



## About *ClinicalTrials.gov*

- Clinical Trials = research studies in which new treatments are tested in patients to see if they are safe and effective.
- Provides easy access to information on clinical trials for a wide range of serious or life-threatening diseases and conditions.
- Language used in the text is intended to be suitable for the general public.
- Developed by the U.S. National Institutes of Health (NIH), through its National Library of Medicine (NLM), in collaboration with NIH Institutes and the Food and Drug Administration (FDA).
- Contains clinical studies sponsored by NIH, other Federal agencies and the pharmaceutical industry.
- Available at [clinicaltrials.gov](http://clinicaltrials.gov); alternatively, from NLM's home page ([www.nlm.nih.gov](http://www.nlm.nih.gov)), click on Health Information and then click on the link to *ClinicalTrials.gov* from that page.



## Menu bar

- Appears directly below the logo on all pages.
- Facilitates navigation.
- Click on **Home** to return to the home page of *ClinicalTrials.gov*.
- **Search** returns to a cleared out search query box.
- Use **Browse** to reach the Browse option page (discussed later in this workbook).
- Use **Resources** to learn more about clinical trials. This page also provides links to other consumer health-oriented resources.
- Click on **Help** to get detailed search information.
- Click on **What's New** to see a variety of information: the FDA guidance document, Frequently Asked Questions, linking information, and other timely information.
- Click on **About** to read an overview of *ClinicalTrials.gov*.

## The Footnote

[U.S. National Library of Medicine](#), [Contact NLM Customer Service](#)  
[National Institutes of Health](#), [Department of Health & Human Services](#)  
[Copyright and Privacy Policy](#), [Freedom of Information Act](#), [Accessibility](#)

- Click on **National Library of Medicine** to reach NLM's home page.
- Click **Contact NLM Customer Service** to send a customer service inquiry.
- Click **National Institutes of Health (NIH)** to reach NIH's home page.
- Click **Department of Health & Human Services (DHHS)** to reach its home page.
- Click **Freedom of Information Act (FOIA)** to reach the NIH FOIA Office home page.
- Click on **Copyright and Privacy Policy** to NLM's copyright and privacy policy page.

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## Finding Clinical Trials in *ClinicalTrials.gov*

There are three ways to look for clinical trial records:

- Use **Basic Search** to find information broadly.
- Use **Focused Search** to find studies meeting specific criteria.
- Use **Browse** to find studies sorted by condition or by sponsor.

*Basic Search*

### Search Clinical Trials

Enter words or phrases, separated by commas:

 [Tips](#)

### Search by Specific Information

[Focused Search](#) - search by disease, location, treatment, sponsor...

