
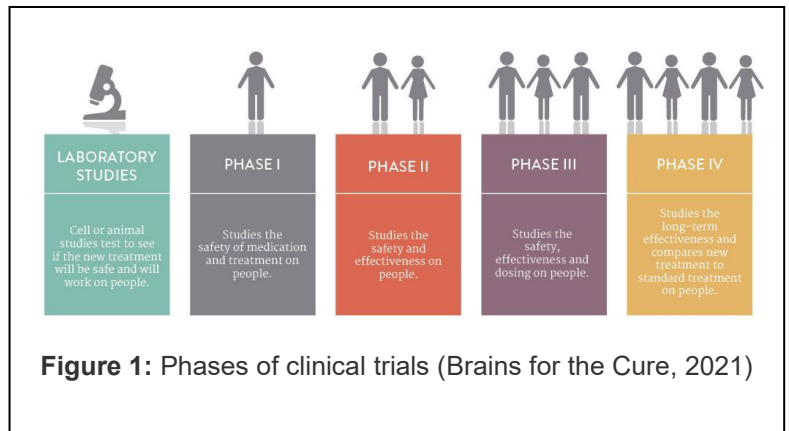
	<b>SKILLS CENTER STANDARD OPERATING PROCEDURE</b>	<b>A BIOFIZZ</b>  <b>PRODUCTON</b>
<b>Searching Clinical Trial Data</b>  <b>Module Hours: 2.0</b>	<b>Effective Date: 08/07/2024</b>	<b>Revision # 1.0</b> <b>A. Siclair</b> <b>Checked: M. Guzie</b>



## 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

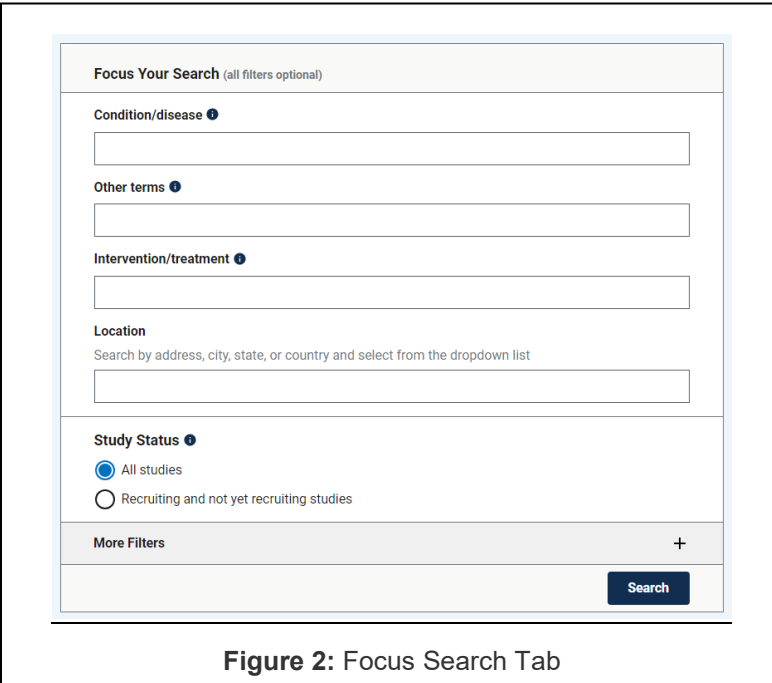
6.1.1. Go to the website: <https://clinicaltrials.gov/>

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), use the [Table view](#) for viewing.

