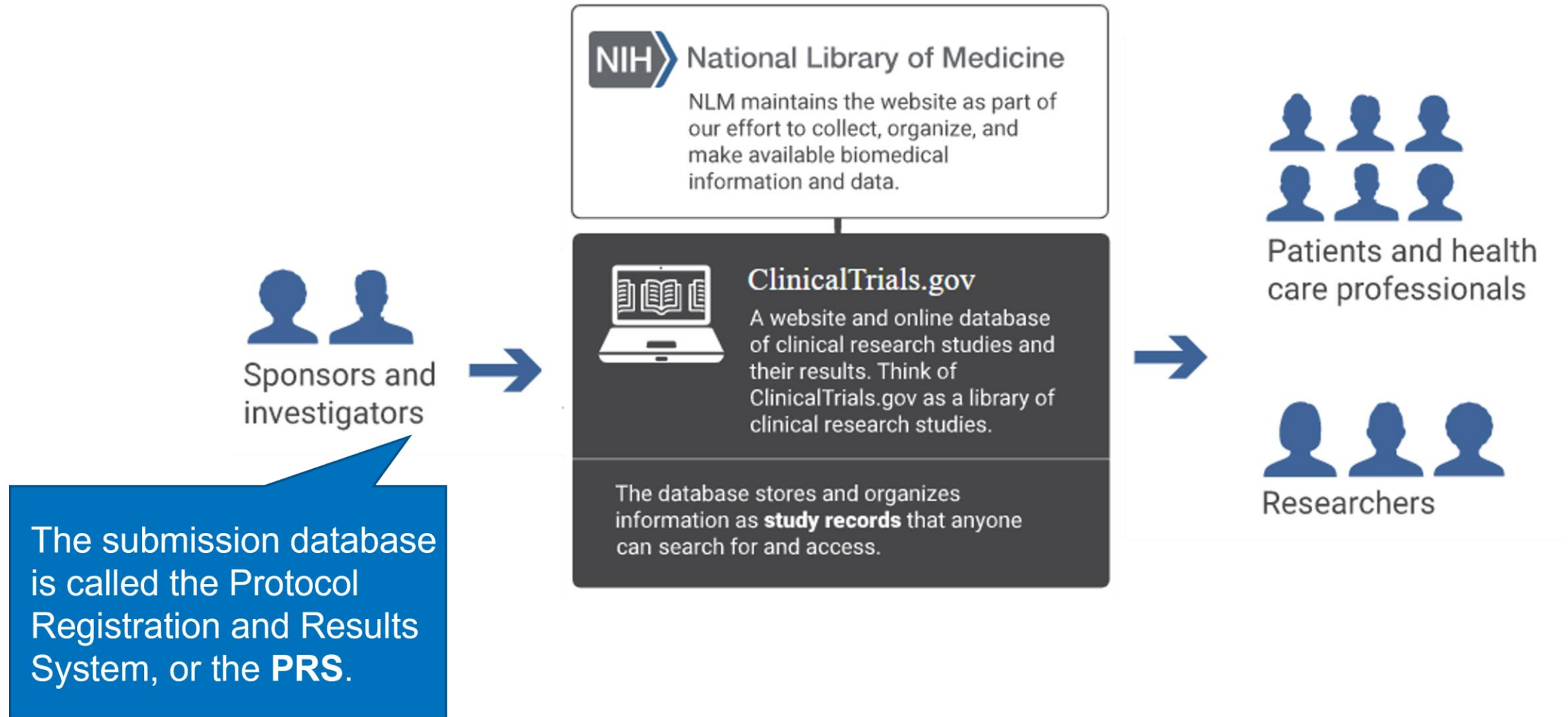


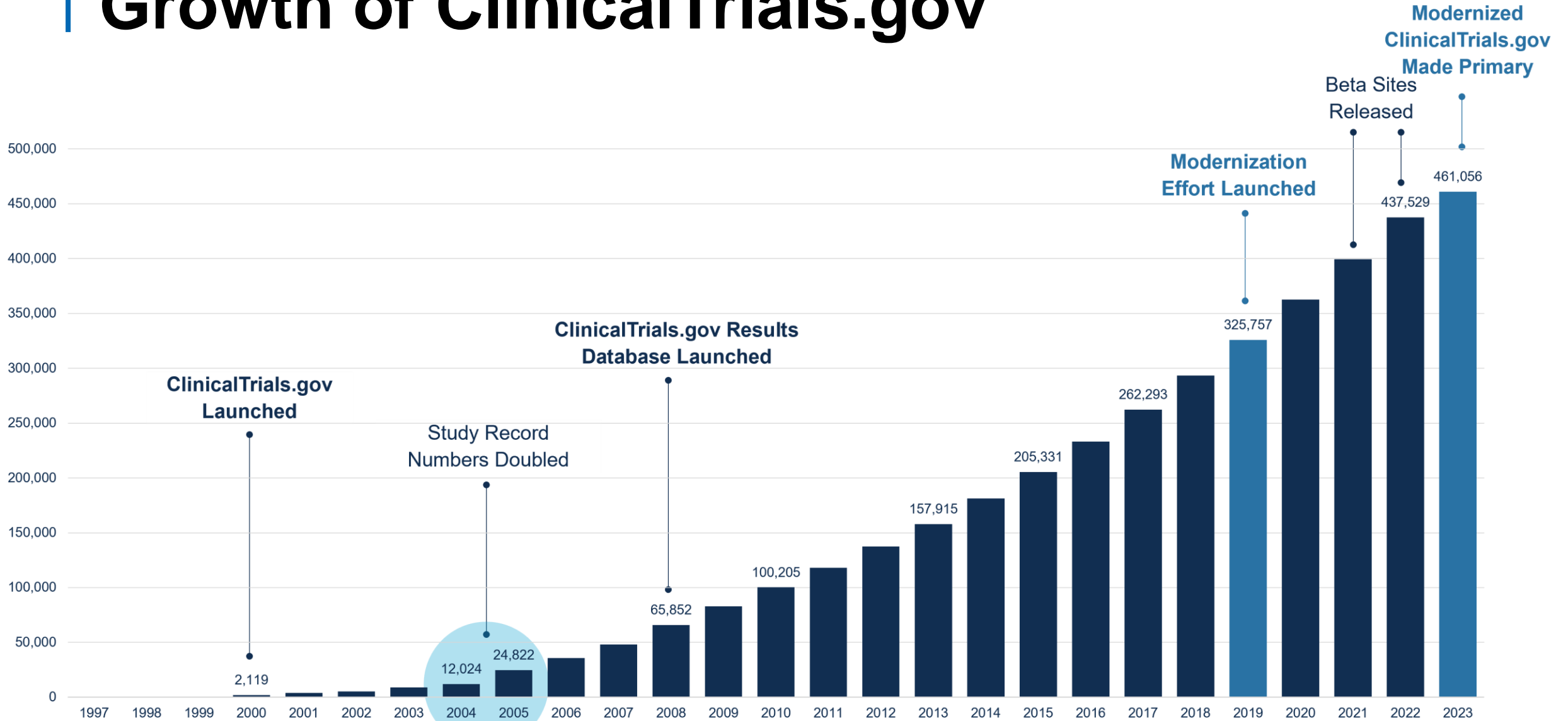
ClinicalTrials.gov Modernization

Christina Robinson, MA
ClinicalTrials.gov Product Owner

What Is ClinicalTrials.gov?



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.

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

Who Is Being Served by Modernization?

External Stakeholders



Patients and Their Advocates



Data Submitters



Data Researchers

Internal Stakeholders



Policy and Oversight Teams



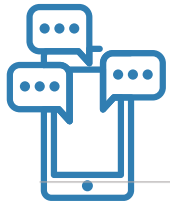
Information Specialists,
Reviewers, and Developers

| 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+**



1,000+

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

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+**



100+

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

2

Public meetings

5

Webinars reaching **1,900+ attendees**

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+**

3

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

2

Progress reports **viewed 140 times**

16

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

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.”

