

# Using ClinicalTrials.gov as a Resource

February 28, 2022

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NIH/NLM/NCBI



# | Topics

- ClinicalTrials.gov Overview
- Accessing COVID-19 Studies
- Modernization Effort





# ClinicalTrials.gov Overview

# What is ClinicalTrials.gov?



## Sponsors and investigators

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



## 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. Each record includes information about the study, such as:

- Study name and description
- Disease or health problem studied
- Who can join and how many participants are needed
- What researchers learned from the study (results)



## Patients and health care professionals

- Find studies that patients may be able to join
- Learn about clinical research



## Researchers

- See if results are reported and match research plan
- Look for studies available on a specific topic
- Identify unmet research and medical needs

# ClinicalTrials.gov Homepage

## Features:

- Tabular menu content
- Links to an important disclaimer and information about the risks and benefits of study participation
- Targeted information for different types of users
- Basic and advanced search options

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore **405,781** research studies in all 50 states and in 220 countries.

See [listed clinical studies](#) related to the coronavirus disease (COVID-19)

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

**IMPORTANT:** Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

### Find a study (all fields optional)

#### Status ⓘ

- Recruiting and not yet recruiting studies  
 All studies

#### Condition or disease ⓘ (For example: breast cancer)

#### Other terms ⓘ (For example: NCT number, drug name, investigator name)

#### Country ⓘ

**Search**

[Advanced Search](#)

[Help](#) | [Studies by Topic](#) | [Studies on Map](#) | [Glossary](#)

#### Patients and Families

Search for actively recruiting studies that you may be able to participate in or learn about new interventions/treatments that are being considered.

[Learn more](#)

#### Researchers

Search the database to stay up to date on developments in your field, find collaborators, and identify unmet needs.

[Learn more](#)

#### Study Record Managers

Learn about registering studies and about submitting their results after study completion.

[Learn more](#)

# ClinicalTrials.gov Homepage

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- Basic and advanced search options

NIH U.S. National Library of Medicine  
**ClinicalTrials.gov**

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾ [PRS Login](#)

ClinicalTrials.gov is a database of privately and publicly funded clinical studies

### Find a study (all fields optional)

**Status** ⓘ

Recruiting and not yet recruiting studies  
 All studies

**Condition or disease** ⓘ (For example: breast cancer)

breast cancer X

**Other terms** ⓘ (For example: NCT number, drug name, investigator name)

Carboplatin X

**Country** ⓘ


United States ▾ X

**State** ⓘ **City** ⓘ **Distance** ⓘ

▾ X ▾ X ▾

[Search](#) [Advanced Search](#)

out submitting



# ClinicalTrials.gov Search List

## Features:

- Side bar with options to refine the search
- Ability to show/hide columns
- Tabs to access additional search characteristics

40 Studies found for: Carboplatin | Recruiting, Not yet recruiting Studies | breast cancer | United States

Also searched for Breast Neoplasms, Neoplasm, Paraplatin and more. [See Search Details](#)

