
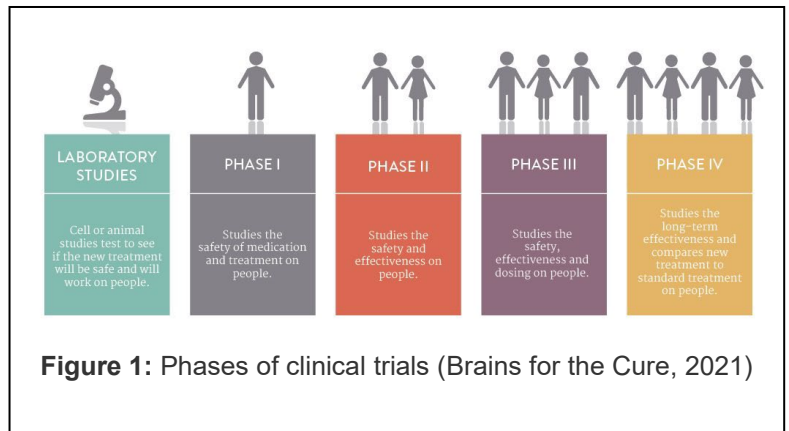
	SKILLS CENTER STANDARD OPERATING PROCEDURE	A BIOFIZZ  PRODUCTON
Searching Clinical Trial Data Module Hours: 2.0	Effective Date: 03/15/2021	Revision # 1.0 A. Siclair Checked: M. Guzie



BACKGROUND

After pharmacological experimentation and other laboratory studies in animal models or cell culture, there must be a transition to clinical trials (Figure 1). Clinical trials are vital to the development of human treatments because, although animal models are beneficial, the pharmacokinetics and pharmacodynamics of drugs and their actions are variable between various mammals.



The ClinicalTrials.gov website is one of the main collections of clinical trial data. The site was created as a result of the Food and Drug Administration Modernization Act of 1997 which stated that a database of existing trials must be created for study of pharmacological disease treatment (NIH, 2018). Released by the NIH in 2000, the website originally contained a handful of NIH funded studies but has grown to incorporate studies funded from around the world (NIH, 2020). The impact has spanned across 219 countries with registration rates consistently increasing (NIH, 2018). The site is used by healthcare professionals, researchers and the public alike to become more informed about current studies focused on a wide range of diseases and disorders. The information is normally updated as a study develops, so that the newest data can be found and utilized to inform others about the progress being made (NIH, 2018).

Searching existing clinical trial data can be beneficial when trying to establish a basis for one's own research, or to understand what progress is being made in a specific subsection of medicine. This procedure will introduce the basics to navigating the clinical trial data and help develop an understanding of the different features of the website.

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1. PURPOSE

The purpose of this procedure is to become comfortable with searching clinical trial data and analyzing the available information.

2. SCOPE

This procedure applies to qualified skills center users.

3. RESPONSIBILITY



- 3.1. It is the responsibility of the user to understand and perform the procedure described in this document.
- 3.2. It is the responsibility of the user performing the procedure to fully document any deviations from the written procedure.
- 3.3. It is the responsibility of the user to become trained on the procedure.

4. DEFINITIONS

- 4.1. Clinical trial – A research study in which human volunteers are assigned some sort of medical intervention based on a protocol, and then medical and health effects are measured.
- 4.2. Intervention – A drug or medical approach to treatment that is being studied.

5. MATERIALS/EQUIPMENT

- 5.1. ClinicalTrials.gov website: <https://clinicaltrials.gov/>

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6. PROCEDURE

6.1. Basic Search for Clinical Trial Studies

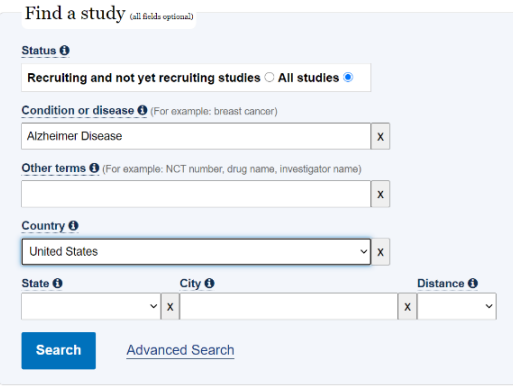
6.1.1. Go to the website: <https://clinicaltrials.gov/>

6.1.2. For basic search, enter in the desired condition, followed by other terms of interest and search. (Figure 2)

- Alzheimer's Disease was used as the example for this procedure.