Homepage – Key Features


NIH National Library of Medicine
National Center for Biotechnology Information

PRIS Login

ClinicalTrials.gov

About This Site ▾ Find Studies ▾ Data About Studies ▾ Study Basics ▾ PRS Info ▾

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 or 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 +

 Feedback

NIH National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov Menu

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

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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 Results – Key Features

Search Results

Viewing 1-10 out of 43 studies

[Synonyms of conditions or disease \(42\)](#)

Selected (0) [Download](#)

RECRUITING NCT02484404

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...

CONDITIONS

[Breast Neoplasms](#) [Colorectal Neoplasms](#)

LOCATIONS

[Bethesda, Maryland, United States](#)

RECRUITING NCT04711109

Studying the Effect of Denosumab on Preventing **Breast Cancer** in Women With a BRCA1 Germline Mutation

CONDITIONS

[Breast Carcinoma](#) [Breast Neoplasms](#) [Neoplasms](#) [Breast Cancer](#)

[Show 2 more conditions](#)

LOCATIONS

[Washington, District of Columbia, United States](#)

[Show all locations \(40\)](#)

Focus Your Search

(all filters optional)

Condition or disease ⓘ

breast cancer

Other terms ⓘ

Intervention/Treatment ⓘ

Location

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

Washington Monument, 15th Street

Set Radius

1 mi 500 mi

50 mile radius

Study Status ⓘ

Looking for participants

Not yet recruiting (1)

Recruiting (42)

No longer looking for participants

[Clear Filters \(5\)](#) [Apply Filters](#)

Card View Table View

Feedback

Search Results

Viewing 1-10 out of 43 studies

[Synonyms of conditions or disease \(42\)](#)

Focus Your Search (5)

Selected (0) [Download](#)

RECRUITING

Phase I/II Study of the Anti-Programmed Death Ligand-1 Durvalumab Antibody (MEDI4736) in Combination With Olaparib...

NCT02484404

CONDITIONS

[Breast Neoplasms](#) [Colorectal Neoplasms](#)

LOCATIONS

[Bethesda, Maryland...](#)

RECRUITING

Studying the Effect of Denosumab on Preventing **Breast Cancer** in Women With a BRCA1 Germline Mutation

NCT04711109

CONDITIONS

[Breast Carcinoma](#) [Breast Neoplasms](#)

[Neoplasms](#) [Breast Cancer](#)

[Show 2 more conditions](#)

LOCATIONS

[Washington, District...](#)

[Show all locations \(40\)](#)

Feedback

Search Results – Table View

Focus Your Search
(all filters optional)

Condition or disease 1

Other terms 1

Intervention/Treatment 1

Location

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

Set Radius

1 mi 500 mi

50 mile radius

Study Status 1

Looking for participants

Not yet recruiting (1)

Recruiting (42)

No longer looking for participants

≪ Hide

Search Results

Viewing 1-10 out of 43 studies

[Synonyms of conditions or disease \(42\)](#)