### Browse

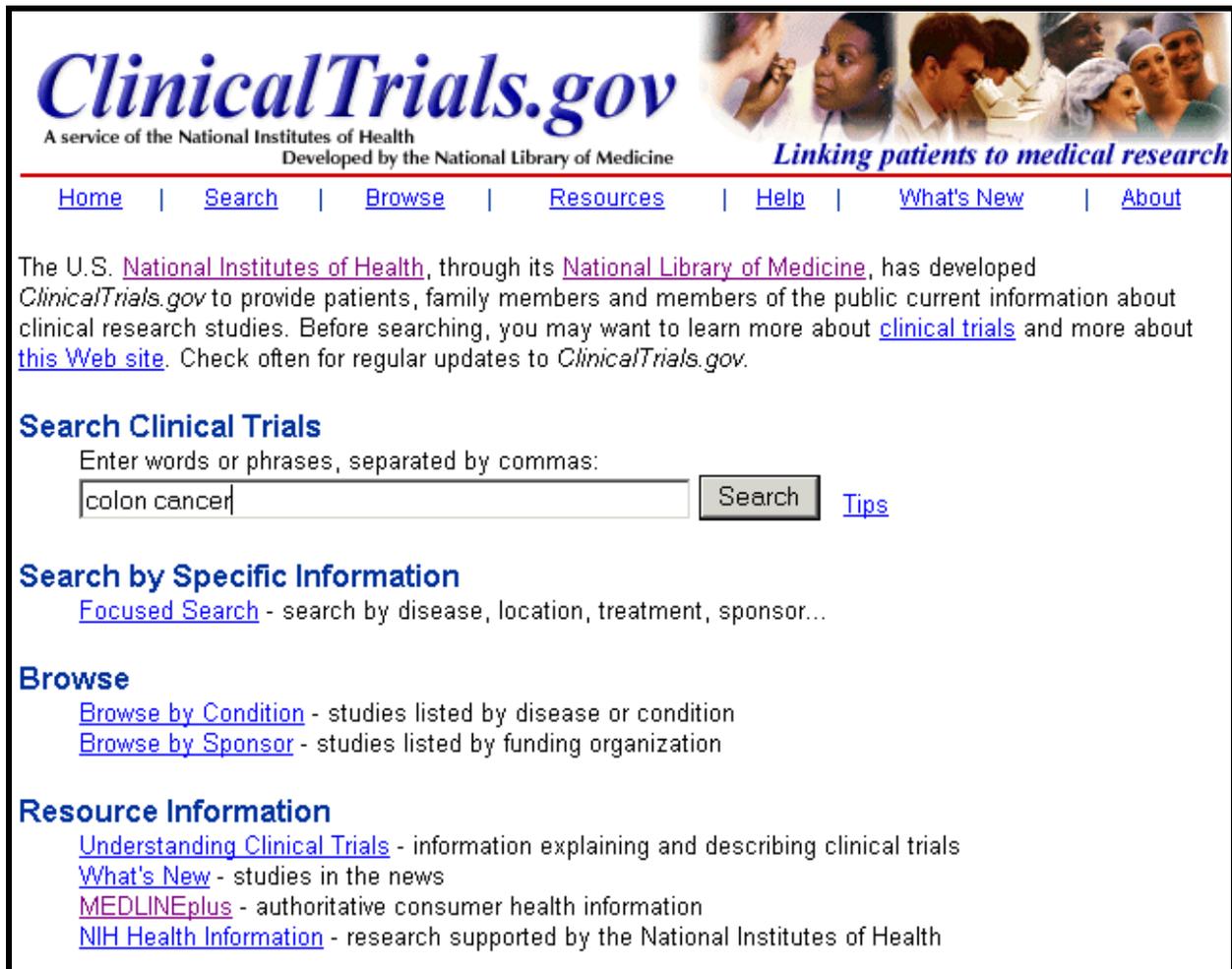
[Browse by Condition](#) - studies listed by disease or condition  
[Browse by Sponsor](#) - studies listed by funding organization

*Focused Search*

*Browse*

## Basic Search screen:

- Type your search term(s) in to the query box.



**ClinicalTrials.gov**  
A service of the National Institutes of Health  
Developed by the National Library of Medicine

*Linking patients to medical research*

[Home](#) | [Search](#) | [Browse](#) | [Resources](#) | [Help](#) | [What's New](#) | [About](#)

The U.S. [National Institutes of Health](#), through its [National Library of Medicine](#), has developed *ClinicalTrials.gov* to provide patients, family members and members of the public current information about clinical research studies. Before searching, you may want to learn more about [clinical trials](#) and more about [this Web site](#). Check often for regular updates to *ClinicalTrials.gov*.

### Search Clinical Trials

Enter words or phrases, separated by commas:

[Tips](#)

### Search by Specific Information

[Focused Search](#) - search by disease, location, treatment, sponsor...

### Browse

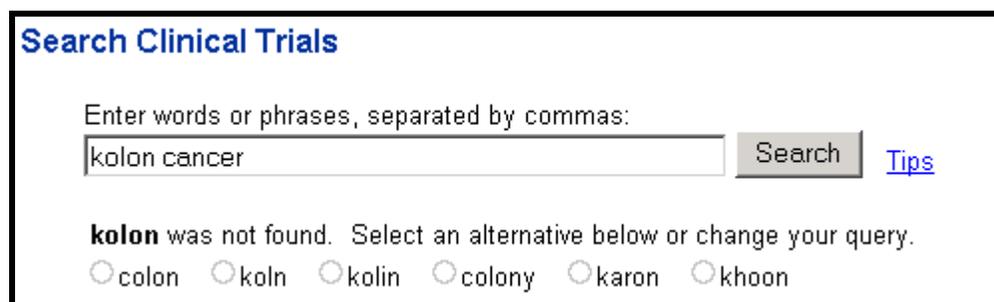
[Browse by Condition](#) - studies listed by disease or condition  
[Browse by Sponsor](#) - studies listed by funding organization

### Resource Information

[Understanding Clinical Trials](#) - information explaining and describing clinical trials  
[What's New](#) - studies in the news  
[MEDLINEplus](#) - authoritative consumer health information  
[NIH Health Information](#) - research supported by the National Institutes of Health

## Spell Check

- Some misspelled words can be recognized, and suggestions provided:



**Search Clinical Trials**

Enter words or phrases, separated by commas:

[Tips](#)

**kolon** was not found. Select an alternative below or change your query.

colon  koln  kolin  colony  karon  khoon

## Working with Results

- You can see how your search was handled by clicking on the **Query Details** button.