Applied Filters:  Recruiting  Not yet recruiting

List **By Topic** On Map Search Details

Hide Filters Download Subscribe to RSS

Show/Hide Columns

Showing: 1-10 of 40 studies 10 studies per page

Row	Saved	Status	Study Title	Conditions	Interventions	Location
1	<input type="checkbox"/>	Recruiting	<a href="#">Comparison of Single-Agent Carboplatin vs the Combination of Carboplatin and Everolimus for the Treatment of Advanced Triple-Negative Breast Cancer</a>	<ul style="list-style-type: none"><li>Breast Cancer</li></ul>	<ul style="list-style-type: none"><li>Drug: Carboplatin</li><li>Drug: Everolimus</li></ul>	<ul style="list-style-type: none"><li>Mount Sinai New York, New York, United States</li><li>Mount Sinai West New York, New York, United States</li><li>Icahn School of Medicine at Mount Sinai New York, New York, United States</li></ul>
2	<input type="checkbox"/>	Not yet recruiting	<a href="#">SGT-53, Carboplatin, and Pembrolizumab for the Treatment of Metastatic Triple Negative Inflammatory Breast Cancer</a>	<ul style="list-style-type: none"><li>Anatomic Stage IV Breast Cancer AJCC v8</li><li>Breast Inflammatory Carcinoma</li><li>Metastatic Triple-Negative Breast Carcinoma</li><li>Prognostic Stage IV Breast Cancer AJCC v8</li></ul>	<ul style="list-style-type: none"><li>Drug: Carboplatin</li><li>Biological: Pembrolizumab</li><li>Genetic: Transferrin Receptor-Targeted Liposomal p53 cDNA</li></ul>	<ul style="list-style-type: none"><li>Northwestern University Chicago, Illinois, United States</li></ul>
3	<input type="checkbox"/>	Recruiting	<a href="#">Phase II Breast Ca Carboplatin + Paclitaxel With Pertuzumab + Trastuzumab or Bevacizumab</a>	<ul style="list-style-type: none"><li>Breast Carcinoma</li></ul>	<ul style="list-style-type: none"><li>Drug: Carboplatin</li><li>Drug: Paclitaxel</li><li>Drug: Bevacizumab</li><li>(and 2 more...)</li></ul>	<ul style="list-style-type: none"><li>UC Irvine Health/Chao Family Comprehensive Cancer Center Orange, California, United States</li></ul>
4	<input type="checkbox"/>	Recruiting	<a href="#">Pembrolizumab and Carboplatin in Treating Patients With Circulating Tumor Cells Positive Metastatic Breast Cancer</a>	<ul style="list-style-type: none"><li>Estrogen Receptor Negative</li><li>Estrogen Receptor</li></ul>	<ul style="list-style-type: none"><li>Drug: Carboplatin</li><li>Other: Laboratory Biomarker Analysis</li></ul>	<ul style="list-style-type: none"><li>Northwestern University Chicago, Illinois, United States</li></ul>

Filters

Apply Clear

Status  Not yet recruiting  Recruiting

Recruitment  Enrolling by invitation  Active, not recruiting  Suspended  Terminated  Completed  Withdrawn  Unknown status<sup>†</sup>

Expanded Access

Eligibility Criteria

Age  years OR

Age Group  Child (birth-17)  Adult (18-64)  Older Adult (65+)

Sex  All  Female  Male

# ClinicalTrials.gov Study Record Example

## Comparison of Single-Agent Carboplatin vs the Combination of Carboplatin and Everolimus for the Treatment of Advanced Triple-Negative Breast Cancer

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT02531932

Recruitment Status <sup>?</sup>: Recruiting  
First Posted <sup>?</sup>: August 25, 2015  
Last Update Posted <sup>?</sup>: October 25, 2021  
See [Contacts and Locations](#)

### Sponsor:

Amy Tiersten

### Collaborator:

Novartis

### Information provided by (Responsible Party):

Amy Tiersten, Icahn School of Medicine at Mount Sinai

Study Details

Tabular View

No Results Posted

Disclaimer

<sup>?</sup> How to Read a Study Record

## Study Description

Go to

### Brief Summary:

The purpose of this study is to evaluate the safety and effectiveness of **carboplatin** compared to the combination of **carboplatin** and everolimus for the treatment of advanced triple-negative breast cancer (TNBC).

Condition or disease <sup>?</sup>	Intervention/treatment <sup>?</sup>	Phase <sup>?</sup>
Breast Cancer	Drug: Carboplatin Drug: Everolimus	Phase 2

## Study Design

Go to

Study Type <sup>?</sup>: Interventional (Clinical Trial)

Estimated Enrollment <sup>?</sup>: 72 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: None (Open Label)

Primary Purpose: Treatment



# Submission of Studies for Posting to ClinicalTrials.gov

*QC review is not equivalent to peer review:*

*Submissions are not verified against external sources (e.g., the full study protocol)*

