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)

ICMJE = International Committee of Medical Journal Editors; FDAAA 801 = Section 801 of the Food and Drug Administration Amendments Act of 2007; NIH = National Institutes of Health; NCI = National Cancer Institute
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  • Complement a literature review: source of “grey” literature and unpublished trials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

- 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

https://clinicaltrials.gov/beta/
Understanding Search
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

From: https://clinicaltrials.gov/ct2/show/NCT00722163
“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/

From: https://clinicaltrials.gov/ct2/show/NCT00722163
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
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”
Need Help?
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.

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:** national institute of mental health

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

- **Mental health conditions**

  **Conditions:** mental disorders

- **Currently Enrolling**

  **Recruitment:** Open Studies

  No locations (yet!)
Sample Search: Location “near Virginia”
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

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</tr>
<tr>
<td>State 2:</td>
<td>United States, Maryland</td>
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<td>Country 2:</td>
<td>--- Optional ---</td>
</tr>
<tr>
<td>State 3:</td>
<td>United States, District of Columbia</td>
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<tr>
<td>Country 3:</td>
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<tr>
<td>Location Terms:</td>
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</tbody>
</table>
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
RSS Feed

- Choose “Subscribe to RSS” on search results page

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.

```xml
<rss version="2.0">
  <channel>
    <title>ClinicalTrials.gov: Open Studies | mental disorders | national institute of mental health | United States, Virginia | United States, Virginia</title>
    <link>https://clinicaltrials.gov/ct2/results/rss.xml?recr=Open&amp;cond=mental+disorders&amp;spons=national+Institute+of+mental+health&amp;state=NA%3AUS3AVA&amp;state2=NA%3AUS3AMD&amp;</link>
    <description>Studies found on ClinicalTrials.gov by a search of: Open Studies | mental disorders | national institute of mental health | United States, Virginia | United States, Virginia</description>
    <language>en-us</language>
    <pubDate>Sun, 26 Mar 2017 11:24:38 EDT</pubDate>
    <ttl>1440</ttl>
  </channel>
</rss>
```

Neuropharmacologic Imaging and Biomarker Assessments of Response to Acute and Repeated-Dosed Ketamine Infusions in Major Depressive Disorder
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:

• Email: register@clinicaltrials.gov

• Try the Beta site & please provide feedback!