Selected (0)
Download
Manage Columns

	Study Title	NCT Number	Status	Conditions	Interventions
<input type="checkbox"/>	Phase I/II Study of the Anti-Programmed Death Ligand-1 Duryalumab Antibody (MED14736) in Combination With Olaparib and/or Cediranib for Advanced Solid Tumors and Advanced or Recurrent Ovarian, Triple Negative Breast, Lung, Prostate and Colorectal Can...	NCT02484404	Recruiting	<ul style="list-style-type: none"> • Colorectal Neoplasms • Breast Neoplasms 	<ul style="list-style-type: none"> • Drug: Olaparib • Drug: Cediranib • Drug: Durvalumab
1					
<input type="checkbox"/>	Studying the Effect of Denosumab on Preventing Breast Cancer in Women With a BRCA1 Germline Mutation	NCT04711109	Recruiting	<ul style="list-style-type: none"> • BRCA1 Mutation • Breast Cancer • Breast Diseases • 3 more 	<ul style="list-style-type: none"> • Drug: Denosumab • Drug: Placebo • Other: Quality-of-Life Ass
2					
<input type="checkbox"/>	Clinical Information and Biospecimen Collection From Patients With Recurrent or Stage IV Breast Cancer	NCT03737695	Recruiting	<ul style="list-style-type: none"> • Anatomic Stage IV Breast Cancer AJCC v 8 • Invasive Breast Carcinoma • Metastatic Breast Carcinoma • 2 more 	<ul style="list-style-type: none"> • Procedure: Biospecimen C • Other: Medical Chart Rev
3					
<input type="checkbox"/>	Testing the Application of Mepitel Film During Radiation Therapy to Reduce Radiation Related Redness and Peeling in Breast Cancer Patients Following Mastectomy.	NCT04989504	Recruiting	<ul style="list-style-type: none"> • Breast Carcinoma • Mastectomy Patient 	<ul style="list-style-type: none"> • Other: Best Practice • Device: Wound Dressing • Other: Quality-of-Life Ass • 1 more
4					
<input type="checkbox"/>	The PROMISE Study: Duavee in Women With DCIS	NCT02694809	Recruiting	<ul style="list-style-type: none"> • Ductal Breast Carcinoma In Situ • Postmenopausal 	<ul style="list-style-type: none"> • Drug: Conjugated Estroge • Other: Laboratory Biomar • Other: Pharmacological S • 3 more
5					

Expanded Table View

>> Show

Search Results

Viewing 1-10 out of 43 studies

[Synonyms of conditions or disease \(42\)](#)

Card View
Table View

Selected (0)
Download
Manage Columns

	Study Title	NCT Number	Status	Conditions	Interventions	Sponsor
<input type="checkbox"/>	Phase I/II Study of the Anti-Programmed Death Ligand-1 Durvalumab Antibody (MED14736) in Combination With Olaparib and/or Cediranib for Advanced Solid Tumors and Advanced or Recurrent Ovarian, Triple Negative Breast, Lung, Prostate and Colorectal Can...	NCT02484404	Recruiting	<ul style="list-style-type: none"> Colorectal Neoplasms Breast Neoplasms 	<ul style="list-style-type: none"> Drug: Olaparib Drug: Cediranib Drug: Durvalumab 	National Cancer Institute (NCI)
<input type="checkbox"/>	Studying the Effect of Denosumab on Preventing Breast Cancer in Women With a BRCA1 Germline Mutation	NCT04711109	Recruiting	<ul style="list-style-type: none"> BRCA1 Mutation Breast Cancer Breast Diseases 3 more 	<ul style="list-style-type: none"> Drug: Denosumab Drug: Placebo Other: Quality-of-Life Assessment 	Alliance for Clinical Trials in Oncology
<input type="checkbox"/>	Clinical Information and Biospecimen Collection From Patients With Recurrent or Stage IV Breast Cancer	NCT03737695	Recruiting	<ul style="list-style-type: none"> Anatomic Stage IV Breast Cancer AJCC v 8 Invasive Breast Carcinoma Metastatic Breast Carcinoma 2 more 	<ul style="list-style-type: none"> Procedure: Biospecimen Collection Other: Medical Chart Review 	Mayo Clinic
<input type="checkbox"/>	Testing the Application of Mepitel Film During Radiation Therapy to Reduce Radiation Related Redness and Peeling in Breast Cancer Patients Following Mastectomy	NCT04989504	Recruiting	<ul style="list-style-type: none"> Breast Carcinoma Mastectomy Patient 	<ul style="list-style-type: none"> Other: Best Practice Device: Wound Dressing Material Other: Quality-of-Life Assessment 1 more 	Alliance for Clinical Trials in Oncology
<input type="checkbox"/>	The PROMISE Study: Duavee in Women With DCIS	NCT02694809	Recruiting	<ul style="list-style-type: none"> Ductal Breast Carcinoma In Situ Postmenopausal 	<ul style="list-style-type: none"> Drug: Conjugated Estrogens/Bazedoxifene Other: Laboratory Biomarker Analysis Other: Pharmacological Study 3 more 	Northwestern University

Feedback

Manage Table Columns

Manage Columns

Choose the columns you want to see in the table by selecting or deselecting the box next to each column. Rearrange the column order by using the arrows.

