

Searching ClinicalTrials.gov

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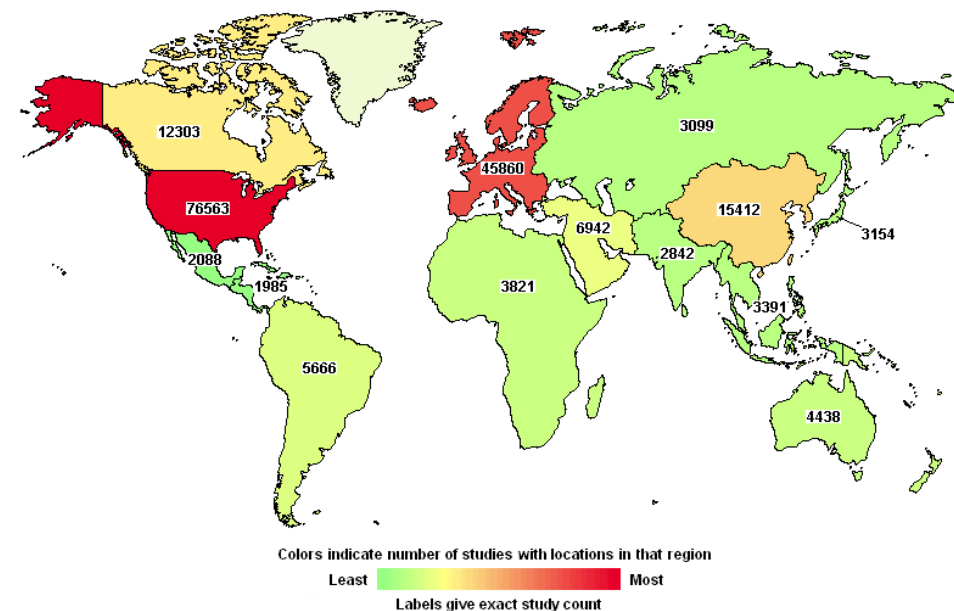


Agenda

- Overview/Background
- Beta Site
- Understanding Search
- Sample Search
- RSS Feeds

About ClinicalTrials.gov

- Clinical studies registry and results database
 - ~240,000 interventional & observational studies
 - Studies with locations in 50 states and 197 countries
 - Privately and publicly funded studies involving human subjects
 - Study information submitted by sponsor or principal investigator
- Website and registry launched in February 2000
 - Results database launched September 2008
 - ~25,000 studies with results
- Database updated nightly
- Usage
 - 200 million page views per month
 - 65,000 visitors per day



Why Register and Report Results?

- **Required by most medical journals (ICMJE)**
 - Registration for all clinical trials (all interventions)
- **Federal law (FDAAA 801) and regulations (42 CFR Part 11)**
 - Registration & results submission for “applicable clinical trials”
- **Expectation for all NIH-supported clinical trials**
 - Registration & results submission, even if not subject to FDAAA 801
 - Note: NCI previously established a results policy (effective 1/8/2015)

What's in a record?

- **Registration section**

- Submitted at trial initiation
- Summarizes information from trial protocol, e.g.,
 - Condition(s)
 - Interventions
 - Study Design
 - Outcome Measures
- Includes recruitment information (e.g., eligibility, locations)

- **Results section**

- Submitted after trial completion
- Summarizes trial results
 - Participant flow
 - Baseline characteristics
 - Outcome measure summary results (including statistical analyses)
 - Adverse events

Uses of ClinicalTrials.gov

- Identify trials to volunteer for
- Track progress of a trial & find summary results when available
- Discover the clinical research landscape
 - Complement a literature review: source of “grey” literature and unpublished trials
 - Support planning of a new protocol
 - IRB review of previous/ongoing studies
 - Funding review of research gaps/overlaps

ClinicalTrials.gov Beta Site

ClinicalTrials.gov BETA

A service of the U.S. National Institutes of Health

[Leave beta test site](#)

Saved Studies (0)

[Give us feedback](#)

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

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Search

Condition / Disease: x

Intervention / Treatment: x

Other Terms: x

Location: US State: ▾ x

Country: ▾ x

[Advanced Search](#)

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

- Beta site made available for testing on February 1st
 - Features informed by initial usability evaluations with new and experienced users (patients and professionals)
- Changes focus on search options and managing search results
- Additional feedback appreciated
- More improvements expected
 - 21st Century Cures Act
 - Partnership planned with 18F for further work

Understanding Search

ClinicalTrials.gov

A service of the U.S. National Institutes of Health
[Try our beta test site](#)

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. [Learn more about clinical studies](#) and [about this site](#), including relevant [history](#), [policies](#), and [laws](#).