## Sponsors and Investigators:

- Submit study information to ClinicalTrials.gov via the Protocol Registration and Results System (PRS)



## ClinicalTrials.gov review staff:

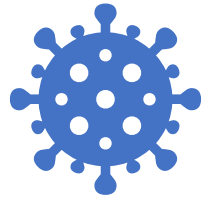
- Perform quality control (QC) review to identify apparent errors, deficiencies, and inconsistencies
- Process registration information within 5 business days
- Perform reviews of applicable clinical trials within 30 days



## Benefits of Comprehensive Registration and Results Reporting

*All contribute to  
increased public  
trust in clinical  
research*

- Honor commitment to participants that their contributions will advance science; support enrollment
- Mitigate publication bias
- Advance stewardship and accountability
  - Identify unmet research needs
  - Facilitate complete reporting
  - Avoid unnecessary study duplication
  - Evaluate research integrity
- Support evidence-based medicine



# Accessing COVID-19 Studies

# NIH Director's Statement (10 November 2020)

– Francis S. Collins, M.D., Ph.D., Former Director, National Institutes of Health

## NIH calls on clinical researchers to swiftly share COVID-19 results



NIH is taking an all-hands-on-deck approach to speeding life-saving research for vaccines, treatments, and diagnostic tests to end the COVID-19 pandemic. Through the establishment of major public-private initiatives such as the [Accelerating COVID-19 Therapeutic Interventions and Vaccines \(ACTIV\)](#) and the [Rapid Acceleration of Diagnostics \(RADx\)](#) initiatives, NIH and its partners have launched dozens of COVID-19 vaccine and treatment clinical trials and funded dozens of new and innovative testing technologies at an unprecedented rate.

To maintain this record pace, it will be crucial for clinical researchers involved in COVID-19 and SARS-CoV-2 clinical trials to share their results as swiftly as possible. Toward this end, I strongly encourage the clinical research community to register their clinical trials and submit summary results information for COVID-19 and SARS-CoV-2 trials as quickly as possible and ahead of regulatory and policy deadline requirements to [ClinicalTrials.gov](#), the publicly accessible database operated by NIH's National Library of Medicine.

To ensure such information is accessible as quickly as possible, NIH is prioritizing the processing of COVID-19 submissions to [ClinicalTrials.gov](#) to make the information rapidly available in a matter of days, not weeks. We are also providing one-on-one support to researchers during the process of submitting results information to [ClinicalTrials.gov](#) to address questions and optimize reporting.

NIH has taken several additional actions to speed access and discoverability for researchers, clinicians, and the public of critical information from COVID-19 and SARS-CoV-2 research, including:

1. Supporting the infrastructure for timely dissemination of COVID-19 clinical trial data.
2. Making it easier to find information about COVID-19-related studies on [ClinicalTrials.gov](#), including information about studies listed on the World Health Organization's International Clinical Trial Registry Platform. These efforts have made information about more than 6,400 COVID-19 related clinical studies readily available to those who need it.

# COVID-19: Links to Resources, Search Filters

**COVID-19 Information**

[Public health information \(CDC\)](#) | [Research information \(NIH\)](#) | [SARS-CoV-2 data \(NCBI\)](#) | [Prevention and treatment information \(HHS\)](#) | [Español](#)

Try the modernized [ClinicalTrials.gov beta website](#). Learn more about the [modernization effort](#).

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 405,464 research studies in all 50 states and in 220 countries.

