

ClinicalTrials.gov: Meeting Transparency and Reporting Requirements

Miah Jung, Pharm.D., M.S.
Office of Scientific Investigations
Center for Drug Evaluation and Research
U.S. Food and Drug Administration



Knowledge Check

Why register, update and report results information on ClinicalTrials.gov?

- A. Fulfill ethical obligations to patients, the general public and the research community
- B. Promote scientific integrity and reduce publication and outcome reporting bias
- C. Fulfill regulatory requirements
- D. All of the above

Knowledge Check

Why register, update and report results information on ClinicalTrials.gov?

- A. Fulfill ethical obligations to patients, the general public and the research community
- B. Promote scientific integrity and reduce publication and outcome reporting bias
- C. Fulfill regulatory requirements
- D. All of the above**

What is ClinicalTrials.gov?

- ClinicalTrials.gov is a registry and results information database of publicly and privately supported clinical studies of human participants conducted around the world
- Run by the National Library of Medicine (NLM) at the National Institutes of Health (NIH)
 - Established under Food and Drug Administration Modernization Act (FDAMA) of 1997
 - Requirements for submitting trials and results information expanded by Food and Drug Administration Amendments Act of 2007 (FDAAA)
 - Regulations codified in 42 CFR Part 11, effective 2017

What is ClinicalTrials.gov?

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾ PRS Login

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 442,054 research studies in all 50 states and in 221 countries.

See listed clinical studies related to the coronavirus disease (COVID-19)

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

Find a study (all fields optional) Saved Studies (6)

Status ⓘ

Recruiting and not yet recruiting studies

All studies

Condition or disease ⓘ (For example: breast cancer)

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

Country ⓘ

[Advanced Search](#)

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



Welcome to the modernized ClinicalTrials.gov! (Return to the [classic website](#))

NIH National Library of Medicine
 National Center for Biotechnology Information PRS Login

ClinicalTrials.gov About This Site ▾ Data About Studies ▾ Study Basics ▾ PRS Info ▾

ClinicalTrials.gov is a place to learn about clinical studies from around the world.

! The U.S. government does not review or approve the safety and science of all studies listed on this website. +

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

Focus Your Search (all filters optional)

Condition or disease ⓘ

Other terms ⓘ

Intervention/Treatment ⓘ

Location

Search by address, city, state, or country and select from the dropdown list

Study Status ⓘ

All studies

Recruiting and not yet recruiting studies

More Filters +

About

[About ClinicalTrials.gov](#)

[Release Notes](#)

Help

[Give us feedback](#)

[Glossary](#)

[Customer Support](#)

Legal

[Disclaimer](#)

[Terms and Conditions](#)

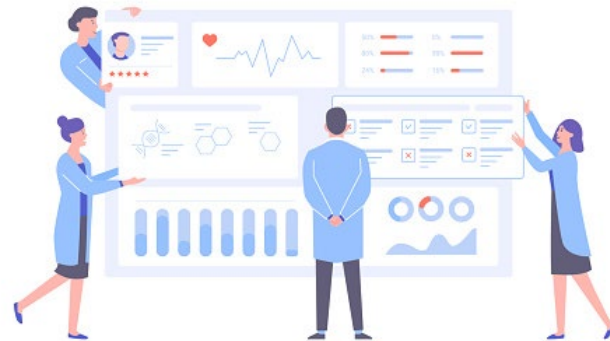
ClinicalTrials.gov

National Library of Medicine
 8600 Rockville Pike, Bethesda, MD 20894

Feedback

Responsibilities for ClinicalTrials.gov

- NIH/NLM: Implementation responsibilities
- FDA: Compliance and enforcement
 - Informed consent statement regarding ClinicalTrials.gov [21 CFR 50.25(c)]
 - Certification of Compliance (Form FDA 3674)
 - Clinical trial registration and results information submission requirements [42 CFR Part 11]



FDA's Compliance & Enforcement Activities

- Risk based compliance activities related to ClinicalTrials.gov are incorporated into FDA's Bioresearch Monitoring (BIMO) program
 - Inspection program
 - Complaint evaluations
 - Surveillance efforts
- Encourage voluntary compliance with ClinicalTrials.gov requirements
- Work closely with NIH to ensure compliance and enforcement activities are carried out in a coordinated fashion

