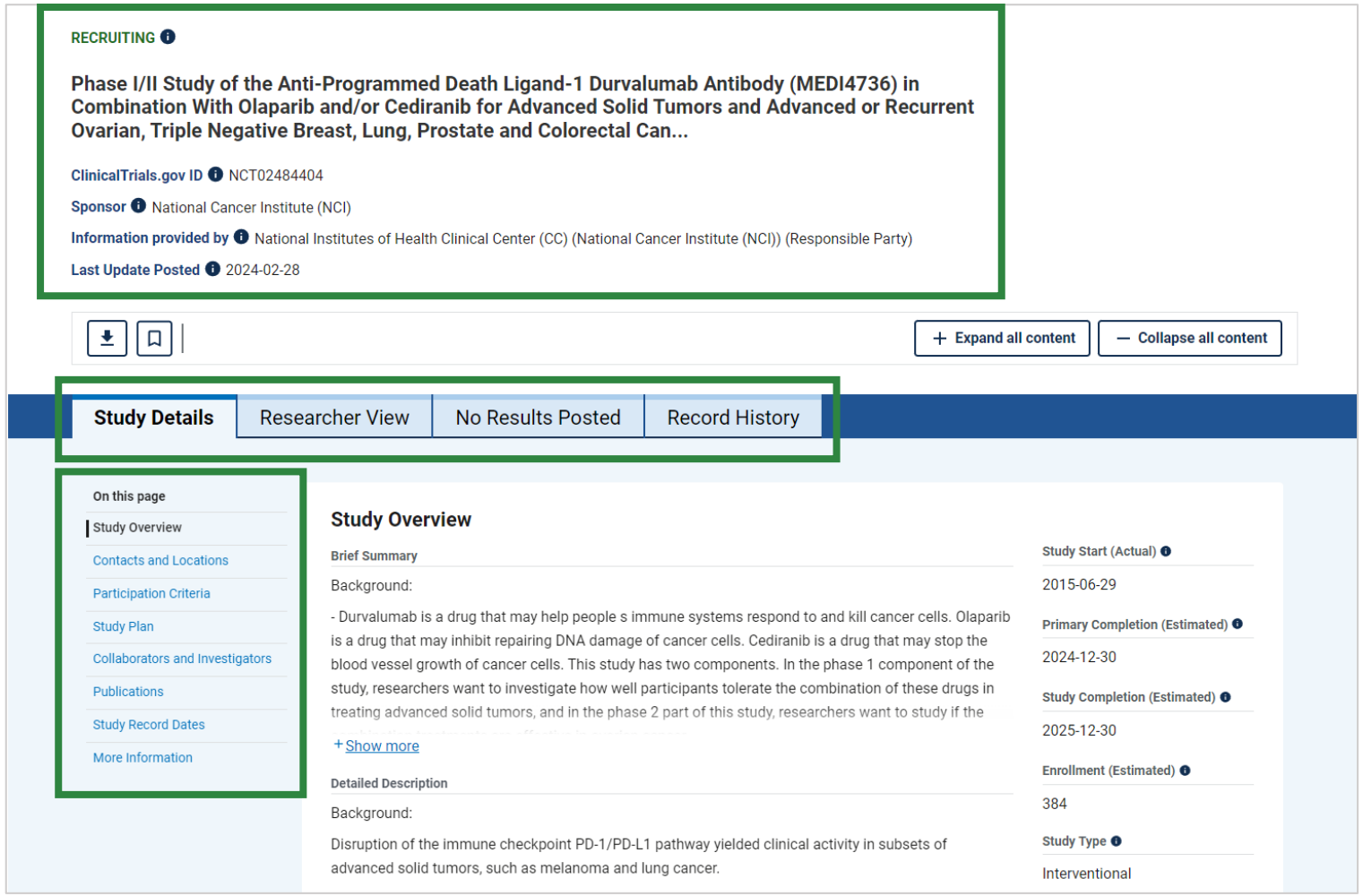


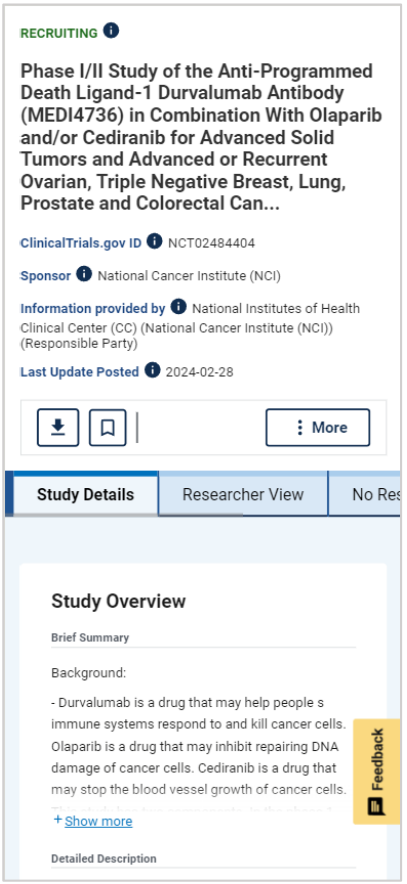
Sample Improvements to the Search Results