See [listed clinical studies related to the coronavirus disease \(COVID-19\)](#)

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine. **IMPORTANT:** Listing a study on this site does not mean it has been evaluated by the U.S. Department of Health and Human Services. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

Find a study (all fields optional)

**Status**

Recruiting and not yet recruiting studies

All studies

**Condition or disease** (For example: breast cancer)

**Other terms** (For example: NCT number, drug name, investigator name)

**Country**

[Advanced Search](#)

Home > Search Results

[Modify Search](#) [Start Over](#)

7589 Studies found for: **COVID-19**

Also searched for **COVID** and **SARS-CoV-2**. [See Search Details](#)

Your search included: **COVID-19**

Learn more about clinical studies related to COVID-19:



- **ClinicalTrials.gov:** [Federally-funded clinical studies related to COVID-19](#)
- **WHO Trial Registry Network:** [COVID-19 studies from the ICTRP database](#)
- **NIH:** [COVID-19 Treatment Guidelines](#)
- **ClinicalTrials.gov:** [Views of Listed COVID-19 Studies \(Beta\)](#)

[List](#) [By Topic](#) [On Map](#) [Search Details](#)

[Hide Filters](#)

[Download](#) [Subscribe to RSS](#)

Filters

Showing: 1-100 of 7,589 studies  studies per page

[Show/Hide Columns](#)

Row	Saved	Status	Study Title	Conditions	Interventions	Sponsor/Collaborators	Funder Type
1	<input type="checkbox"/>	Active, not recruiting	<a href="#">Duvelisib to Combat COVID-19</a>	• COVID-19	• Drug: Duvelisib • Procedure: Peripheral blood draw • Drug: Placebo	• Washington University School of Medicine • Verastem, Inc.	Other / Industry
<b>Study Design:</b>				• Allocation: Randomized • Intervention Model: Single Group Assignment • Masking: Triple (Participant, Care Provider, Investigator) • Primary Purpose: Treatment			
<b>NCT Number:</b>				NCT04372602			
<b>Locations:</b>				• Washington University School of Medicine Saint Louis, Missouri, United States			

# COVID-19: Links to Resources, Search Filters



U.S. National Library of Medicine  
**ClinicalTrials.gov**

Home > WHO COVID-19 Studies

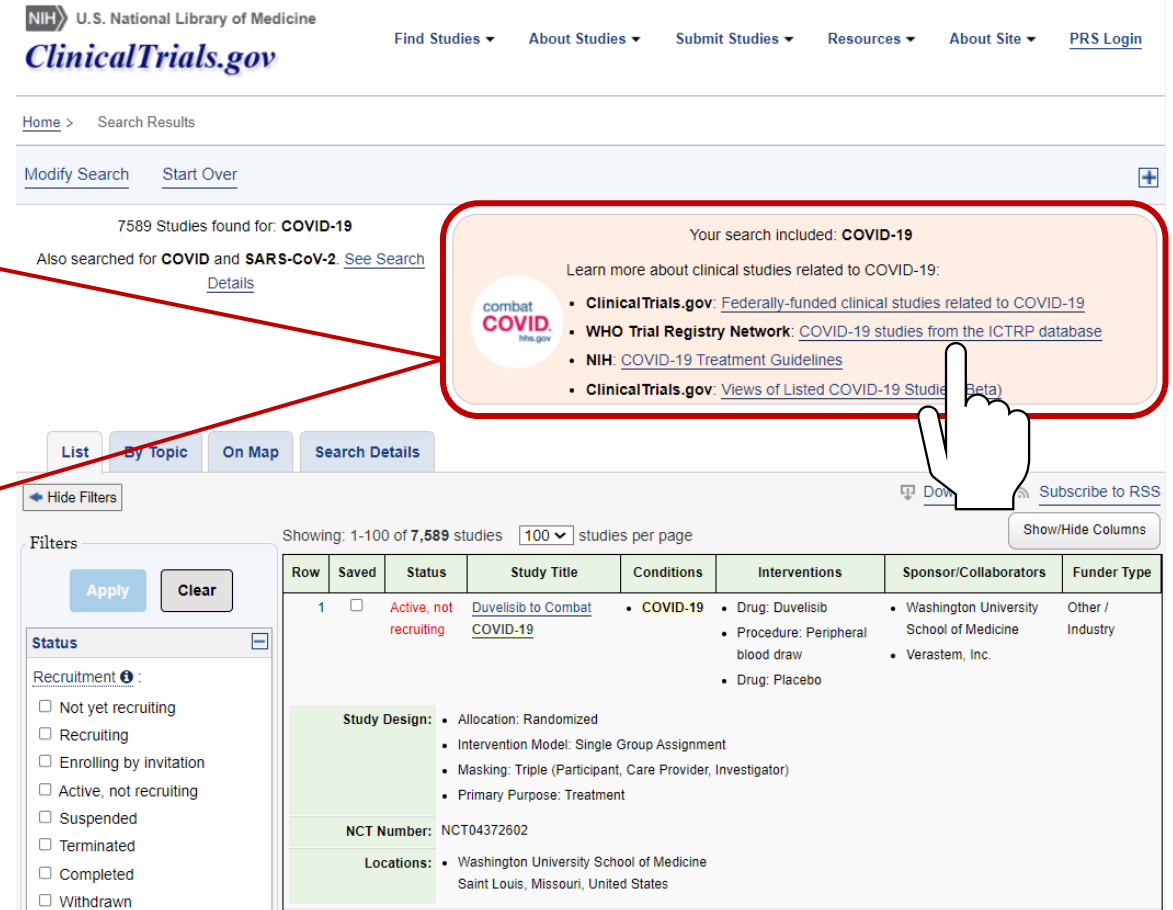
### COVID-19 Studies from the World Health Organization Database