6.1.3. A new window will pop up listing many clinical trials that match the given search parameters. (Figure 3)

- **List**: gives the most relevant studies based on the search terms.
- **By topic**: gives categories or alphabetical lists of the related studies.
- **On map**: gives results by location.
- **Search details**: gives studies with related or synonymous terms and/or conditions.



Find a study (all fields optional)

Status

Recruiting and not yet recruiting studies All studies

Condition or disease (For example: breast cancer)

Alzheimer Disease

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

Country

United States

State

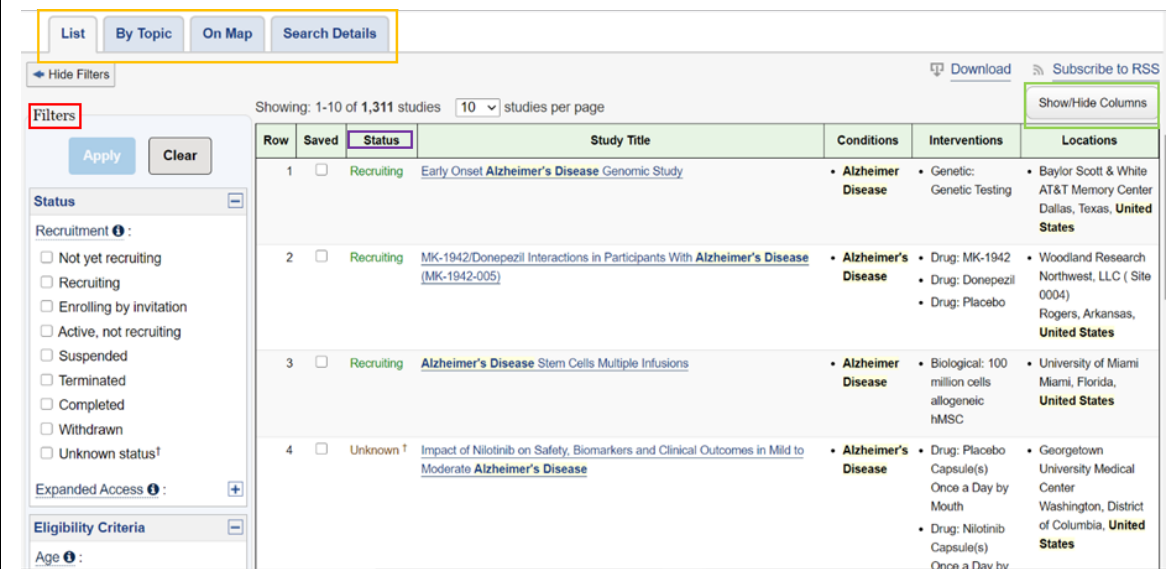
City

Distance

Search [Advanced Search](#)

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

Figure 2: The basic search feature of the ClinicalTrials.gov website.



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

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

Showing: 1-10 of 1,311 studies 10 studies per page [Show/Hide Columns](#)

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	<input type="checkbox"/>	Recruiting	Early Onset Alzheimer's Disease Genomic Study	• Alzheimer Disease	• Genetic: Genetic Testing	• Baylor Scott & White AT&T Memory Center Dallas, Texas, United States
2	<input type="checkbox"/>	Recruiting	MK-1942/Donepezil Interactions in Participants With Alzheimer's Disease (MK-1942-005)	• Alzheimer's Disease	• Drug: MK-1942 • Drug: Donepezil • Drug: Placebo	• Woodland Research Northwest, LLC (Site 0004) Rogers, Arkansas, United States
3	<input type="checkbox"/>	Recruiting	Alzheimer's Disease Stem Cells Multiple Infusions	• Alzheimer Disease	• Biological: 100 million cells allogeneic hMSC	• University of Miami Miami, Florida, United States
4	<input type="checkbox"/>	Unknown †	Impact of Nilotinib on Safety, Biomarkers and Clinical Outcomes in Mild to Moderate Alzheimer's Disease	• Alzheimer's Disease	• Drug: Placebo Capsule(s) Once a Day by Mouth • Drug: Nilotinib Capsule(s) Once a Day by	• Georgetown University Medical Center Washington, District of Columbia, 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

Figure 3: Window of clinical trails matching the basic search query.

