# ClinicalTrials.gov Modernization

Christina Robinson, MA
ClinicalTrials.gov Product Owner

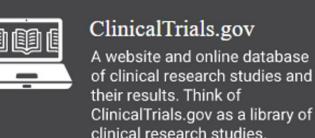NIH National Library of Medicine

ClinicalTrials.gov

# What Is ClinicalTrials.gov?



National Library of Medicine

NLM maintains the website as part of our effort to collect, organize, and make available biomedical information and data.

ClinicalTrials.gov

A website and online database of clinical research studies and their results. Think of ClinicalTrials.gov as a library of clinical research studies.

The database stores and organizes information as **study records** that anyone can search for and access.

Sponsors and investigators

The submission database is called the Protocol Registration and Results System, or the **PRS**.

Patients and health care professionals

Researchers

# Growth of ClinicalTrials.gov

# ClinicalTrials.gov Modernization Effort

To 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

**Improve the user experience.**

**Upgrade the technical infrastructure and processes to enhance sustainability.**

**Support the existing legal, regulatory, and policy framework.**

NIH National Library of Medicine

ClinicalTrials.gov

# 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 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

NIH National Library of Medicine

**ClinicalTrials.gov**

# Who Is Being Served by Modernization?

## External Stakeholders

Patients and Their Advocates

Data Submitters

Data Researchers

## Internal Stakeholders

Policy and Oversight Teams

Information Specialists, Reviewers, and Developers

# ClinicalTrials.gov as Part of NLM

**As part of the National Library of Medicine, 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 to aid understanding of study data.

# Outreach and Engagement

**38** **Social media posts**
sent from National Center for Biotechnology Information and National Library of Medicine accounts **to an audience of 850,000+**

**2,500+**
**Feedback comments**
submitted by users of the beta public site and PRS Beta

**84**
**Communications sent or posted**,
including 32 Hot Off the PRS! e-bulletins, 32 What's New updates, 11 *NLM Technical Bulletin* articles, 7 NLM Announces updates, 1 OER Open Mike post, and 1 NLM News article **to an audience of 50,000+**

**1,000+**
**Comments** with ideas for improving the PRS and public site from a request for information in 2020 and from an expert review

**100+**
**Interviews** with data submitters, data researchers, patients, and patient advocates

**2**
Public meetings

**5**
Webinars reaching **1,900+ attendees**

**3**
Educational videos **viewed 1,100+ times**

**2**
Progress reports **viewed 140 times**

**7**
**Blog posts**
5 posts and 1 mention on *Musings from the Mezzanine* **to an audience of 500,000**

2 posts on the NCBI Insights Blog **to an audience of 700+**

**16**
**NLM Board of Regents Working Group**
meetings to provide expert user input to the design and development process

NIH National Library of Medicine

ClinicalTrials.gov

# User Perspectives and Challenges



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

"I want advanced search on the homepage."

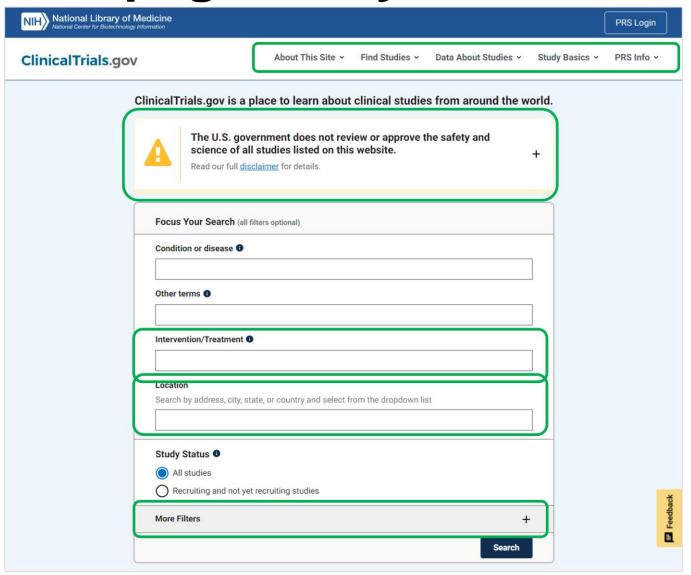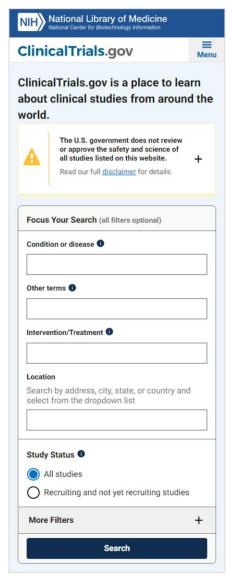"I want search to be as easy as Google."