The following are ongoing and completed COVID-19 studies listed on the World Health Organization's International Clinical Trials Registry Platform (WHO ICTRP). Information in the WHO ICTRP comes from clinical trial databases maintained by other countries or regions of the world. COVID-19 studies listed on ClinicalTrials.gov are not included in the list below, but can be found using our [search for COVID-19](#).

To give researchers and the public rapid access to studies on COVID-19 in other countries, ClinicalTrials.gov will update this list weekly. You can also access the information directly from the [WHO ICTRP](#).

Showing: 1-10 of 5,988 studies | 10 studies per page

TrialID	Public title	Date registration	Source Register	web address	Recruitment Status
PER-002-21	A Multicenter, Adaptive, Randomized, Double-blinded, Placebo-controlled Phase III/III Trial to Evaluate the Efficacy and Safety of Monoclonal Antibody SCTA01 against SARS-CoV-2 in Hospitalized Patients with Severe COVID-19		REPEC	<a href="https://repec.ins.gob.pe/maestro/ajax/exportar-ficha-datos-publico/5/en/">https://repec.ins.gob.pe/maestro/ajax/exportar-ficha-datos-publico/5/en/</a>	
PER-008-21	A Phase III Randomized, Double-blind, Placebo-controlled, Multicenter Study to Determine the Safety and Efficacy of AZD7442 for the Treatment of COVID-19 in Non-hospitalized Adults		REPEC	<a href="https://repec.ins.gob.pe/maestro/ajax/exportar-ficha-datos-publico/1945/en/">https://repec.ins.gob.pe/maestro/ajax/exportar-ficha-datos-publico/1945/en/</a>	



U.S. National Library of Medicine  
**ClinicalTrials.gov**

Home > Search Results

7589 Studies found for: **COVID-19**

Also searched for **COVID** and **SARS-CoV-2**. [See Search Details](#)

Your search included: **COVID-19**

Learn more about clinical studies related to COVID-19:

- ClinicalTrials.gov**: Federally-funded clinical studies related to COVID-19
- WHO Trial Registry Network**: COVID-19 studies from the ICTRP database
- NIH**: COVID-19 Treatment Guidelines
- ClinicalTrials.gov**: Views of Listed COVID-19 Studies (Beta)

Showing: 1-100 of 7,589 studies | 100 studies per page

Row	Saved	Status	Study Title	Conditions	Interventions	Sponsor/Collaborators	Funder Type
1	<input type="checkbox"/>	Active, not recruiting	<a href="#">Duvellisib to Combat COVID-19</a>	• COVID-19	• Drug: Duvellisib • Procedure: Peripheral blood draw • Drug: Placebo	• Washington University School of Medicine • Verastem, Inc.	Other / Industry