[Find Studies](#) [About Clinical Studies](#) [Submit Studies](#) [Resources](#) [About This Site](#)

IMPORTANT: Information on ClinicalTrials.gov is provided by the sponsor or principal investigator of the clinical study, and posting to this site does not necessarily reflect endorsement by NIH. ClinicalTrials.gov does not independently verify the scientific validity or relevance of the submitted information beyond a limited quality control review for apparent errors, deficiencies, or inconsistencies. **Talk with a trusted healthcare professional before choosing to participate in a clinical study.**

ClinicalTrials.gov currently lists **239,763 studies** with locations in all 50 States and in **197 countries**.

Text Size [▼](#)

Search for Studies

Example: "Heart attack" AND "Los Angeles"

Search Help

- How to search
- How to find results of studies
- How to read a study record

Locations of Recruiting Studies

Location	Percentage
Non-U.S. only	56%
U.S. only	39%
Both U.S. and non-U.S.	5%

Total N = 41,542 studies
(Data as of March 23, 2017)

- See more trends, charts, and maps

For Patients and Families

- How to find studies
- See studies by topic
- Learn about clinical studies
- Learn more

For Researchers

- How to submit studies
- Download content for analysis
- About the results database
- Learn more

For Study Record Managers

- Why register?
- How to register your study
- FDAAA 801 requirements
- Learn more

Learn More

- Final Rule Webinar Series
- Tutorials for using ClinicalTrials.gov
- Glossary of common site terms
- For the press
- Using our RSS feeds

[HOME](#) [RSS FEEDS](#) [SITE MAP](#) [TERMS AND CONDITIONS](#) [DISCLAIMER](#) [CUSTOMER SUPPORT](#)

Advanced Search

Fill in any or all of the fields below. Click on the label to the left of each search field for more information or read the [Help](#).

 [Search Terms:](#) [Help](#)

[Study Type:](#)

[Study Results:](#)

[Recruitment:](#)

Eligibility Criteria:

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

[Gender:](#)

[Accepts Healthy Volunteers:](#) Healthy volunteers may participate in the study

Targeted Search:

 [Conditions:](#)

[Interventions:](#)

[Title Acronym/Titles:](#)

[Outcome Measures:](#)

 [Sponsor/Collaborators:](#) Exact match

[Sponsor \(Lead\):](#) Exact match

[Study IDs:](#)

Locations:

[State 1:](#)

[Country 1:](#)

[State 2:](#)

[Country 2:](#)


[State 3:](#)

[Country 3:](#)

[Location Terms:](#)

Additional Criteria:

[Phase:](#) Phase 0 Phase 1 Phase 2
 Phase 3 Phase 4

 [Funder Type:](#) NIH Other U.S. Federal agency
 Industry All others (individuals, universities, organizations)

[First Received:](#) From To (MM/DD/YYYY)

[Last Updated:](#) From To (MM/DD/YYYY)

[Help](#)

Understanding Search Fields: “Search Terms” vs. “Conditions”

- Search Terms:
 - General search of ALL fields (title, conditions, interventions, etc.)
 - Pulls broader set of studies
 - Less specific search results
- Conditions:
 - Disease/disorder/illness being studied
 - Specified by sponsor/PI
 - Search system maps provided Condition term with synonyms

“Conditions” Example of Mapping

- Term “Psychosis” provided by sponsor
 - Mapped to “Mental Disorders”
 - Record retrieved in a search of “Condition: Mental Disorders”

Keywords provided by Ontario Mental Health Foundation:

Cognitive Behavioural therapy

→ **Psychosis**

Additional relevant MeSH terms:

Psychotic Disorders

→ **Mental Disorders**

Schizophrenia Spectrum and Other **Psychotic Disorders**

“Conditions” Example of Mapping

Keywords provided by Ontario Mental Health Foundation:

Cognitive Behavioural therapy

Psychosis



Additional relevant MeSH terms:

Psychotic Disorders

Mental Disorders

Schizophrenia Spectrum and Other **Psychotic Disorders**

MeSH: Medical Subject Headings

<https://meshb.nlm.nih.gov/>

Understanding Search Fields: “Sponsor” vs. “Collaborator”

- Sponsor:
 - Entity responsible for the data and science of the study
 - May be an organization or person
- Collaborator:
 - Provides support for study
 - Funding/data analysis/design

Targeted Search:

<u>Conditions:</u>	<input type="text"/>	
<u>Interventions:</u>	<input type="text"/>	
<u>Title Acronym/Titles:</u>	<input type="text"/>	
<u>Outcome Measures:</u>	<input type="text"/>	
 <u>Sponsor/Collaborators:</u>	<input type="text"/>	<input type="checkbox"/> Exact match
 <u>Sponsor (Lead):</u>	<input type="text"/>	<input type="checkbox"/> Exact match
<u>Study IDs:</u>	<input type="text"/>	

Understanding Search Fields: “Sponsor” vs. “Collaborator”

This study has been completed.



Sponsor:

Harvard Medical School



Collaborator:

National Heart, Lung, and Blood Institute (NHLBI)

Information provided by (Responsible Party):

Harvard Medical School

Understanding Search Fields: “Funder Type: NIH Funded”

- Funder Type
 - Provides funding/support for the study
 - Can search:
 - NIH
 - Other U.S. Federal agency (FDA, CDC, VA)
 - Industry (Pharmaceutical/device companies)
 - All others (foundations, universities, etc.)
 - Target searches of NIH-funded studies without/in addition to “Sponsor/Collaborators” field

Understanding Search Fields: “Funder Type: NIH Funded”

Additional Criteria:

Phase:

- Phase 0 Phase 1 Phase 2
 Phase 3 Phase 4



Funder Type:

- NIH Other U.S. Federal agency
 Industry All others (individuals, universities, organizations)

First Received: From To (MM/DD/YYYY)

Last Updated: From To (MM/DD/YYYY)

Need Help?

Glossary of Common Site Terms

[Find Studies](#) ▾

[About Clinical Studies](#) ▾

[Submit Studies](#) ▾

[Resources](#) ▾

[About This Site](#) ▾

[Home](#) > [About Clinical Studies](#) > [Glossary of Common Site Terms](#)

[Text Size](#) ▾

Glossary of Common Site Terms

This glossary will help you understand words and phrases frequently used on ClinicalTrials.gov. Many of these words are also used by clinical researchers and others in the same or a similar manner. But the definitions below are provided to explain content on ClinicalTrials.gov only.

For help with medical terms, see the [MedlinePlus® Medical Dictionary](#).

Study record managers should refer to the [Protocol Registration Data Element Definitions](#), [Expanded Access Data Element Definitions](#), and [Results Data Element Definitions](#) for help with the data items required to register a study and submit results using the ClinicalTrials.gov Protocol Registration and Results System.

[A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [X](#) [Y](#) [Z](#)

Available at: <https://clinicaltrials.gov/ct2/about-studies/glossary>

Sample Search

- **Want:**
 - Sponsored or funded by NIMH
 - Mental health conditions
 - Currently enrolling
 - Located near Virginia

Sample Search

- **Advanced Search Terms:**

- Sponsored or funded by NIMH

Sponsor/Collaborators:

Funder Type: NIH Other U.S. Federal agency
 Industry All others (individuals, universities, organizations)

- Mental health conditions

Conditions:

- Currently Enrolling

Recruitment:

No locations (yet!)