**ClinicalTrials.gov** *Linking patients to medical research*  
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[Home](#) | [Search](#) | [Browse](#) | [Resources](#) | [Help](#) | [What's New](#) | [About](#)

Search results for *colon cancer [ALL-FIELDS]* are shown below.

Show all trials, including those no longer recruiting patients.

[Search-Within-Results](#) [Query Details](#)

Click here.

You are then taken to the Query Details screen:

**Query Details**

**Modify Your Search**

Search  [Tips](#)

**Possibly Relevant MEDLINEplus Topics**

- [Cancer \(General\)](#)
- [Cancer-Living with Cancer](#)
- [Colorectal Cancer](#)

Individual Terms	Count
"colon cancer" Also searched: cancer, colon cancer of the colon cancer of cola malignant colonic tumor malignant tumor of cola malignant neoplasm of cola	111
"cancer" Also searched: neoplasms tumor malignant malignancies new growth neoplastic growth	2770
"colon" Also searched: kola	131

## Results (cont'd)

- The results of your search will be displayed in a brief list format in a ranked order based on your search criteria.
- The current status of the trial (e.g., recruiting), title, and conditions being studied (e.g., rheumatoid arthritis; diabetes; breast cancer) are shown for each clinical trial.
- The display default is for “recruiting” and “not yet recruiting” trials. To see *all* trials (including trials no longer recruiting), click on the box next to “Show all trials...”
- If you want to see the details of a trial use the title link.
- If you want to see the details of multiple trials, you can select the ones you like (checkbox) and then use the Display Selected Studies button.

Search results for *colon cancer* [ALL-FIELDS] are shown below.

Show all trials, including those no longer recruiting patients. Search-Within-Results Query Details

110 studies were found. Here are studies 1 to 50. Next 50

- Recruiting** [Immunotherapy After Surgery in Treating Patients With Breast Cancer, Colon Cancer, or Melanoma](#)  
Conditions: stage II melanoma; recurrent colon cancer; stage II breast cancer; stage I colon cancer; recurrent melanoma; stage III colon cancer; stage I melanoma; ...
- Recruiting** [Laparoscopic-Assisted Surgery Compared With Open Surgery in Treating Patients With Colon Cancer](#)  
Conditions: stage III colon cancer; stage I colon cancer; adenocarcinoma of the colon; stage II colon cancer
- Recruiting** [Combination Chemotherapy in Treating Patients With Colon Cancer](#)  
Conditions: stage III colon cancer; stage II colon cancer; adenocarcinoma of the colon
- Recruiting** [Genetic Study in Patients With Stage II or Stage III Colon Cancer](#)  
Conditions: stage III colon cancer; stage II colon cancer; adenocarcinoma of the colon
- Recruiting** [Combination Chemotherapy With or Without Irinotecan in Treating Patients With Stage III Colon Cancer](#)  
Conditions: stage III colon cancer; adenocarcinoma of the colon
- Recruiting** [Genetic Trial to Study Diarrhea in Patients With Stage III Colon Cancer Who Are Receiving Chemotherapy](#)  
Conditions: stage III colon cancer; diarrhea; neutropenia; adenocarcinoma of the colon
- Not yet recruiting** [Monoclonal Antibody Therapy in Treating Patients With Lymphoma, Colon Cancer, or Prostate Cancer That Has Not Responded to Vaccine Therapy](#)  
Conditions: recurrent colon cancer; recurrent grade III follicular large cell lymphoma; recurrent mantle cell lymphoma; ...
- Recruiting** [Curcumin for the Prevention of Colon Cancer](#)  
Conditions: prevention of colorectal cancer; colon cancer

- Recruiting** [Vaccine Therapy in Treating Patients With Colorectal Cancer Metastatic to the Liver](#)  
Conditions: recurrent colon cancer; liver metastases; stage IV rectal cancer; recurrent rectal cancer; stage IV colon cancer
- Recruiting** [Erlotinib and Combination Chemotherapy in Treating Patients With Metastatic Colorectal Cancer](#)  
Conditions: recurrent colon cancer; stage IV rectal cancer; recurrent rectal cancer; stage IV colon cancer