- **Sort Studies:** Orders studies based on relevance or newest first



**Figure 2: Focus Search Tab**

- Figure 3



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

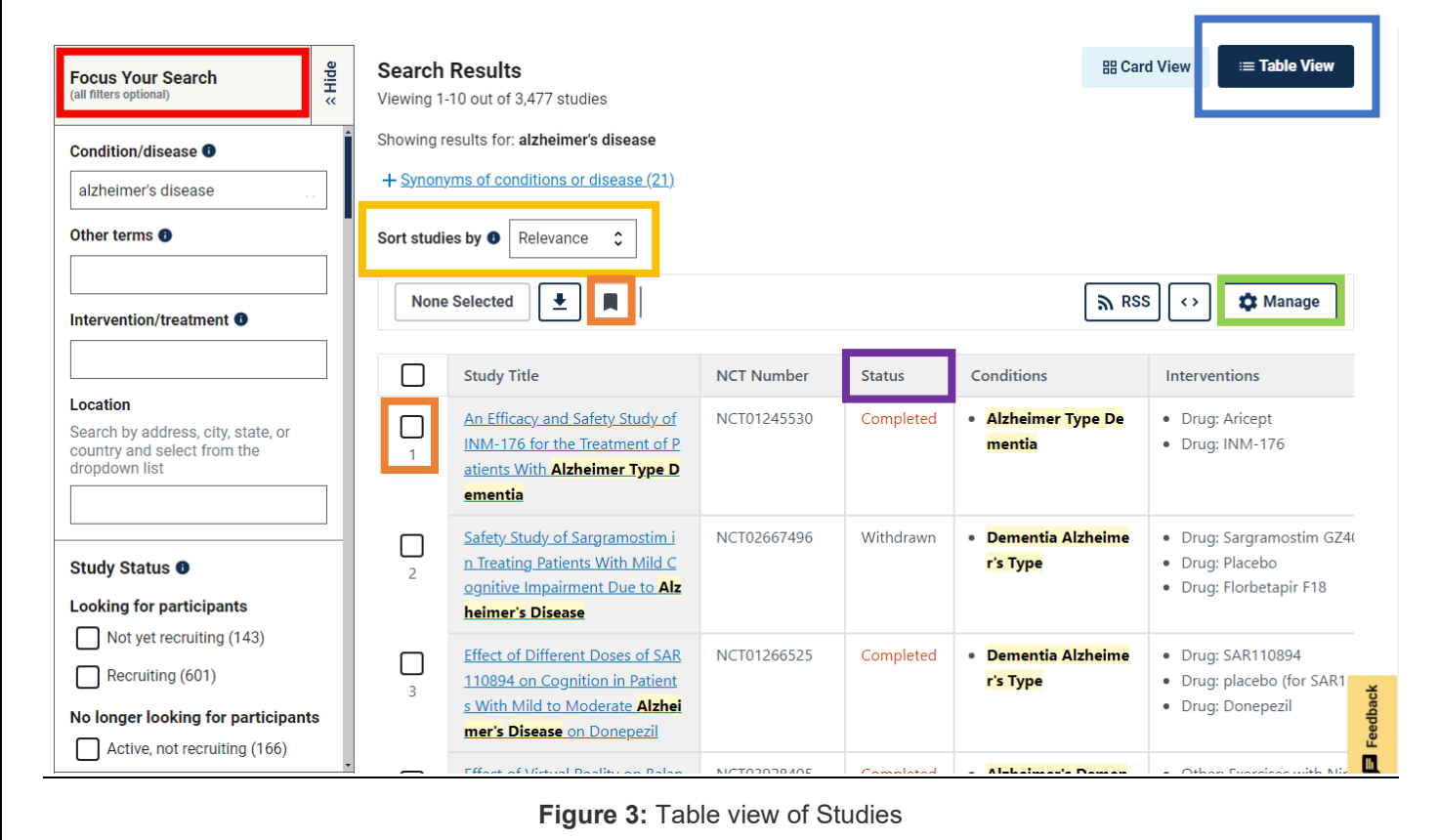
- Filters include the type of current recruitment, eligibility criteria, the current phase of the trial, etc.