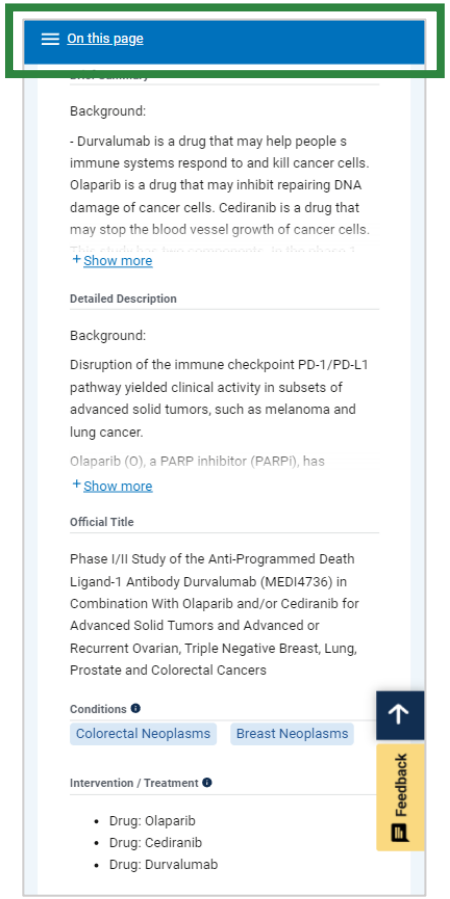




Sample Improvements to the Study Record



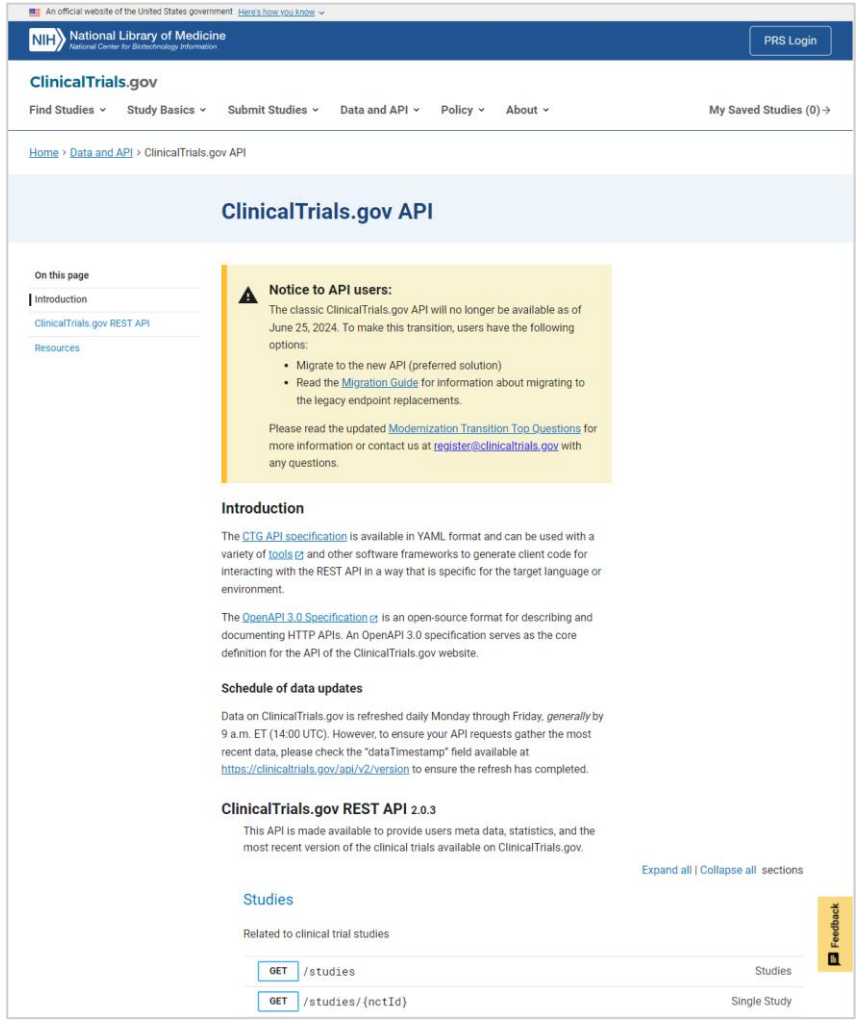




Application Programming Interface

The modernized API:

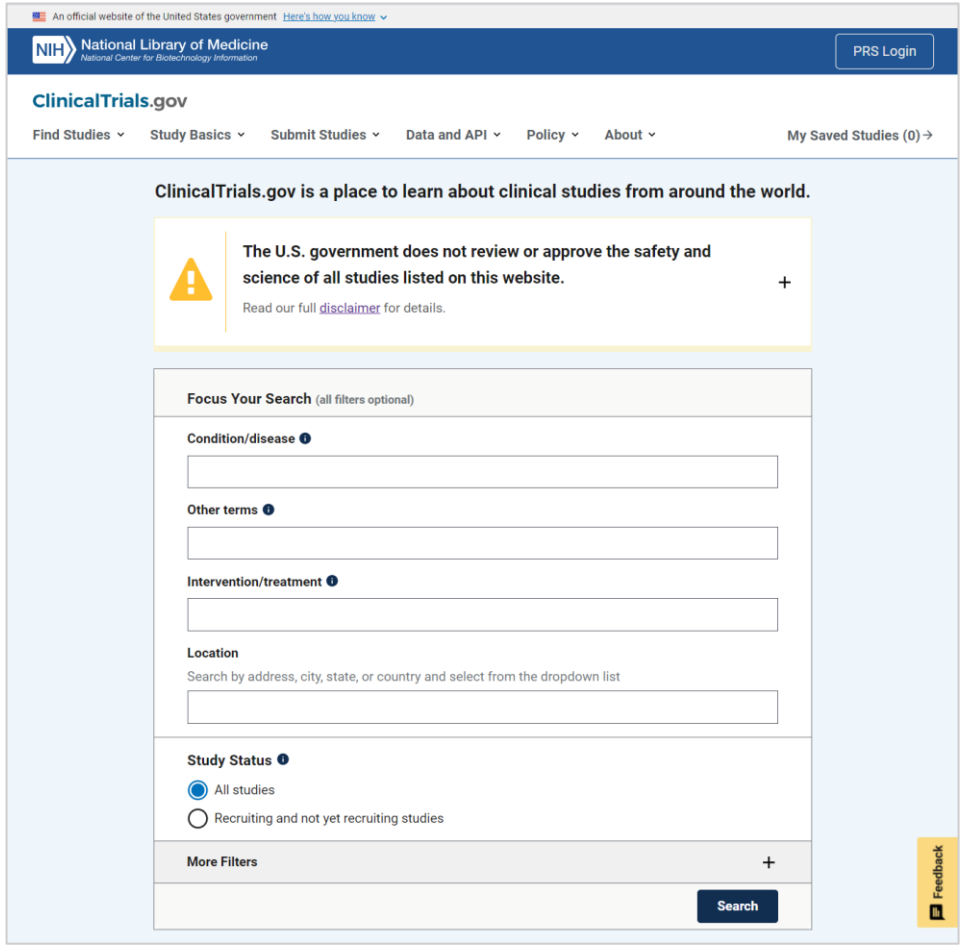
- Uses OpenAPI Specification version 3.0
- Exists within the main website
- Supports XML legacy endpoints



Hidden Benefits of Modernization

The modernized public website:

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



Future Features of ClinicalTrials.gov

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

Poll Question

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

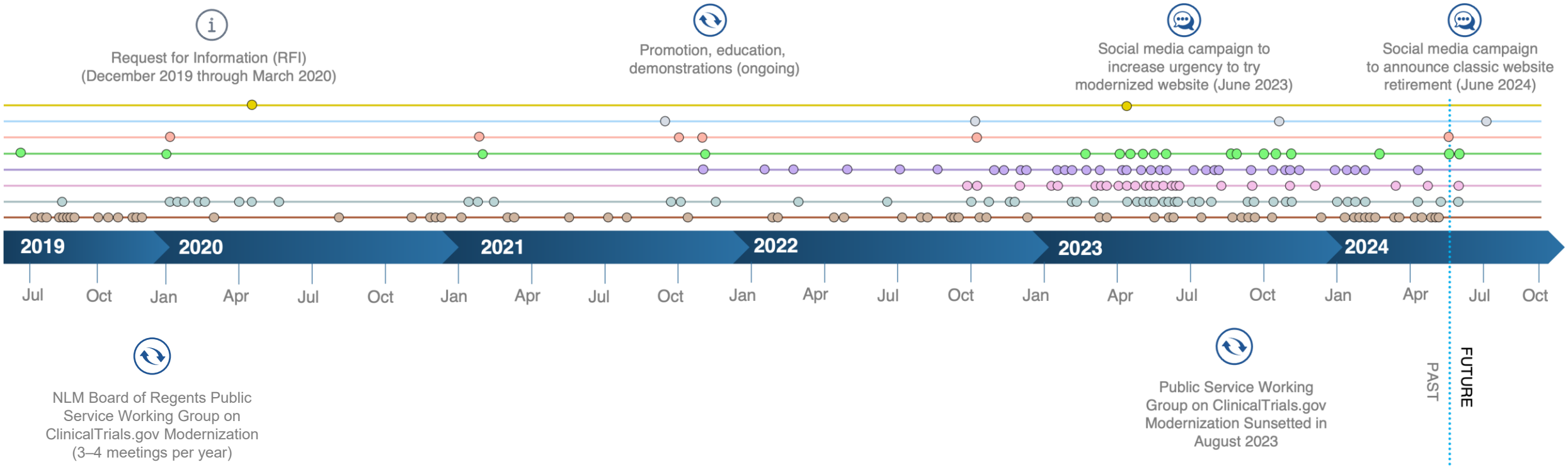
A. Locating policies or reporting requirements for clinical trials
B. How to save studies
C. How to download citations of clinical trials
D. Difference between CSV and API
E. Search tips

Stakeholder Engagement

Key:

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

Public Engagement



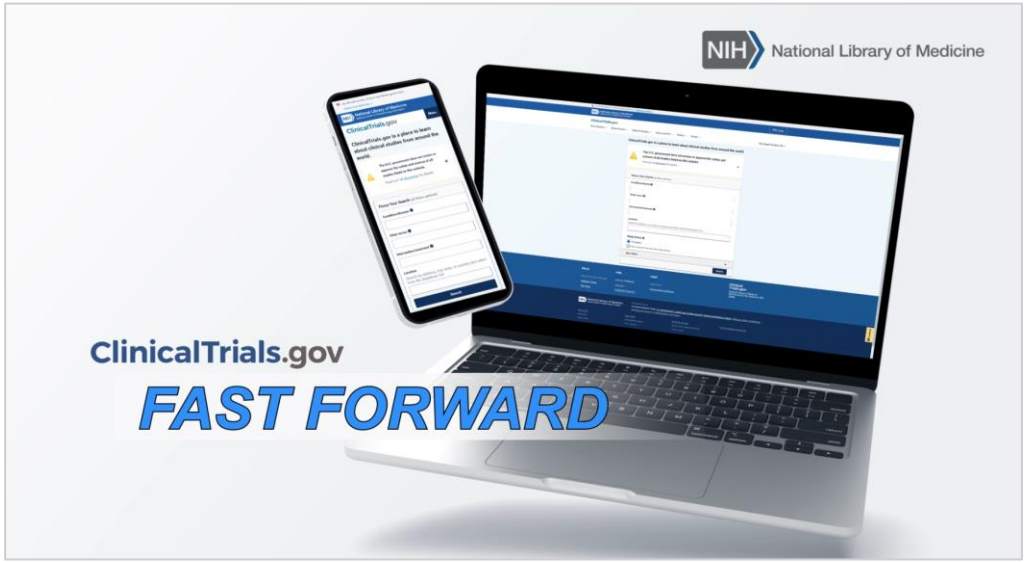
Engagement with the National Library of Medicine (NLM) Board of Regents