**Filters**

**Status**

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Suspended
- Terminated
- Completed
- Withdrawn

**Recruitment** ⓘ :

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Suspended
- Terminated
- Completed
- Withdrawn

**Study Design** :

- Allocation: Randomized
- Intervention Model: Single Group Assignment
- Masking: Triple (Participant, Care Provider, Investigator)
- Primary Purpose: Treatment

**NCT Number**: NCT04372602

**Locations** :

- Washington University School of Medicine  
Saint Louis, Missouri, United States

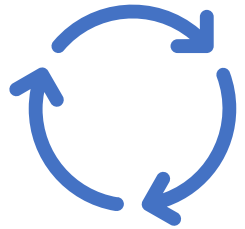
## Additional links:

- Filter search results for federally-funded COVID-19 studies
- Provide NIH COVID-19 Treatment Guidelines
- Categorize COVID-19 studies by location, funder, vaccine/drug, etc. (“Views of Listed COVID-19 Studies (Beta)”)

# ClinicalTrials.gov and COVID-19 Information

ClinicalTrials.gov serves as a centralized resource for COVID-19 clinical research:

- There are over **7,550 COVID-19–related study records** on ClinicalTrials.gov as of February 2022
  - And nearly **6,000 COVID-19–related studies** from World Health Organization portal
- **Registration** information is processed within 2 business days
- **Results** reviews are expedited and performed within 7 days of submission
- “Responses to Top Questions from Responsible Parties Related to Coronavirus (COVID-19)” was last updated May 2021 and is provided on the Support Materials page (Submit Studies tab)
  - See: <https://prsinfo.clinicaltrials.gov/TopQuestionsFromResponsibleParties-Covid19.pdf>



# Modernization Effort



# Vision for Modernization

ClinicalTrials.gov serves as an essential, integral, and trusted part of the research ecosystem to advance medical knowledge.

1

**Clinical trial information is current, complete, and reliable.**



2

**Anyone can easily find and use information about clinical trials.**



3

**Trial information, resources, and tools provide value to the research ecosystem.**



# Who do we impact?

## EXTERNAL STAKEHOLDERS



Patients and Their Advocates



Data Submitters



Data Researchers

## INTERNAL STAKEHOLDERS



Policy and Oversight Teams



Information Specialists,  
Reviewers, and Developers

# Accessing the Modernized Public Site

**COVID-19 Information**  
[Public health information \(CDC\)](#) | [Research information \(NIH\)](#) | [SARS-CoV-2 data \(NCBI\)](#) | [Prevention and treatment information \(HHS\)](#) | [Español](#)

Try the modernized [ClinicalTrials.gov beta](#) website. Learn more about the [modernization effort](#).

NIH U.S. National Library of Medicine  
**ClinicalTrials.gov**

Home | About Studies | Submit Studies | Resources | About Site | PRS Login

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Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

**Find a study** (all fields optional)

**Status** ⓘ  
 Recruiting and not yet recruiting studies  
 All studies

**Condition or disease** ⓘ (For example: breast cancer)  
 X

**Other terms** ⓘ (For example: NCT number, drug name, investigator name)  
 X

**Country** ⓘ  
 X

**Search** [Advanced Search](#)

[Help](#) | [Studies by Topic](#) | [Studies on Map](#) | [Glossary](#)

# Modernized Public Site

The screenshot displays the ClinicalTrials.gov website. At the top left is the NIH logo with the text "National Library of Medicine" and "National Center for Biotechnology Information". To the right is a "PRS Login" button. Below this is the "ClinicalTrials.gov" logo with a "BETA" badge, and navigation links for "Resources" and "About". The main banner features the text "ClinicalTrials.gov is a place to learn about clinical studies from around the world." and an "About ClinicalTrials.gov" button. An illustration of a smartphone with a bar chart, a magnifying glass, and a stethoscope is positioned on the right. Below the banner are thumbs up and thumbs down icons. The section "I want to search for clinical studies" includes a paragraph explaining the search process. Below this are three radio buttons: "All studies" (selected), "Looking for participants", and "Studies with results". There are three input fields: "Keywords (Optional)", "Location (Optional)", and "Distance (Optional)" with a dropdown menu showing "- Select -". A "Search" button is located to the right of the input fields. At the bottom right, there are two buttons: "Give feedback" (green) and "Classic website" (red).