Selected (7) [De-select all](#) **Not Selected (18)** [Select all](#)

- Study Title (locked)
- NCT Number ↓
- Status ↑ ↓
- Conditions ↑ ↓
- Interventions ↑ ↓
- Sponsor ↑ ↓
- Study Type ↑

- Collaborators
- Acronym
- Outcome Measures
- Sex
- Age
- Phase
- Enrollment
- Funder type
- Study Design
- Other IDs

Background Table:

Study Title	Sponsor
Phase I/II gramme alumab n Combi nd/or Ce olid Tum Recurr ve Breas olorecta	National Cance titude (NCI)
Studying ab on Pr r in Won mline M	Alliance for Clir Trials in Oncolc
Clinical I cimen C With Rec ast Canc	Mayo Clinic
Testing t tel Film I py to Re Redness Cancer i ectomy.	Alliance for Clir Trials in Oncolc
The PRO Women	Northwestern l ersity

Return to Expanded Table View

Show >>

Search Results

Viewing 1-10 out of 43 studies

[Synonyms of conditions or disease \(42\)](#)

☰ Card View
☰ Table View

Selected (0)
↓ Download
+ Manage Columns

	Study Title	NCT Number	Status	Conditions	Interventions	Sponsor
<input type="checkbox"/>	Phase I/II Study of the Anti-Programmed Death Ligand-1 Durvalumab Antibody (MED14736) in Combination With Olaparib and/or Cediranib for Advanced Solid Tumors and Advanced or Recurrent Ovarian, Triple Negative Breast, Lung, Prostate and Colorectal Can...	NCT02484404	Recruiting	<ul style="list-style-type: none"> Colorectal Neoplasms Breast Neoplasms 	<ul style="list-style-type: none"> Drug: Olaparib Drug: Cediranib Drug: Durvalumab 	National Cancer Institute (NCI)
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Feedback

Study Record – Key Features

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 Cancer Institute (NCI) (Responsible Party)

Last Update Posted ⓘ 2023-08-21

Study record dates +

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

On this page

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

Download | Expand all content | Collapse all content

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 combination treatments are effective in ovarian cancer....
[+ Show more](#)

Detailed Description:
Background:

STUDY START (ACTUAL) ⓘ
2015-06-29

PRIMARY COMPLETION (ESTIMATED) ⓘ
2024-01-30

STUDY COMPLETION (ESTIMATED) ⓘ
2025-12-30

ENROLLMENT (ESTIMATED) ⓘ
384

Feedback

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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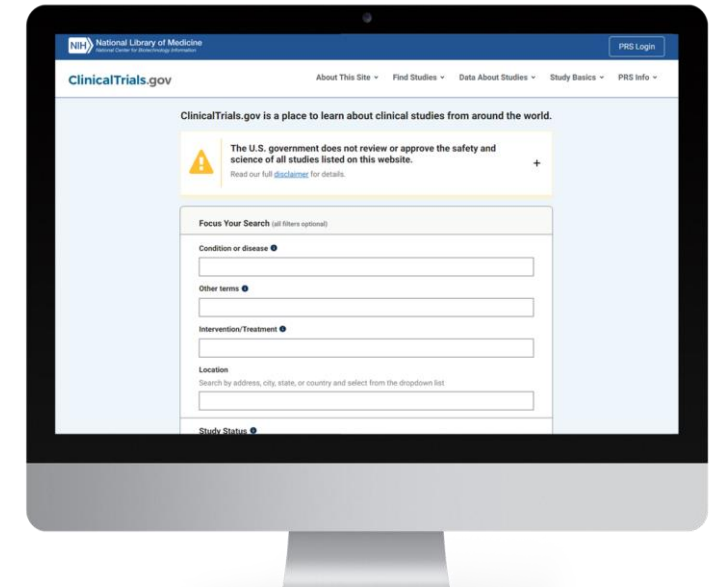
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[+ Show more](#)

Detailed Description:

Feedback

2021–24 Strategic Roadmap: Modernized ClinicalTrials.gov



2021

2022

2023

2024



Product
Development

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

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