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 **Manage** button can be used to add or remove column descriptors that customize the search parameters to your needs. (Figure 3)

### 6.2. Analysis of a Specific Study

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**Figure 3: Table view of Studies**



<input type="checkbox"/>	Study Title	NCT Number	Status	Conditions	Interventions
<input checked="" type="checkbox"/>	<a href="#">An Efficacy and Safety Study of INM-176 for the Treatment of Patients With Alzheimer Type Dementia</a>	NCT01245530	Completed	Alzheimer Type Dementia	Drug: Aricept Drug: INM-176
<input type="checkbox"/>	<a href="#">Safety Study of Sargramostim in Treating Patients With Mild Cognitive Impairment Due to Alzheimer's Disease</a>	NCT02667496	Withdrawn	Dementia Alzheimer's Type	Drug: Sargramostim GZ41 Drug: Placebo Drug: Florbetapir F18
<input type="checkbox"/>	<a href="#">Effect of Different Doses of SAR110894 on Cognition in Patients With Mild to Moderate Alzheimer's Disease on Donepezil</a>	NCT01266525	Completed	Dementia Alzheimer's Type	Drug: SAR110894 Drug: placebo (for SAR110894) Drug: Donepezil
<input type="checkbox"/>	<a href="#">Effect of Virtual Reality on Patients With Alzheimer's Disease</a>	NCT03038405	Completed	Alzheimer's Disease	Other Exercises with Ni...

6.2.1. Use the left hand **Focus Your Search** filter to include only “Completed” and “With Results” studies.


- The trial used for an example in this procedure: <https://clinicaltrials.gov/study/NCT01782742?cond=alzheimer%27s%20disease&viewType=Table&aggFilters=results:with,status:com&term=BEAT-AD&rank=1>


6.2.2. Choose one of the studies after applying the filter and record the NCT #.


- You can **save the study** for future use by checking the open box of the study and selecting the bookmark icon in the top of the table (Figure 3)
- Click on the Study Title hyperlink to be directed to the detailed page of that study.
- Numerous key points will be delineated on the **Study Details** page as you scroll down. (Figure 4)
- Significant dates from the trial are listed on this page to the right hand side of the “Study Overview”


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

ClinicalTrials.gov ID  NCT01782742

Sponsor  The Cleveland Clinic

Information provided by  The Cleveland Clinic (Responsible Party)

Last Update Posted  2016-02-12

  | + Expand all content | - Collapse all content

**Study Details** | Researcher View | Results Posted | Record History

On this page

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





**Study Overview**

**Brief Summary**

Retinoid X receptors (RXR) are nuclear receptors that have been linked to numerous metabolic pathways relevant to Alzheimer's disease (AD) and Aβ (harmful protein) production and removal. The study drug "bexarotene" is an FDA approved anti-cancer agent but is not approved for use in Alzheimer's disease. Bexarotene acts as an RXR agonist that has reduced Aβ (harmful protein) in the brain in experimental models of Alzheimer's disease.



This study aims to determine the safety and effect on abnormal proteins found in the brain (based on brain scans) of 300 mg of "bexarotene" administered for one month compared to placebo (inactive agent). [- Show less](#)

Official Title

<b>Study Start</b> 	2013-02
<b>Primary Completion (Actual)</b> 	2014-08
<b>Study Completion (Actual)</b> 	2014-12
<b>Enrollment (Actual)</b> 	20

**Figure 4:** Table view of Studies

- Additional information is described below by section
  1. **Study overview:** Talks about the basis behind the study, the intervention used, the current phase of the trial, etc.
  2. **Contacts and locations:** Gives information about the location and sponsors of the trial.
  3. **Participation criteria:** Gives the information about what permitted and prevented participants from being chosen for the trial.
  4. **Study Plan:** Describes the way the experiment is modeled and the participant demographics.
  5. **Collaborations and Investigators:** List responsible parties.
  6. **Publications:** Publications arising from the study
  7. **Study record dates:** Provides dates the study was performed
  8. **More information.**



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6.2.3. The **Results Posted** tab gives more insight into what occurred or is occurring during the study. Numerous sections are included on this page.

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.
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.
9. 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>
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## 8. MODULE METHODS TASK

This 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. Filter your studies to “Completed” and “With results” and choose a study from the filtered list.
3. What is the NCT # of your chosen study?
4. Who was the sponsor of the trial?
5. What is the intervention of the chosen study?
6. How was the intervention administered?
7. How many participants, if any, dropped out of the trial?
8. What was the required eligibility for the participants in this study?
9. What is one interesting thing that you learned about the protocol or results of this trial?
10. Do you think the data from clinical trials is useful for basic research, why or why not?