# Modernized Search List

## Classic Site

40 Studies found for: Carboplatin | Recruiting, Not yet recruiting Studies | breast cancer | United States  
 Also searched for Breast Neoplasms, Neoplasm, Paraplatin and more. [See Search Details](#)

Applied Filters:  Recruiting  Not yet recruiting

List By Topic On Map Search Details

Hide Filters Download Subscribe to RSS

Showing: 1-10 of 40 studies 10 studies per page Show/Hide Columns

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	<input type="checkbox"/>	Recruiting	<a href="#">Comparison of Single-Agent Carboplatin vs the Combination of Carboplatin and Everolimus for the Treatment of Advanced Triple-Negative Breast Cancer</a>	• Breast Cancer	• Drug: Carboplatin • Drug: Everolimus	• Mount Sinai Downtown New York, New York, United States • Mount Sinai West New York, New York, United States • Icahn School of Medicine at Mount Sinai New York, New York, United States
2	<input type="checkbox"/>	Not yet recruiting	<a href="#">SGT-53, Carboplatin, and Pembrolizumab for the Treatment of Metastatic Triple Negative Inflammatory Breast Cancer</a>	• Anatomic Stage IV Breast Cancer AJCC v8 • Breast Inflammatory Carcinoma • Metastatic Triple-Negative Breast Carcinoma • Prognostic Stage IV Breast Cancer AJCC v8	• Drug: Carboplatin • Biological: Pembrolizumab • Genetic: Transferrin Receptor-Targeted Liposomal p53 cDNA	• Northwestern University Chicago, Illinois, United States
3	<input type="checkbox"/>	Recruiting	<a href="#">Phase II Breast Ca Carboplatin + Paclitaxel With Pertuzumab + Trastuzumab or Bevacizumab</a>	• Breast Carcinoma	• Drug: Carboplatin • Drug: Paclitaxel • Drug: Bevacizumab • (and 2 more...)	• UC Irvine Health/Chao Family Comprehensive Cancer Center Orange, California, United States
4	<input type="checkbox"/>	Recruiting	<a href="#">Pembrolizumab and Carboplatin in Treating Patients With Circulating Tumor Cells</a>	• Estrogen Receptor Negative	• Drug: Carboplatin • Other: Laboratory	• Northwestern University Chicago, Illinois, United States

Filters

Apply Clear

Status

Recruitment:

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Suspended
- Terminated
- Completed
- Withdrawn
- Unknown status†

Expanded Access: +

Eligibility Criteria

Age:  years OR

Age Group:

- Child (birth–17)
- Adult (18–64)
- Older Adult (65+)

Sex:

- All
- Female

## Modernized Site

### Narrow your search

[Clear all filters](#)

#### Study Status

Looking for participants

- Not yet recruiting (0)
- Recruiting (6)

No longer looking for participants

- Active, not recruiting (12)
- Completed (6)
- Terminated (1)

Other

- Enrolling by invitation (0)
- Suspended (1)
- Withdrawn (0)
- Unknown (0)

Expanded Access: ▾

#### Eligibility Criteria

### Search Results for:

Breast Cancer AND Carboplatin (includes synonymous conditions like Neoplasms, Oncology, and [28 related terms](#))

Viewing 1-6 out of 6 studies 10 studies per page [Download](#)

RECRUITING

**Doxorubicin Hydrochloride and Cyclophosphamide Followed by Paclitaxel With or Without Carboplatin in Treating Patients Wit...**

CONDITIONS

[Breast Adenocarcinoma](#) [Estrogen Receptor Negative](#)