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6.1.4. The **Filters** section along the left-hand side gives further ability to narrow results. (Figure 3)

- Filters include the type of current recruitment, eligibility criteria, the current phase of the trial, etc.

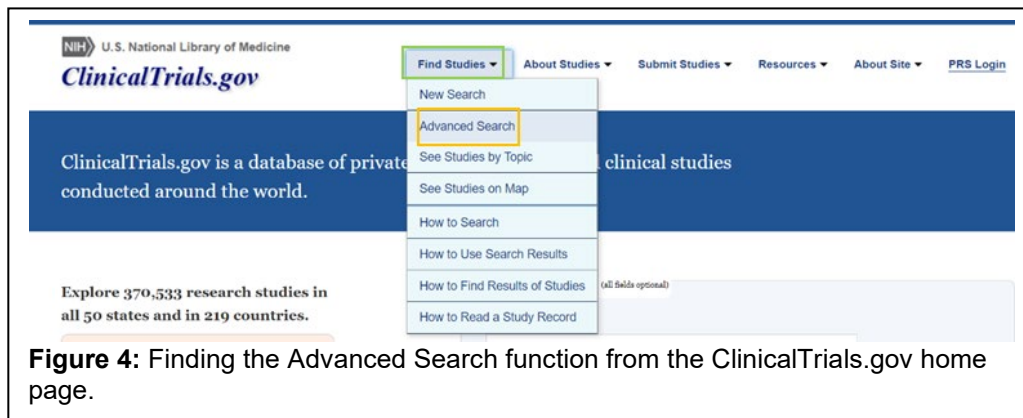
6.1.5. Some studies will have a “Has Results” link within the **Status** column, coupled with a status of “Completed”. This is an active link that can take you to the trial results. (Figure 3)

6.1.6. The **Show/Hide Columns** button can be used to add or remove column descriptors that customize the search parameters to your needs. (Figure 3)



6.2. Advanced Search for Clinical Trial Studies

6.2.1. Go to the home page of the ClinicalTrials.gov site.

6.2.2. Hover over the **Find Studies** button and click **Advanced Search**. (Figure 4)



6.2.3. Fill in the desired parameters given, including the condition, the stage of the study, information about the drug/intervention target, etc. (Figure 5)

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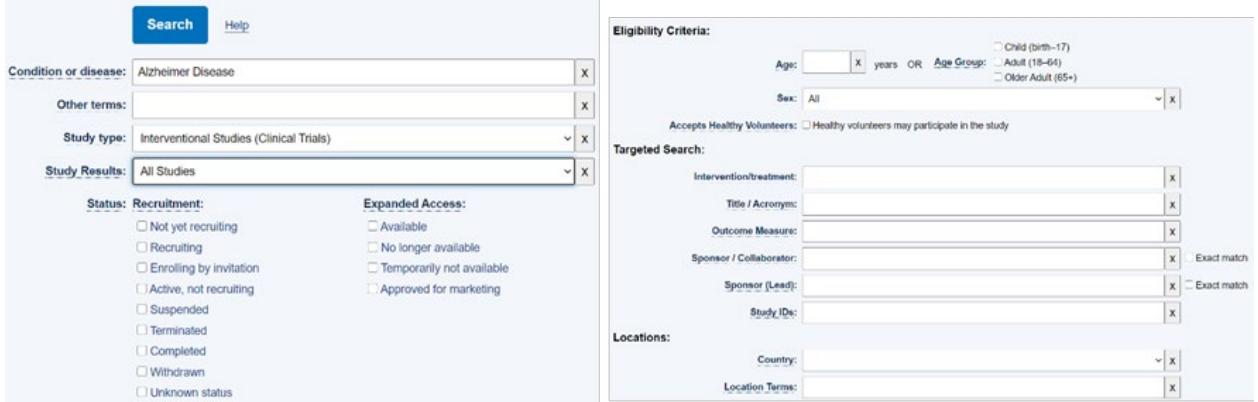


Figure 5: Available parameters to conduct an advanced search.