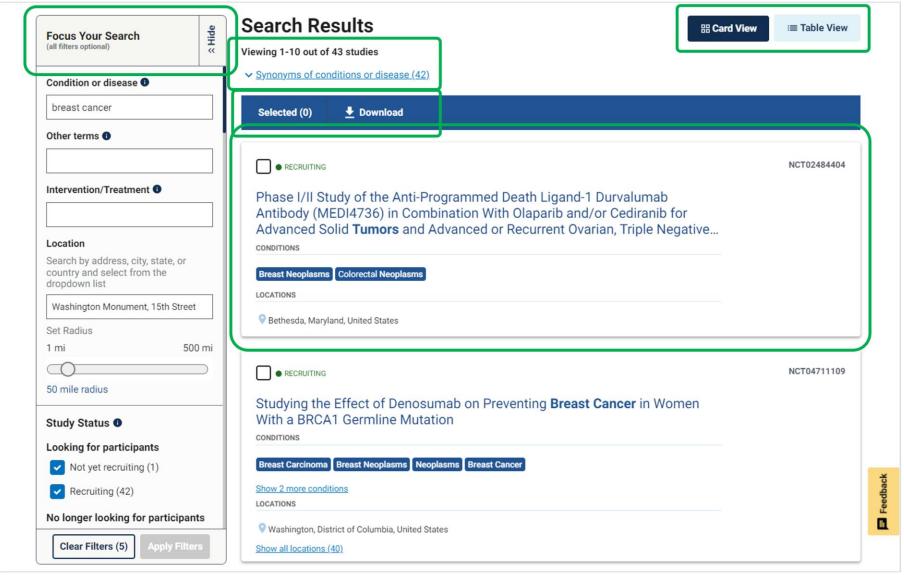"I want to see as much study data in as small a space as possible on the homepage."

"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."
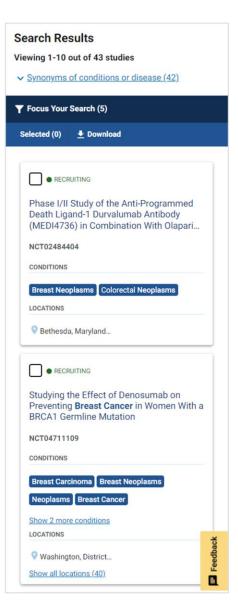
ClinicalTrials.gov