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

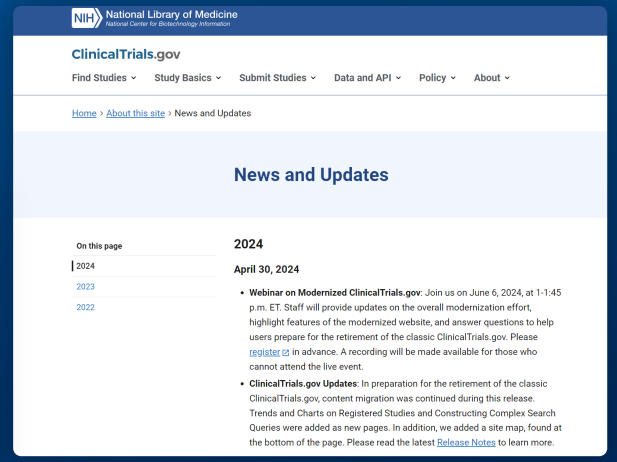
2022–23 report

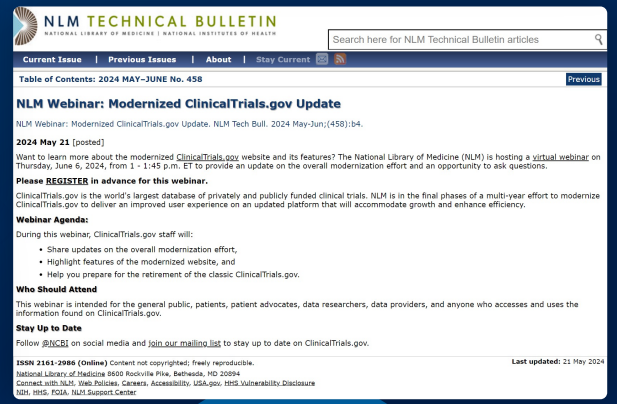
- Modernized ClinicalTrials.gov launched

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

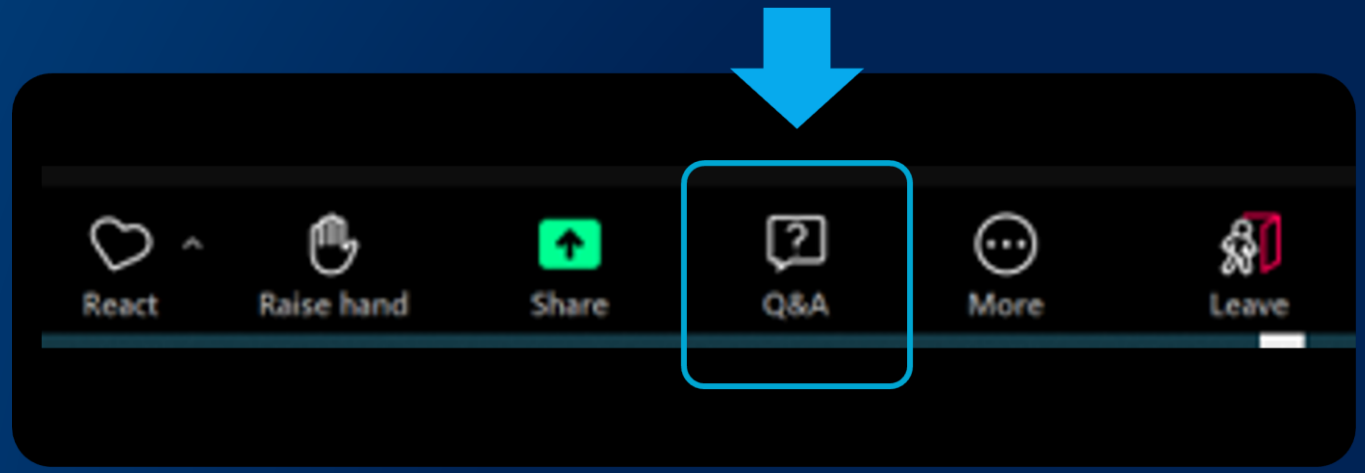




Moderated Q&A Instructions

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

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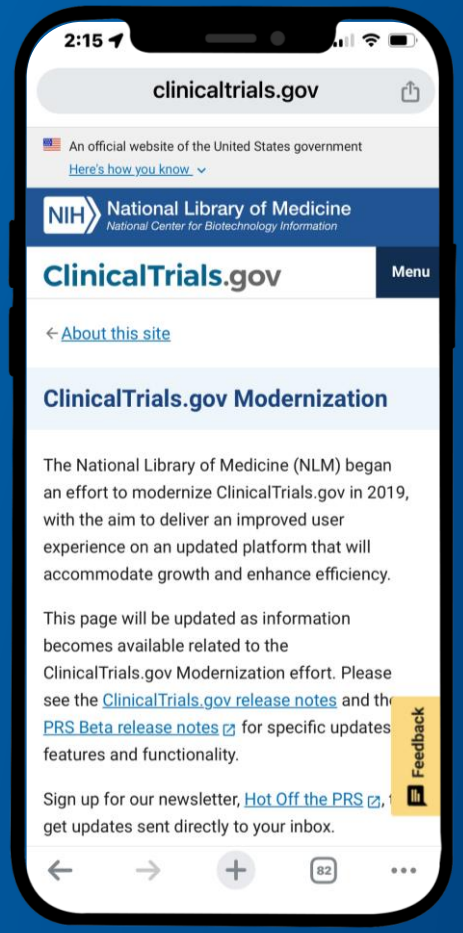
Attendees will:

- 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