6.2.4. After searching, click on the Study Title to get details about a trial, same as with basic search.



6.3. Analysis of a Specific Study

6.3.1. Click on a specific study that has been marked “Completed” and is listed with a “Has Results” tab.

- The trial used for an example in this procedure: <https://clinicaltrials.gov/ct2/show/results/NCT01782742?cond=Alzheimer+Disease&cntry=US&draw=2&rank=7>

6.3.2. The Study Details tab will be the first to open.

- You can **save the study** for future use by checking the box in the top right of the page. (Figure 6)
- Note that significant dates from the trial are listed in the red box underneath the website identifier for the study.
- Numerous key points will be delineated on the **Study Details** page as you scroll down. (Figure 6)
 1. Study description: Talks about the basis behind the study, the intervention used, the current phase of the trial, etc.
 2. Study design: Describes the way the experiment is modeled and the participant demographics.
 3. Arms and interventions: Describes how the treatment/intervention will be administered in detail. This looks different for observational studies.

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4. Outcome measures: These are the things that will be or were used in the study to measure the effect of the intervention on the participants.
5. Eligibility criteria: Gives the information about what permitted and prevented participants from being chosen for the trial.
6. Contacts and locations: Gives information about the location and sponsors of the trial.
7. More information: Gives information on references and publications that are associated with the data and results from the study.



Home > Search Results > Study Record Detail Save this study

Trial record 7 of 1311 for: Alzheimer Disease | United States

[◀ Previous Study](#) | [Return to List](#) | [Next Study ▶](#)

Bexarotene Amyloid Treatment for Alzheimer's Disease (BEAT-AD)

ClinicalTrials.gov Identifier: NCT01782742

⚠ 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. Read our [disclaimer](#) for details.

Recruitment Status ⓘ : Completed
First Posted ⓘ : February 4, 2013
Results First Posted ⓘ : February 12, 2016
Last Update Posted ⓘ : February 12, 2016

Sponsor:
The Cleveland Clinic



Information provided by (Responsible Party):
The Cleveland Clinic

Study Details
Study Results
Tabular View
Disclaimer
How to Read a Study Record

Study Type Interventional

Figure 6: Example study that can be obtained from either a basic or advanced search.



- 6.3.3. The [Study Results](#) tab gives more insight into what occurred or is occurring during the study. Numerous sections are included on this page. (Figure 6)
1. Participant flow: Describes the progress of the participants as the study develops.
 2. Baseline characteristics: The beginning data collected at the start of the study for all participants, including controls.
 3. Outcome measure: Describes the protocol-decided measurement that will be analyzed as the main result of the study, coupled with the results of that measurement for treatment and control groups.

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4. Adverse effects: Negative effects on the life or health of the patients experienced during the trial, or abnormal lab findings.
5. Limitations of the study: Things that could have restricted the results of the study that could be improved upon in the future.
8. More information: Gives information on references and publications that are associated with the data and results from the study, as well as information about involved researchers and sponsors.

7. REFERENCES

- Cummings, J.L. (2016, Feb 12). *Bexarotene Amyloid Treatment for Alzheimer's Disease* [Dataset]. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/results/NCT01782742?cond=Alzheimer+Disease&cntry=US&draw=2&rank=7>
- NIH. (2017, Dec). *How to Find Results of Studies*. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/help/how-find/find-study-results>
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8. MODULE MASTERY TASK

This quiz will test your skillset regarding searching clinical trial data and understanding the related information.

1. Choose a disease and enter it via basic search. What was your chosen disease?
2. Go to the On Map section. What area of the world has the most studies focused on your chosen disease? What is the number?
3. Go to Search Details. What other similar studies did your search query bring up?
4. Filter your studies to "Completed" and choose a study that has results. When were those results first posted?
5. Who was the provider of the results information?
6. What is the intervention of the chosen study?
7. How was the intervention administered?
8. How many participants, if any, dropped out of the trial?
9. What was the required eligibility for the participants in this study?
10. What is one interesting thing that you learned about the protocol or results of this trial?