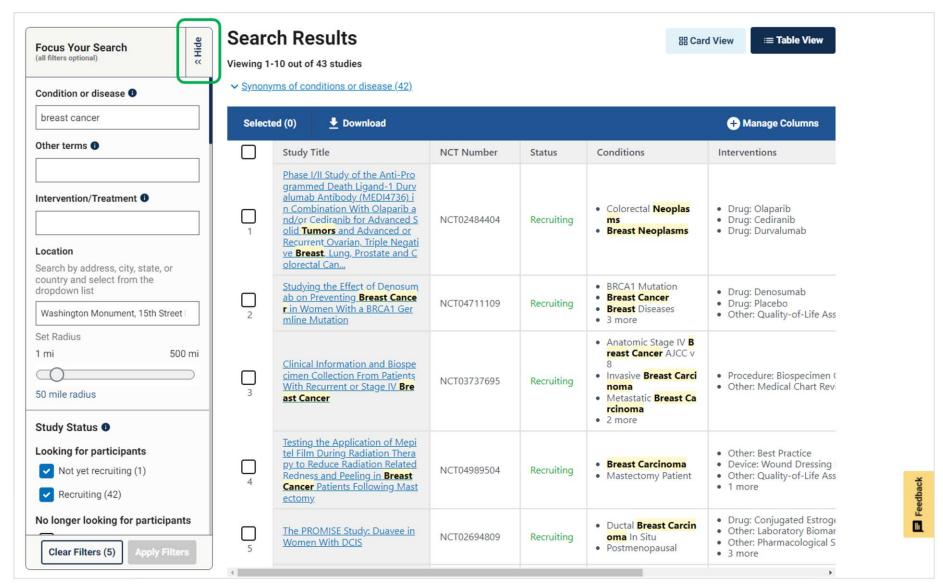# Homepage – Key Features

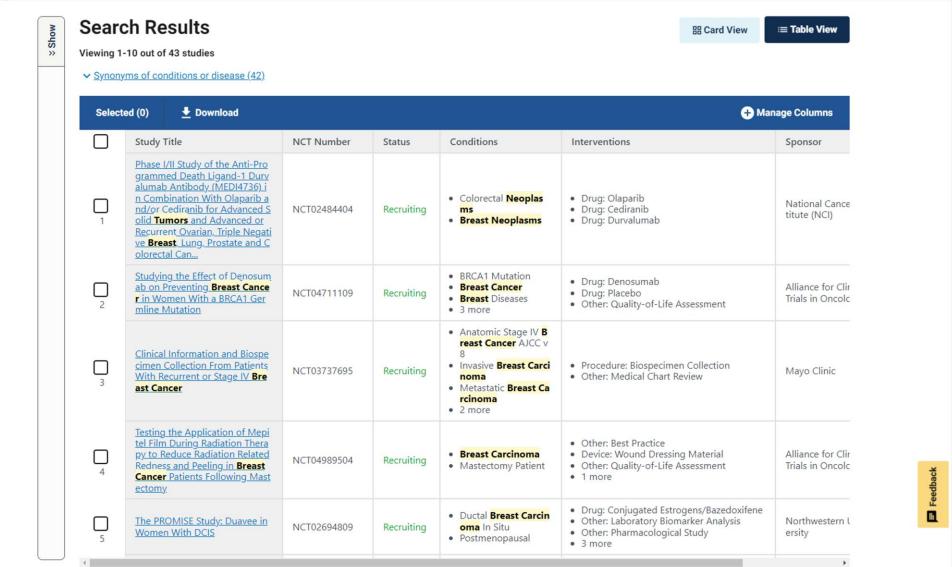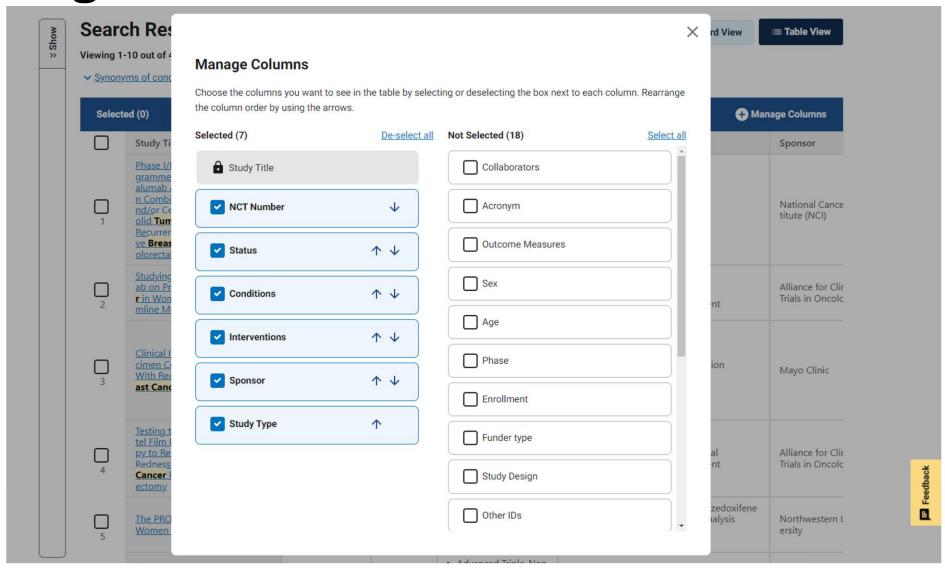# Search Results – Key Features



