ClinicalTrials.gov: Meeting Transparency and Reporting Requirements

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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

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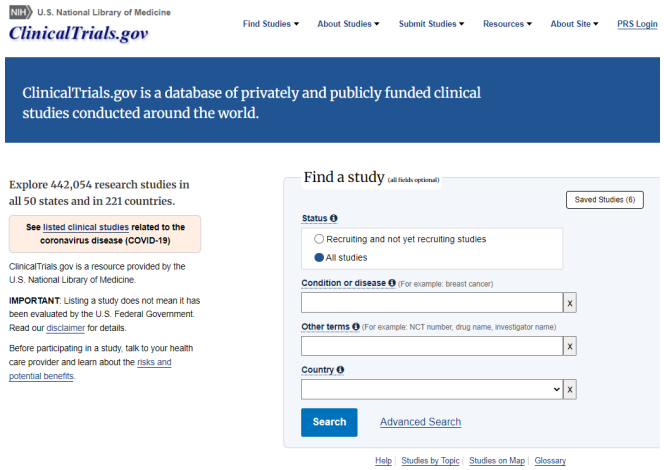
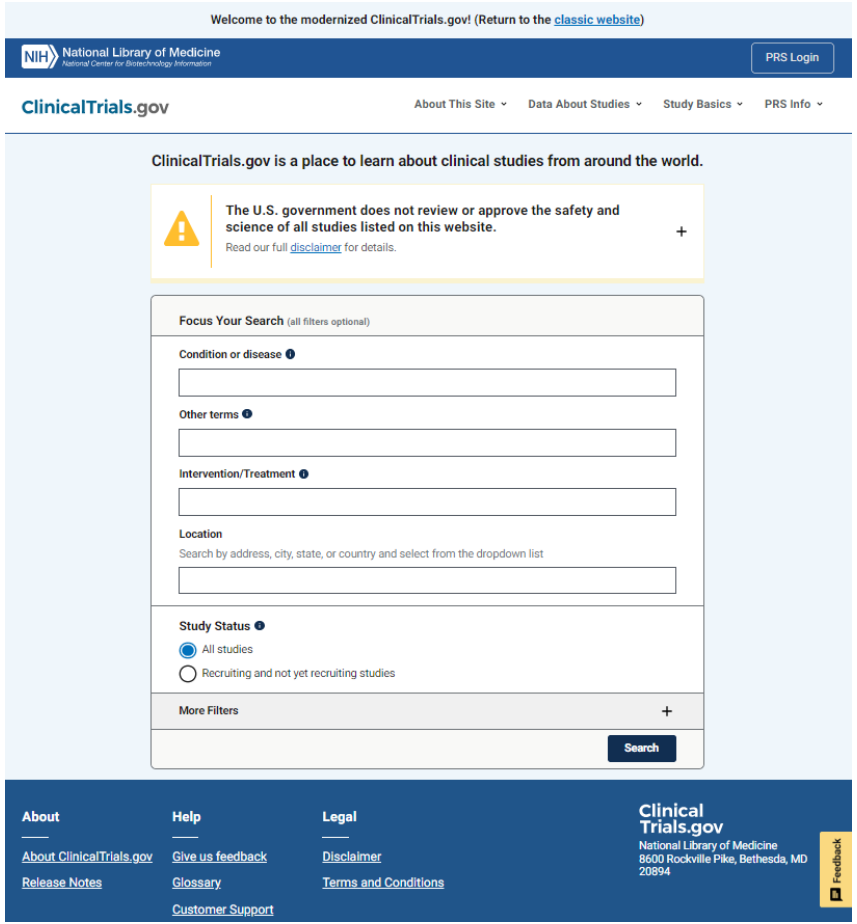
What is ClinicalTrials.gov?

- 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?





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

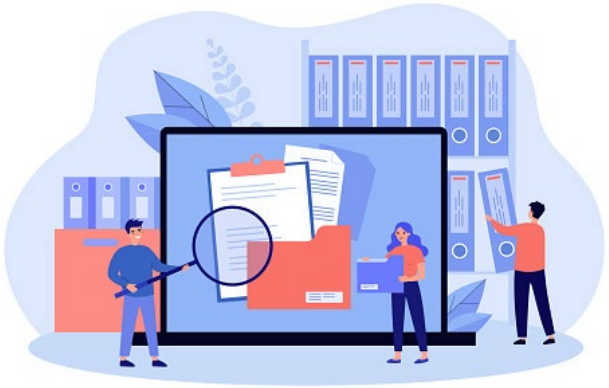
- Risk based compliance activities related to ClinicalTrials.gov are incorporated into FDA's Bioresearch Monitoring (BIMO) program
  - Inspection program
  - Complaint evaluations
  - Surveillance efforts
- Encourage voluntary compliance with ClinicalTrials.gov requirements
- Work closely with NIH to 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
- Contact the NIH/NLM for questions related to submission of registration and results information



Contact Information

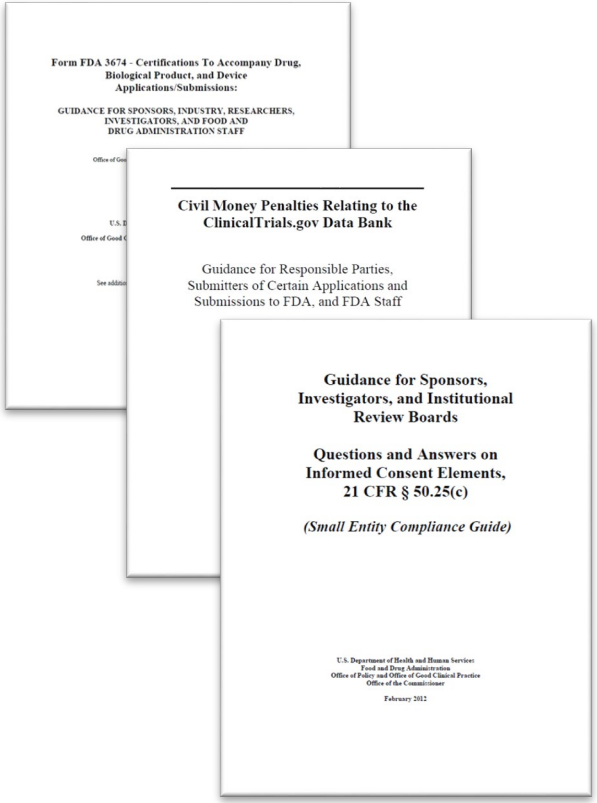
For Help With Registering a Study or Submitting Results Information
If you are a sponsor or investigator and have questions about registering a study or submitting results information, contact ClinicalTrials.gov staff at register@clinicaltrials.gov.

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)