Display Selected Studies

Next 50

## Trial Details

The trial details include:

- Brief Title
- Name of Sponsoring institute
- Purpose
- Name of Disease or Condition
- Name of the Treatment or Intervention
- Phase
- Links to MEDLINE*plus* topics
- Study Type and Design
- Official Title
- Detailed Description
- Eligibility information
- Dates of the study
- Location and Contact Information
- More Information supplied by sponsoring organization
- References

**Curcumin for the Prevention of Colon Cancer**

**This study is currently recruiting patients.**

Sponsored by

[National Cancer Institute \(NCI\)](#)  
University of Michigan Comprehensive Cancer Center

**Purpose**

RATIONALE: Chemoprevention therapy is the use of certain drugs to try to prevent the development of cancer. Curcumin may be effective in preventing the development of colon cancer.

PURPOSE: Phase I trial to determine the dose amount of curcumin that can be tolerated to help in preventing colon cancer in healthy men and women.

Condition	Treatment or Intervention	Phase
prevention of colorectal cancer colon cancer	Drug: chemoprevention of cancer Procedure: cancer prevention intervention Drug: curcumin	<a href="#">Phase I</a>

MEDLINE*plus* related topics: [Colorectal Cancer](#)

Study Type: Prevention

Official Title: Phase I Study of Curcumin for the Chemoprevention of Colon Cancer

Record continues on the next page.

**Further Study Details:**

**OBJECTIVES:** I. Determine the maximum tolerated dose (MTD) of curcumin as a chemopreventive agent of colon cancer in healthy subjects.

II. Determine if tolerable doses of this agent in uniformly milled formulation capsules are bioavailable in these subjects.

III. Determine the pharmacokinetics of this agent and two metabolites at the MTD and next lower escalated dose in these subjects.

**PROTOCOL OUTLINE:** This is a dose escalation study followed by a pharmacokinetic study.

Patients receive a single oral dose of curcumin followed by a standard fatty meal.

Cohorts of 3-6 patients receive escalating doses of curcumin until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose at which 2 of 6 patients experience dose limiting toxicities. Once the MTD is determined, additional patients are accrued to receive curcumin in the pharmacokinetic phase of the study.

Patients are followed at 24, 36, 48, and 72 hours.

**PROJECTED ACCRUAL:** A total of 3-24 patients will be accrued for the dose escalation phase and then 12 additional patients will be accrued for the pharmacokinetic phase of this study within 3 months.

 **Eligibility**

**Ages Eligible for Study:** 18 Years and above

**Criteria****PROTOCOL ENTRY CRITERIA:**

--Disease Characteristics--

Healthy men and women age 18 and over

--Prior/Concurrent Therapy--

Biologic therapy: Not specified

Chemotherapy: Not specified

Endocrine therapy: At least 14 days since prior steroids

This is a partial screen capture of the **Eligibility criteria**.

Detailed Display (cont'd)

**Location and Contact Information**

**Michigan**  
 University of Michigan Comprehensive Cancer Center, Ann Arbor, Michigan, 48109-0752, United States; Recruiting  
 Dean E. Brenner 734-647-1417

Study chairs or principal investigators

Dean E. Brenner, Study Chair  
 University of Michigan Comprehensive Cancer Center

**More Information**

[More information is available for this study.](#)

Study ID Numbers 199/15122; CCUM-9941; NCI-P00-0144; UMN-9941  
 Date study started December 5, 2001  
 Last Updated January 1, 2002  
 NLM Identifier [NCT00027495](#)  
 ClinicalTrials.gov processed this record on 2003-01-13

Search within Results

- Use to narrow your initial search results.
- Click on the Search-Within-Results button.

Search results for *colon cancer* [ALL-FIELDS] are shown below.

Show all trials, including those no longer recruiting patients. Search-Within-Results Query Details

110 studies were found. Here are studies 1 to 50. Next 50

Click **Search-Within-Results** button.

- Enter term(s) and select a field from the pull-down menu:  
 ALL-FIELDS: fields throughout the clinical trial record  
 CONDITION: fields describing the diseases or conditions being studied  
 TREATMENT: fields listing the drugs or interventions being studied  
 LOCATION: fields with address information for participating facilities

**Search Within Results**

You may search within results of previous search:  
**colon cancer [ALL-FIELDS]**

Search-Within-Results for  in  [Tips](#)

U.S. National Library of Medicine  
 National Institutes of Health, Depa

TREATMENT  
 LOCATION

Type in term; then Select a field from the pull-down menu. Click on **Search-Within-Results** button.