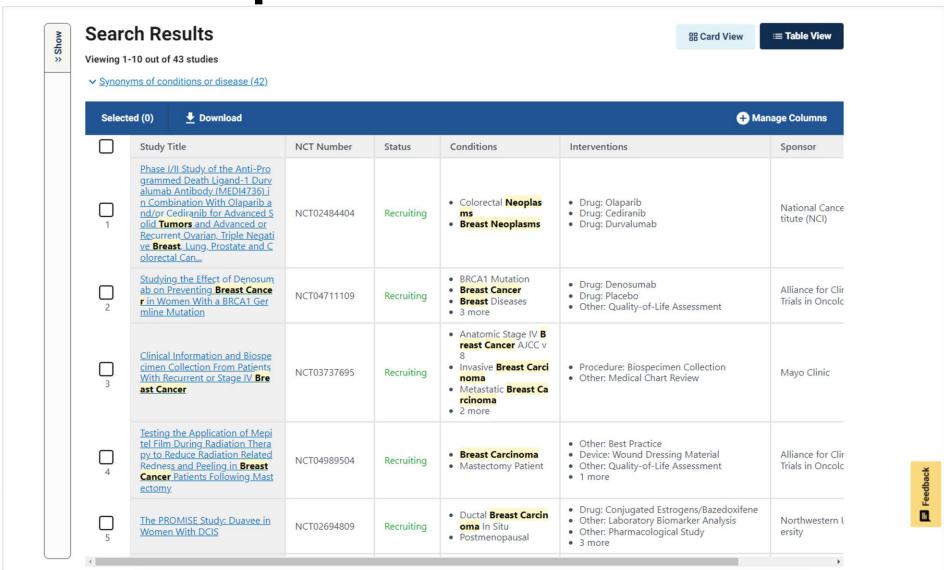National Library of Medicine

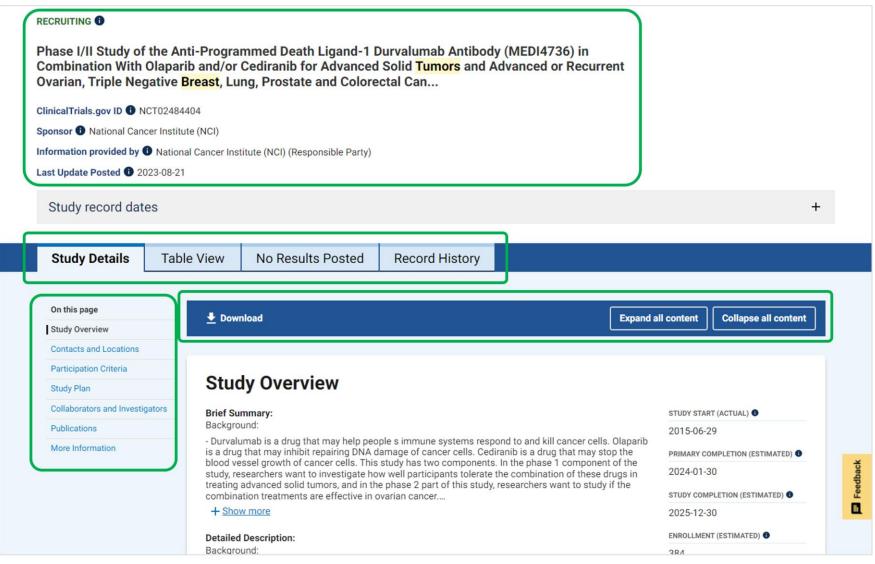ClinicalTrials.gov

# Search Results – Table View

# Expanded Table View

# Manage Table Columns
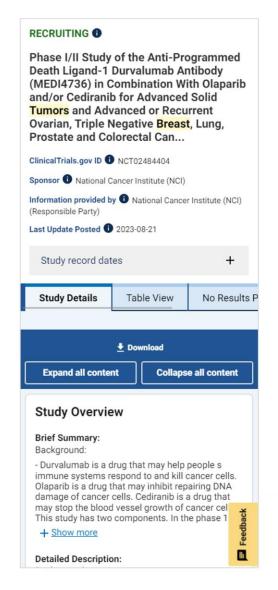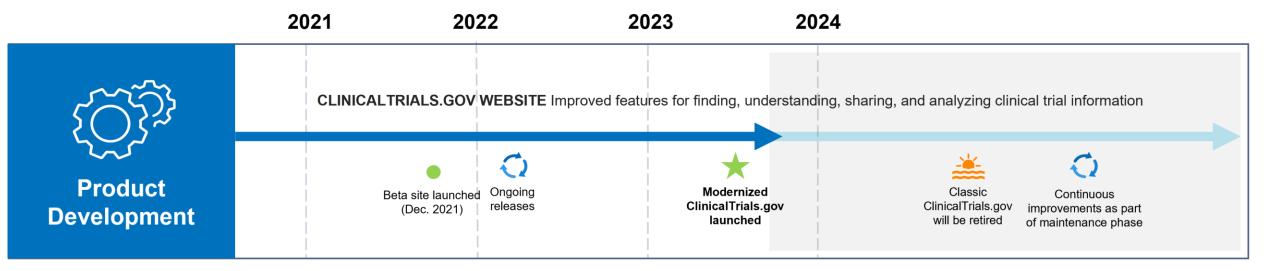
# Return to Expanded Table View

# Study Record – Key Features

# 2021–24 Strategic Roadmap: Modernized ClinicalTrials.gov

**Product Development**

2021 | 2022 | 2023 | 2024

**CLINICALTRIALS.GOV WEBSITE** Improved features for finding, understanding, sharing, and analyzing clinical trial information

Beta site launched (Dec. 2021)

Ongoing releases

**Modernized ClinicalTrials.gov launched**

Classic ClinicalTrials.gov will be retired

Continuous improvements as part of maintenance phase

NIH National Library of Medicine

ClinicalTrials.gov

# Current and Future Efforts

## Ongoing

- Manage saved studies

- Provide RSS

- Next steps to join a study

- Study record history (v3)

- Search results table view (v3)

- Content migration

## Coming Soon

- Download in XML

- Finalize application programming interface (API)

- Rewrite ingest (retire classic website)

# ClinicalTrials.gov Public Site Modernization Team