

ClinicalTrials.gov Modernization

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National Library of Medicine

ClinicalTrials.gov as part of NLM

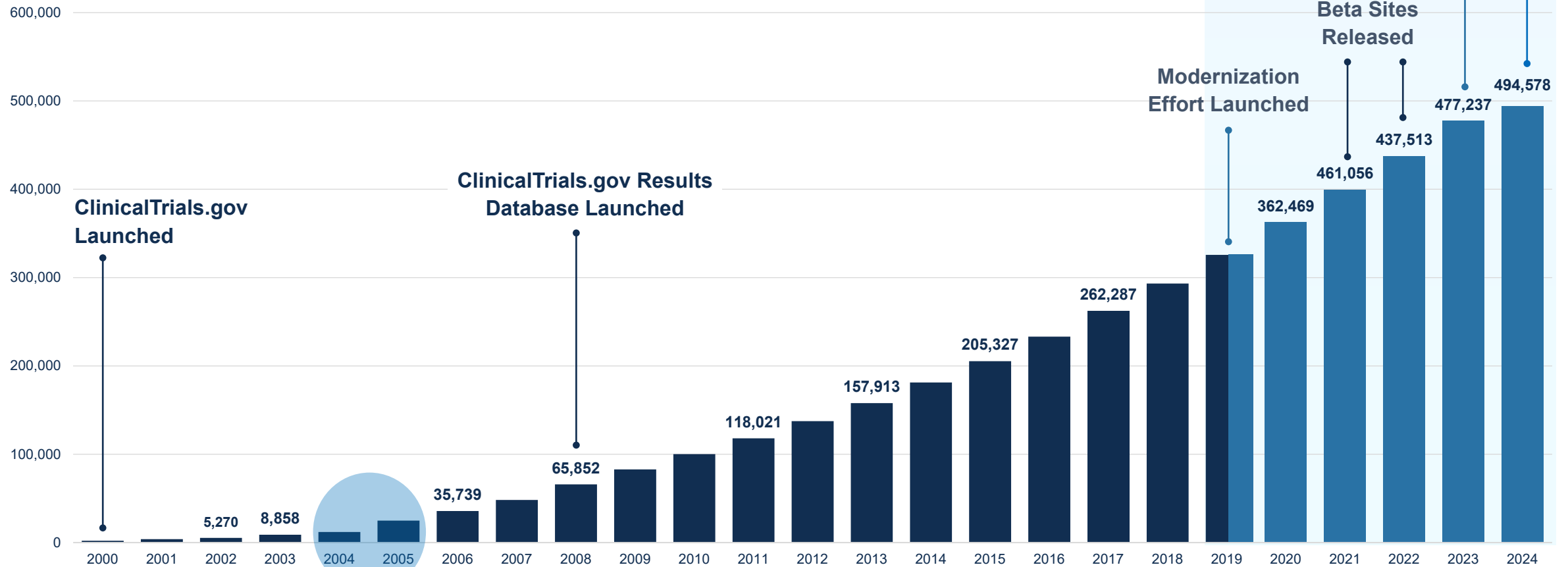
As part of NLM, ClinicalTrials.gov makes study record data available.

- ClinicalTrials.gov provides access to study data, but does not own the data.
- Sponsors are responsible for the data that appear on the website.
- Supporting materials and information related to study records are presented in plain language whenever possible.



Modernization Timeline

Maximize the utility of the growing corpus of information



Updated 5.13.24

ClinialTrials.gov Modernization Effort

Vision:

Ensure that ClinicalTrials.gov continues to be a trusted and valued 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
- Launched ClinicalTrials.gov Beta
- Communicated availability of the beta release to stakeholders



YEAR 3 Implementation

- Launched Protocol Registration and Results System (PRS) Beta
- 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



Where we are now

YEAR 5 Launches and Landings

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

ClinicalTrials.gov Primary Users



Patients and Health Care Professionals

Find studies that patients may be able to join

Learn about clinical research



Researchers

Look for studies available on a specific topic

Identify unmet research and medical needs



Sponsors and Investigators

Submit their study information

Keep the study record up-to-date, which may include adding results from when the study ends

| User Research

Modernization is a user-centered process.