## Map of Locations

Click on the **Map of locations** button to select studies in a particular state or country.

Search results for *colon cancer [ALL-FIELDS] AND leucovorin [TREATMENT]* are shown below.

Include trials that are no longer recruiting patients.

Search-Within-Results    Query Details    **Map of locations**

30 studies were found.

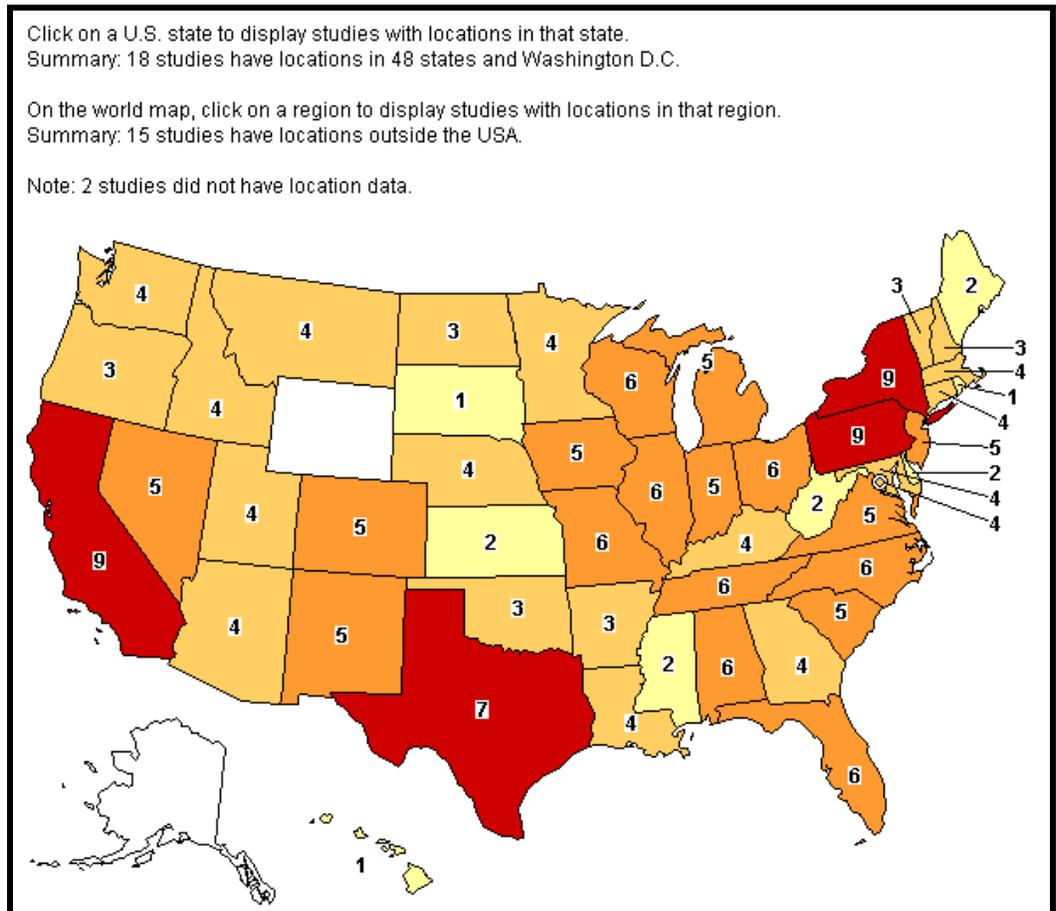
- Recruiting** [High-Dose Fluorouracil With or Without Leucovorin Compared With Standard Fluorouracil Plus Leucovorin Following Surgery in Treating Patients With Stage III Colon Cancer](#)  
Conditions: stage III colon cancer; adenocarcinoma of the colon; mucinous adenocarcinoma of the colon
- Recruiting** [Combination Chemotherapy in Treating Patients With Colon Cancer](#)  
Conditions: adenocarcinoma of the colon; stage II colon cancer; stage III colon cancer

Here's the map of the United States that is displayed:

Click on a state to display studies with locations in that state.  
Summary: 18 studies have locations in 48 states and Washington D.C.

On the world map, click on a region to display studies with locations in that region.  
Summary: 15 studies have locations outside the USA.

Note: 2 studies did not have location data.



If your workstation is not able to display the map graphic, there are buttons at the bottom of the screen to reach the same information.