[HER2/Neu Negative](#) [Progesterone Receptor Negative](#)

[Show 6 more conditions](#)

LOCATIONS

[Independence, Kansas, United ...](#) [Parsons, Kansas, United States](#)

[Chanute, Kansas, United States](#)

[Show all locations \(1,295\)](#)

RECRUITING

**Platinum Based Chemotherapy or Capecitabine in Treating Patients With Residual Triple-Negative Basal-Like Breast Cancer Follow...**

CONDITIONS

[Give feedback](#)

[Classic website](#)

# Modernized Study Record

## Classic Site

Study Details Tabular View No Results Posted Disclaimer ? How to Read a Study Record

### Study Description

Go to [dropdown]

Brief Summary:  
This randomized phase III trial studies how well doxorubicin hydrochloride and cyclophosphamide followed by paclitaxel with or without **carboplatin** work in treating patients with triple-negative breast cancer. Drugs used in chemotherapy, such as doxorubicin hydrochloride, cyclophosphamide, paclitaxel, and **carboplatin**, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. It is not yet known whether doxorubicin hydrochloride and cyclophosphamide is more effective when followed by paclitaxel alone or paclitaxel and **carboplatin** in treating triple-negative breast cancer.

Condition or disease	Intervention/treatment	Phase
Breast Adenocarcinoma	Drug: <b>Carboplatin</b>	Phase 3
Estrogen Receptor Negative	Drug: Cyclophosphamide	
HER2/Neu Negative	Drug: Doxorubicin Hydrochloride	
Progesterone Receptor Negative	Other: Laboratory Biomarker Analysis	
Stage IB Breast Cancer	Drug: Paclitaxel	
Stage IIA Breast Cancer		
Stage IIB Breast Cancer		
Stage IIIA Breast Cancer		
Stage IIIC Breast Cancer		
Triple-Negative Breast Carcinoma		

► Show detailed description

### Study Design

Go to [dropdown]

## Modernized Site

Study Results

### Study Overview

**Brief Summary:**  
This randomized phase III trial studies how well doxorubicin hydrochloride and cyclophosphamide followed by paclitaxel with or without **carboplatin** work in treating patients with triple-negative breast cancer. Drugs used in chemotherapy, such as doxorubicin  
[Show more](#)

**Detailed Description:**  
PRIMARY OBJECTIVES:  
I. To determine whether the addition of carboplatin to an adjuvant chemotherapy regimen of doxorubicin (doxorubicin hydrochloride)/cyclophosphamide followed by paclitaxel will improve  
[Show more](#)

OFFICIAL TITLE  
A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cy... [Show more](#)

CONDITIONS	TYPE OF STUDY	ENROLLMENT (ANTICIPATED)
<b>Breast Adenocarcinoma</b> Estrogen Receptor Negative HER2/Neu Negative Progesterone Receptor Negative <a href="#">Show 6 more conditions</a>	Interventional	782

INTERVENTION / TREATMENT	PHASE	OTHER STUDY
Drug: <b>Carboplatin</b>	Phase 3	NRG-BR00
Drug: Cyclophosphamide		NCI-2015-0

[Return to Top](#)

[Give feedback](#)

[Classic website](#)

# Stay Up to Date with Hot Off the PRS!

- Email bulletin
- Provides timely updates for PRS users on new information about the PRS and ClinicalTrials.gov
- Sign up here:  
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## Regulations + Policies

### **New and Updated FAQs Clarify the Deadline for Submitting Good Cause Extension Requests for Delayed Submission of Results Information**

The Frequently Asked Questions (FAQs) page has new and updated content under the [Results Information and Submission Deadlines section](#):

- New FAQ: [What is the deadline for submitting a good cause extension request for delayed submission of results information?](#)
- Updates related to FAQs clarify that responsible parties may only submit good cause extension requests for delayed submission of results information prior to the date (i.e., the day before) that results information would otherwise be due.

Thank you!



# Major Milestones Related to ClinicalTrials.gov