Sample Search: Results

[Home](#) > [Find Studies](#) > [Search Results](#)

Text Size ▼

192 studies found for: [Open Studies](#) | [mental disorders](#) | [national institute of mental health](#) | [NIH](#)

[Modify this search](#) | [How to Use Search Results](#)

List

By Topic

On Map

Search Details

+ Show Display Options

 Download

 Subscribe to RSS

Only show open studies

Sample Search: Location “near Virginia”

[Home](#) > [Find Studies](#) > [Search Results](#)

[Text Size](#) ▼

192 studies found for: [Open Studies](#) | [mental disorders](#) | [national institute of mental health](#) | [NIH](#)

[Modify this search](#) | [How to Use Search Results](#)



List

By Topic

On Map

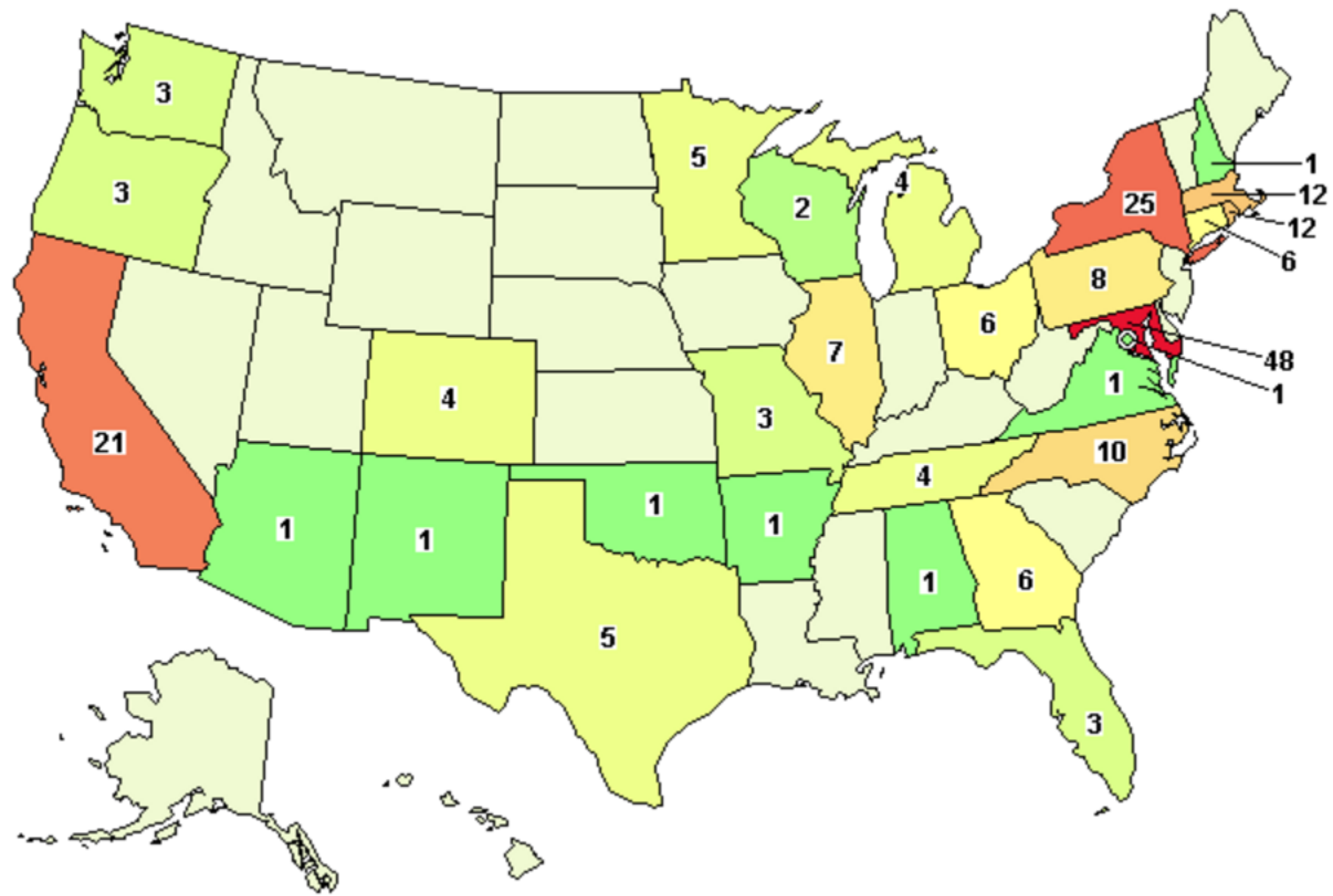
Search Details

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Locations: Search Options

- Can use map view to refine
 - Best for getting overview of all locations
 - Allows review of all studies meeting other search criteria (e.g., Conditions)
- Can use Advanced Search to target up to 3 countries or states
 - Best option if setting up RSS feed or bookmarked search