1,000+

Comments with ideas for improving the PRS and public site from a request for information (RFI) in 2020 and comments received from an expert review

100+

Interviews to date with data submitters, data researchers, patients, and patient advocates

4,500+

Feedback comments submitted by users of the beta public site

17

Board of Regents Working Group meetings to provide expert user input to the design and development process

How We Got Here

“I want search to be as easy as Google.”

“I want advanced search on the homepage.”

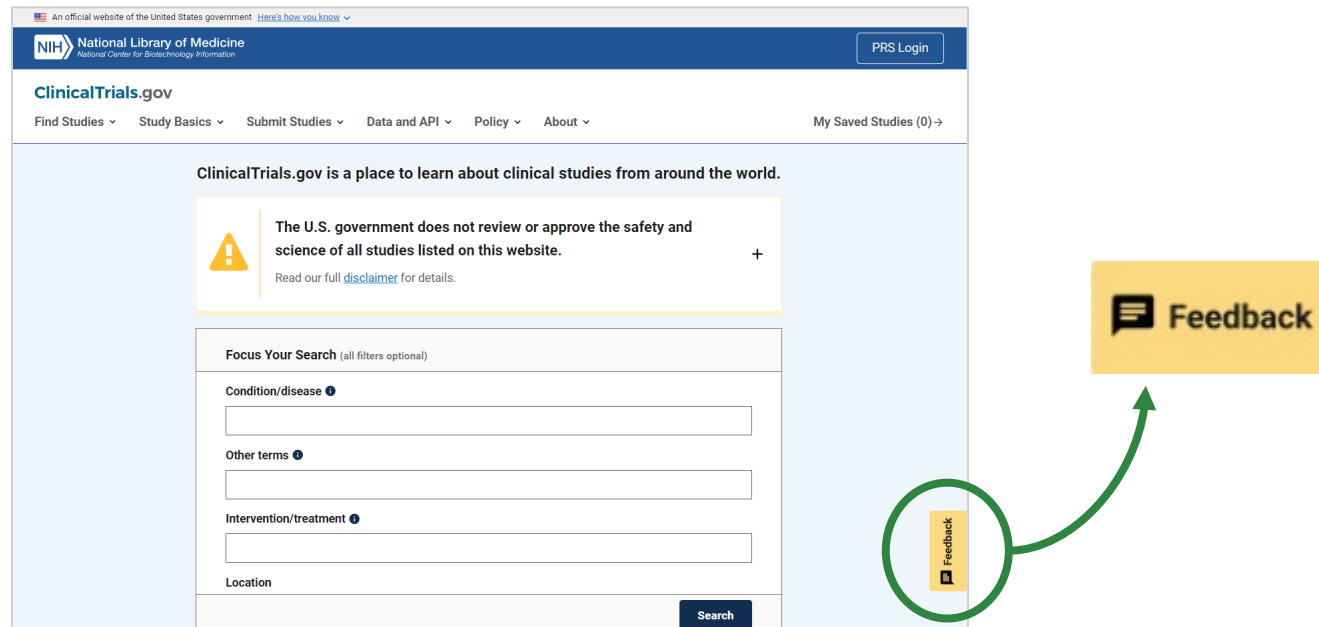


“I want to understand more info for my search results and study record.”

“I want to see as much study data in as small a space as possible on the homepage.”

“I want to enter my trial info as fast and as easily as possible even if that means the info available in API and the public site isn't as complete as it could be.”