## Focused Search

- On the Home or Search screen, use the link: **Focused Search**
- This option lets you conduct a more structured search.
- It is not necessary to fill in all the boxes.
- The labels to the left of each box are links to further explanation.

### Focused Search

**Use this form to focus your search. Fill in any or all of the boxes below. Click on the label to the left of each box for further explanation.**

[Tips](#)

[Disease or Condition:](#)

[Experimental Treatment:](#)

[Trial Facility:](#)

[City:](#)

[State:](#)

[Country:](#)

[Additional Terms:](#)

[Age Group:](#)  Child (birth-17)  Adult (18-65)  Senior (66+)

[Study Phase:](#)  Phase I  Phase II  Phase III  Phase IV

[Supported By:](#)  NIH  Other Federal Agency  
 Industry  University/Organization

[Study ID Number:](#)

Exclude synonyms from search

[Basic Search](#)

*State and Country are pull-down selection lists.*

## Browse

Browsing allows you to look through the entire list of trials by two categories:

- Condition
- Sponsor

### Browse Clinical Trials

Show all trials, including those no longer recruiting patients.

#### Browse by Condition

[Alphabetically](#)

[By Disease Heading](#)

#### Browse by Sponsor

[National Institutes of Health](#)

[Other Federal Agency](#)

[Industry](#)

[University/Organization](#)

## Practice Exercises

1. Are there any trials studying acupuncture?
2. Find Phase III clinical trials for bladder cancer for an adult patient living in Texas. (Hint: Use Focused Search).
3. Using the Browse by Condition mode, retrieve the clinical trials studying Abdominal Neoplasms. Use the Map of locations feature to quickly see the U.S. states where these studies are located.

## Suggested Answers

1. Are there any trials studying acupuncture?

**Search Clinical Trials**

Enter words or phrases, separated by commas:

acupuncture  [Tips](#)

2. Find Phase III clinical trials for bladder cancer for an adult patient living in Texas.  
(Hint: Use Focused Search).

**Focused Search**

Use this form to focus your search. Fill in any or all of the boxes below.  
Click on the label to the left of each box for further explanation.

[Tips](#)

*Enter disease.* [Disease or Condition:](#)

[Experimental Treatment:](#)

[Trial Facility:](#)

[City:](#)

*Select state.* [State:](#)

[Country:](#)

[Additional Terms:](#)

*Check Age Group.* [Age Group:](#)  Child (birth-17)  Adult (18-65)  Senior (66+)

*Check phase of study if known.* [Study Phase:](#)  Phase I  Phase II  Phase III  Phase IV

[Supported By:](#)  NIH  Other Federal Agency  
 Industry  University/Organization

[Study ID Number:](#)

Exclude synonyms from search

[Basic Search](#)

*Click on Search.*

3. Using the Browse by Condition mode, retrieve the clinical trials studying Abdominal Neoplasms. Use the Map of locations feature to quickly see the U.S. states where these studies are located.

You can select the Browse mode from the Home page:

**Browse**

[Browse by Condition](#) - studies listed by disease or condition

[Browse by Sponsor](#) - studies listed by funding organization

OR

You can click on Browse from the Menu Bar:

[Home](#) | [Search](#) | [Browse](#) | [Resources](#) | [Help](#) | [What's New](#) | [About](#)

You can then choose either route offered: Alphabetically or by Disease Heading:

[Browse](#) : **By Condition**

**Show all trials, including those no longer recruiting patients.**

1. [Alphabetically](#)
2. [By Disease Heading](#)

Once you've reached the list of Abdominal Neoplasms studies, click the **Map of locations** button:

**Include trials that are no longer recruiting patients.**

7 studies were found.

1.  **Recruiting** [Treatment of Peritoneal Cancer with Surgery, Perfused Heated Cisplatin, and Chemotherapy](#)  
Conditions: Abdominal Neoplasm; Colonic Neoplasm; Mesothelioma; Peritoneal Neoplasm
2.  **Recruiting** [EF5 in Detecting Oxygen Level and Blood Vessels in Tumor Cells of Patients Undergoing Photodynamic Therapy for Intraperitoneal Cancer](#)  
Conditions: malignant ascites; peritoneal cavity cancer
3.  **Recruiting** [Gemzar\(gemcitabine\) and Alimta\(pemetrexed\) in the Treatment of Patients with Recurrent Platinum-Sensitive and Platinum-Resistant Ovarian or Peritoneal Cancer](#)  
Conditions: Ovarian Cancer; Peritoneal Cancer

N O T E S