Using ClinicalTrials.gov as a Resource

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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

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 Homepage

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- Targeted information for different types of users
- Basic and advanced search options
ClinicalTrials.gov Search List

Features:

- Side bar with options to refine the search
- Ability to show/hide columns
- Tabs to access additional search characteristics
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. Learn the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

Sponsor:
Amy Tiersten

Collaborator:
Novartis

Information provided by (Responsible Party):
Amy Tiersten, Icahn School of Medicine at Mount Sinai

No results posted.

Study Description

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).

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Intervention/treatment</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Cancer</td>
<td>Drug: Carboplatin</td>
<td>Phase 2</td>
</tr>
<tr>
<td></td>
<td>Drug: Everolimus</td>
<td></td>
</tr>
</tbody>
</table>

Study Design

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Intervention (Clinical Trial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated Enrollment</td>
<td>72 participants</td>
</tr>
<tr>
<td>Allocation</td>
<td>Randomized</td>
</tr>
<tr>
<td>Intervention Model</td>
<td>Parallel Assignment</td>
</tr>
<tr>
<td>Masking</td>
<td>None (Open Label)</td>
</tr>
<tr>
<td>Primary Purpose</td>
<td>Treatment</td>
</tr>
</tbody>
</table>
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

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.

Federally-funded clinical studies related to COVID-19 can be searched for through ClinicalTrials.gov.

Search filters include:
- Condition or disease (e.g., COVID-19)
- Status (Active, not recruiting)
- Location (e.g., United States)

Find studies related to COVID-19 by using the search filters on ClinicalTrials.gov.
COVID-19: Links to Resources, Search Filters

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](https://prsinfo.clinicaltrials.gov/TopQuestionsFromResponsibleParties-Covid19.pdf)
Modernization Effort
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

Try the modernized ClinicalTrials.gov beta website. Learn more about the modernization effort.
Modernized Public Site

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

I want to search for clinical studies

ClinicalTrials.gov hosts a large collection of clinical studies from around the world. You can search for studies using keywords such as a condition or disease, drug, or medical device. To help focus your search, you can use more than one keyword.

- All studies
- Looking for participants
- Studies with results

Keywords (Optional)

Location (Optional)

Distance (Optional)

Search

ClinicalTrials.gov
Modernized Search List

Classic Site

Modernized Site
Modernized Study Record

Classic Site

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.

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<tr>
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</tr>
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<tbody>
<tr>
<td>Breast Adenocarcinoma</td>
<td>Drug: Carboplatin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug: Cyclophosphamide</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug: Doxorubicin Hydrochloride</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other: Laboratory Biomarker Analysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug: Paclitaxel</td>
<td></td>
</tr>
</tbody>
</table>

Modernized Site

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

Having trouble viewing this email? View it as a Web page.

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

- The U.S. passed a law (FDA Modernization Act of 1997) to create ClinicalTrials.gov (1997)
- Medical journal editors required sponsors and investigators to make clinical trials available on public databases (2005)
- U.S. law (FDA Amendments Act of 2007) required more types of trials and more information about trials on ClinicalTrials.gov (2007)
- The revised Common Rule (45 CFR 46) required public posting of an informed consent form for government-funded studies (2018)

- ClinicalTrials.gov launched for the public (2000)
- The World Health Organization (WHO) created a policy for reporting of clinical trial information (2006)
- The ClinicalTrials.gov results database launched for the public (2008)
- The U.S. Department of Health and Human Services (HHS) Final Rule went into effect - AND - NIH policy required NIH-funded clinical trials to be listed on ClinicalTrials.gov (2017)