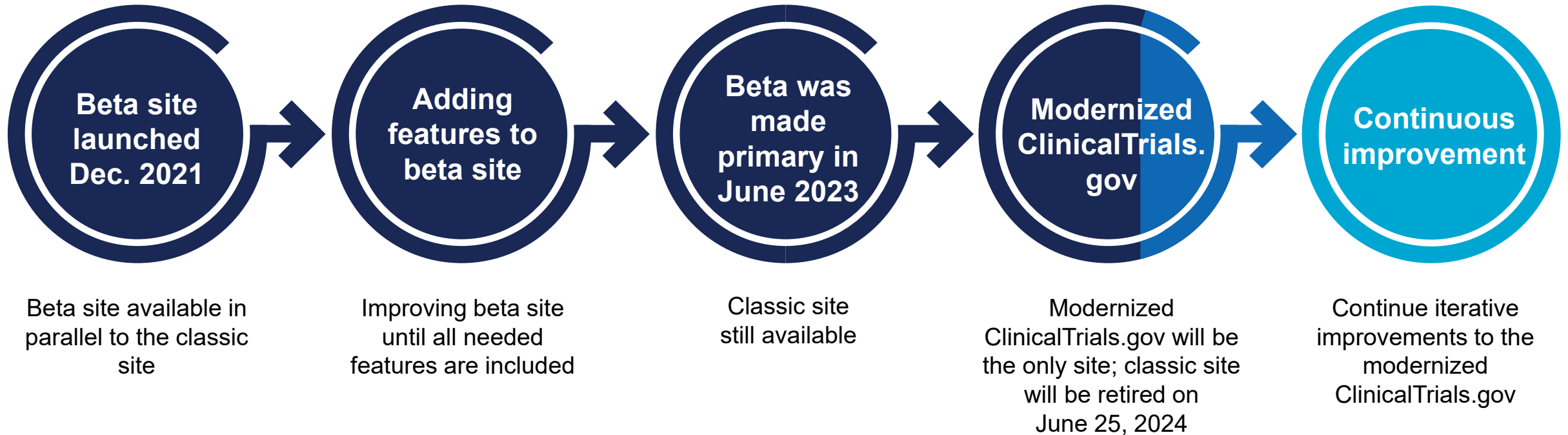
ClinicalTrials.gov User Feedback Process



- We read every single comment.
- We analyze the feedback continuously to identify bugs and issues/requests that come up repeatedly and warrant a change.
- Users who provide an email address with their comment are often invited to participate in Zoom sessions or other activities (e.g., taking a survey) to provide further feedback.

How Users See Change: ClinicalTrials.gov Website

----- Continuous Feedback -----



Updated 5.13.24

Sample Improvements to 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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Location

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

Search

Feedback

Sample Improvements to Search Results

Focus Your Search (all filters optional) Hide

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 [Download] [Bookmark] [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)

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

Card View Table View

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 [Download] [Bookmark] [RSS]

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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 Study Record

RECRUITING ⓘ

Taking AIM at Breast Cancer

ClinicalTrials.gov ID ⓘ NCT04720209

Sponsor ⓘ Dana-Farber Cancer Institute

Information provided by ⓘ Christina Dieli-Conwright, PhD, Dana-Farber Cancer Institute (Responsible Party)

Last Update Posted ⓘ 2024-01-23

↓ | 📄

+ 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

The purpose of this research is to determine whether a 16-week exercise program for individuals with breast cancer and have completed treatment (i.e., surgery, chemotherapy, or radiation) for breast cancer will decrease inflammation in fat tissue.

Detailed Description

This study is about using different types of exercise to reduce inflammation in fat tissue in an effort to minimize the risk of cancer recurrence related to being overweight or obese. The investigators hope to learn whether participating in a specific exercise program can cause inflammation in the fat tissue to decrease.