Locations:

State 1: ▼

Country 1: ▼

State 2: ▼

Country 2: ▼

State 3: ▼

Country 3: ▼

Location Terms:

Locations: Flexibility

- Consider type of disease
 - Rare diseases may have fewer options
- How far is too far for travel?
 - Some patients will travel far to participate
 - Number of visits may be a factor in choosing to travel
- Some studies recruit “nationally” (telehealth, surveys, etc.)
 - Not possible to search in ClinicalTrials.gov
 - Encourage sponsors to provide information in study record
 - Encourage users to contact recruitment coordinator with questions

RSS Feed

- Search as usual
- Choose “Subscribe to RSS” on search results page

48 studies found for: [Open Studies](#) | [mental disorders](#) | [national institute of mental health](#) | [United States, Virginia](#) | [United States, Maryland](#) | [United States, District of Columbia](#) | [NIH](#)

[Modify this search](#) | [How to Use Search Results](#)

List

By Topic

On Map

Search Details

+ Show Display Options


 Download

 [Subscribe to RSS](#)



RSS Feed

- Choose “Subscribe to RSS” on search results page

 **Create an RSS feed from your search for:**

Open Studies | mental disorders | national institute of mental health | United States, Virginia | United States, Maryland | United States, District of Columbia | NIH

Need help? [See RSS Feeds](#)

Choose a feed type:

Show studies that were **first received** in the last 14 days

Show studies that were **added or modified** in the last 14 days

First Received:

Only newly added studies

Added or modified:

(recommended)

New and updated studies

RSS Feed

This XML file does not appear to have any style information associated with it. The document tree is shown below.

```
▼<rss version="2.0">
  ▼<channel>
    ▼<title>
      ClinicalTrials.gov: Open Studies | mental disorders | national institute of mental health | United States, Virginia | United States,
    </title>
    ▼<link>
      https://clinicaltrials.gov/ct2/results/rss.xml?
      recr=Open&cond=mental+disorders&spons=national+institute+of+mental+health&state1=NA%3AUS%3AVA&state2=NA%3AUS%3AMD&am
    </link>
    ▼<description>
      Studies found on ClinicalTrials.gov by a search of: Open Studies | mental disorders | national institute of mental health | United S
      updated in the last 14 days
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    <pubDate>Sun, 26 Mar 2017 11:24:38 EDT</pubDate>
    <ttl>1440</ttl>
    ▼<item>
      ▼<title>
        Neuropharmacologic Imaging and Biomarker Assessments of Response to Acute and Repeated-Dosed Ketamine Infusions in Major Depressiv
      </title>
```

RSS Feed

- URL must be added via RSS feed reader or Outlook (email client)

- Example URL:

https://clinicaltrials.gov/ct2/results/rss.xml?rcv_d=&lup_d=14&recr=Open&cond=mental+disorders&spons=national+institute+of+mental+health&state1=NA%3AUS%3AVA&state2=NA%3AUS%3AMD&state3=NA%3AUS%3ADC&fund=0&show_rss=Y&sel_rss=mod14&count=10000

RSS Feed: Outlook Steps

- Go to “Account Settings”
- Click RSS feed tab
- Click on “New...”
- Add URL
- Check “RSS Feeds” folder in Outlook for updates
 - Won’t be emailed to inbox
- More RSS help: <https://clinicaltrials.gov/ct2/resources/rss>

ClinicalTrials.gov Resources & Help

- Search help pages:
 - <https://clinicaltrials.gov/ct2/help/how-find/index>
- Email: register@clinicaltrials.gov
- **Try the Beta site & please provide feedback!**