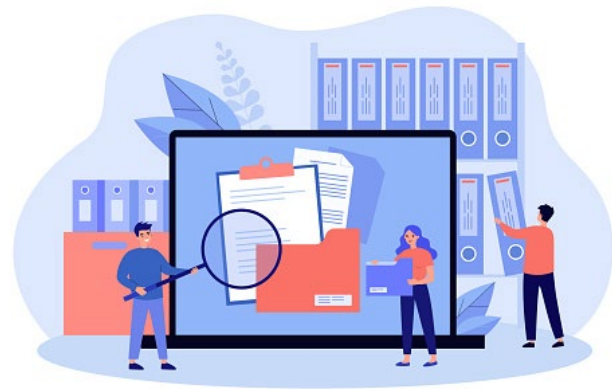


Challenges Meeting ClinicalTrials.gov Reporting Requirements

- Clinical Trials Transformation Initiative (CTTI) project
- Stakeholder interviews and surveys to identify and explore key challenges and identify potential solutions.
- Resulting data will be used to develop best practices for responsible parties and other stakeholders.
- The goal is to ensure ClinicalTrials.gov includes timely and complete information for those seeking information about applicable clinical trials
- [Challenges Meeting U.S. ClinicalTrials.gov Reporting Requirements - CTTI \(ctti-clinicaltrials.org\)](#)

Key Messages

- Clinical trial transparency is important
- Submission of registration and results information by responsible parties is required by law
- NIH/NLM and FDA each have responsibilities related to [ClinicalTrials.gov](https://clinicaltrials.gov)
- Contact the NIH/NLM for questions related to submission of registration and results information



Contact Information

For Help With Registering a Study or Submitting Results Information

If you are a sponsor or investigator and have questions about registering a study or submitting results information, contact ClinicalTrials.gov staff at register@clinicaltrials.gov.

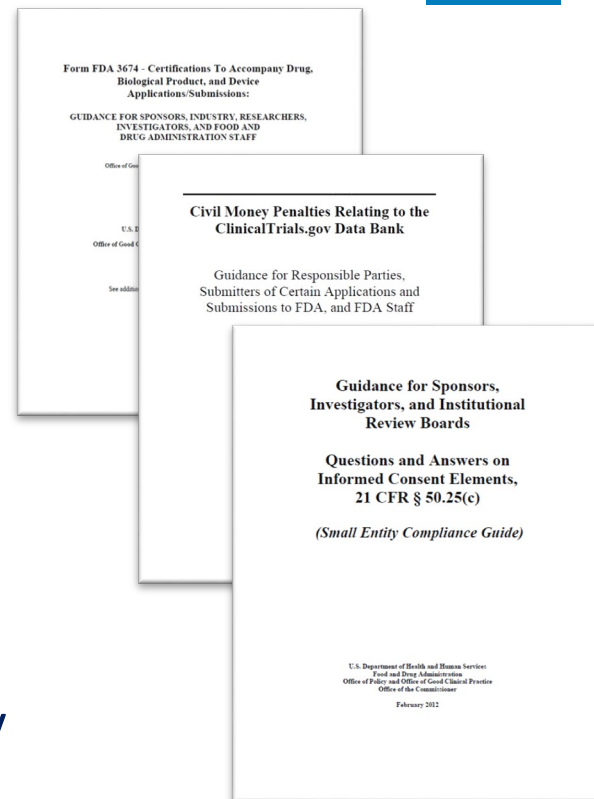
For Questions or Comments About ClinicalTrials.gov

To send the National Library of Medicine questions or comments about the ClinicalTrials.gov site, use the Customer Support link at the bottom of any ClinicalTrials.gov page.

<https://clinicaltrials.gov/ct2/help/for-researcher>

FDA Guidances

- [Form FDA 3674 – Certification to Accompany Drug, Biological Product and Device Applications/Submissions](#), Guidance for Sponsors, Industry, Researchers, and FDA staff
- [Civil Money Penalties Relating to ClinicalTrials.gov Data Bank](#), Guidance for Responsible Parties, Submitters of Certain Applications/Submissions to FDA, and FDA Staff
- [Questions and Answers on Informed Consent Elements, 21 CFR 50.25\(c\)](#), Guidance to Industry



Additional Resources

- [FDA's Role: ClinicalTrials.gov Information](#)
- [ClinicalTrials.gov - Notices of Noncompliance and Civil Money Penalty Actions](#) – NIH/NLM
- [42 CFR Part 11](#)
- [ClinicalTrials.gov](#) – NIH/NLM
- [NIH Checklist](#) for Evaluating Whether a Clinical Trial is an Applicable Clinical Trial
- [Frequently Asked Questions: ClinicalTrials.gov](#) (National Institutes of Health)