The names of the study interventions involved in this study are:

- Circuit-style aerobic and resistance exercise (CARE)

[+ Show more](#)

Study Start (Actual) ⓘ

2021-08-13

Primary Completion (Estimated) ⓘ

2025-06-15

Study Completion (Estimated) ⓘ

2026-06-15

Enrollment (Estimated) ⓘ

300

Study Type ⓘ

Interventional

☰ On this page

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Detailed Description

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[+ Show more](#)

Official Title

Taking AIM at **Breast Cancer**: Targeting Adiposity and Inflammation With Movement to Improve Prognosis in **Breast Cancer** Survivors

Conditions ⓘ

Breast Cancer **Breast Cancer Stage I**

Breast Cancer Stage II

Breast Cancer Stage III

Intervention / Treatment ⓘ

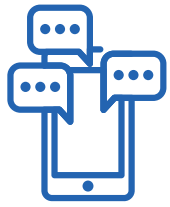
- Other: CARE
- Other: TARE
- Other: Home-Based Stretching

Feedback

Modernized ClinicalTrials.gov Features

	Search Experience	Study Record Experience	Easy-to-Find and Easy-to-Use Content
AVAILABLE	<ul style="list-style-type: none"> Download (JSON, CSV) Search v 3 Search Results—Table View v 2 Enhanced search UI Print view of search results Save search/get search updates Application programming interface (API) v 2 	<ul style="list-style-type: none"> Expanded study record data Fast Healthcare Interoperability Resources (FHIR) API pilot Print view of study registration Table view of study record Study record history v 4 	<ul style="list-style-type: none"> Learn About Studies About ClinicalTrials.gov Learn About FHIR Data About Studies API documentation Information Architecture Content migration Support materials for using search
FUTURE	<ul style="list-style-type: none"> Rewrite ingest Additional download format(s) Expert search capabilities Search Results—Table View v 3 	<ul style="list-style-type: none"> Patient next steps 	

Updated 5.13.24



Outreach and Engagement

59

Social media posts sent from NCBI and NLM accounts to an audience of **850,000+**



1,000+

Comments with ideas for improving the PRS and public site from an RFI in 2020 and from an expert review

4,500+

Feedback comments submitted by users of the beta public site



97

Communications sent or posted to an audience of 50,000+ including 41 Hot off the PRS! (audience of 16K), 35 News & Updates, 12 *NLM Technical Bulletins*, 7 NLM Announces, 1 OER Open Mike, 1 NLM News



17

NLM Board of Regents Working Group meetings to provide expert user input to the design and development process

100+

Interviews with data submitters, data researchers, patients, and patient advocates

2

Public meetings

5

Webinars reaching **1,900+ attendees**

9

Blogs* including 5 *Musings from the Mezzanine* posts (audience of 500,000) and 2 NCBI Insights Blog posts (audience of 700+).

Count includes 2 mentions from *Musings from the Mezzanine* and 2 *Musings from the Mezzanine* – Director's Updates.

5

Educational videos **viewed 1,800+ times**

3

Progress reports **viewed 1,400+ times**

Modernization Webinar



Join us on June 6, 2024,
at 1-1:45 p.m. ET

ClinicalTrials.gov staff will:

- Share an update on the overall modernization effort,
- Highlight features of the modernized website, and
- Help users prepare for the retirement of the classic ClinicalTrials.gov

The screenshot shows a webpage header for the National Library of Medicine (NIH) National Center for Biotechnology Information. Below the header is a search bar and a banner for "NCBI Insights" featuring a DNA double helix graphic. The main content area displays a blog post titled "NLM Webinar: Modernized ClinicalTrials.gov Update". The post includes a photo of a person in a white lab coat holding a tablet displaying the webinar title. To the right of the post are sections for "About NCBI" (with links to "About This Blog" and "NCBI Website"), "NCBI Outreach Events" (with links to "Workshops", "Codeathons", and "Conferences"), and "Subscribe To Our Mailing Lists". Below the photo, the webinar details are listed: "NLM Webinar: Modernized ClinicalTrials.gov Update" with a view count of 3256, and "Date And Time: 06-06-2024 @ 01:00 PM (EDT) to 06-06-2024 @ 01:45 PM (EDT)".

Ways to Learn More



About Modernization

<https://clinicaltrials.gov/ct2/about-site/modernization>



Frequently Asked Questions

<https://clinicaltrials.gov/ct2/manage-recs/faq>



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

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

Thank you!