ClinicalTrials.gov: CDER's Compliance and Enforcement Activities

Rachelle Marie L. Swann, Pharm.D.
Office of Scientific Investigations
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Knowledge Check

What is a potential legal consequence of noncompliance with ClinicalTrials.gov requirements?

A. Civil or judicial actions (e.g., Notice of Noncompliance Letter from FDA)
B. Civil money penalties
C. Grant funding actions
D. All of the above

Knowledge Check

What is a potential legal consequence of noncompliance with ClinicalTrials.gov requirements?

A. Civil or judicial actions (e.g., Notice of Noncompliance Letter from FDA)
B. Civil money penalties
C. Grant funding actions (i.e., restricting or withdrawing funds)
D. All of the above

Responsibilities for ClinicalTrials.gov

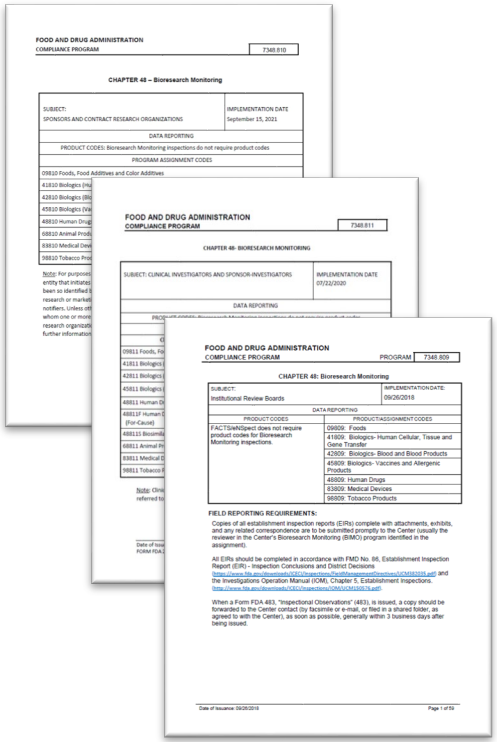
- FDA: Compliance and enforcement
  - Informed consent statement regarding ClinicalTrials.gov [21 CFR 50.25(c)]
  - Certification of Compliance (Form FDA 3674)
  - Clinical trial registration and results information submission requirements [42 CFR Part 11]

FDA's Compliance & Enforcement Activities

- 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

BIMO Inspection Program

- ClinicalTrials.gov requirements addressed in following BIMO compliance programs (CPs):
  - Institutional Review Boards CP 7348.809
  - Sponsors and Contract Research Organizations CP 7348.810
  - Clinical Investigators and Sponsor-Investigators CP 7348.811
- The CPs provide standard instructions for field investigators



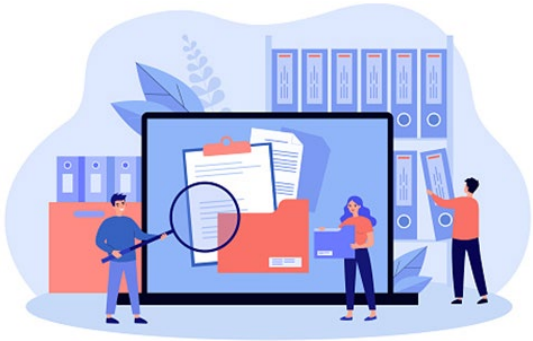
Surveillance Efforts: Risk-Based Compliance Approach

FDA intends to focus its attention in the following areas:

- Applicable clinical trials of products that potentially may pose a higher risk to human subjects or that are intended to address a significant public health need
- Responsible parties/submitters with a pattern of previous noncompliance with the ClinicalTrials.gov requirements
- Applicable clinical trials for which noncompliance exists in conjunction with other statutory and/or regulatory noncompliance pertaining to the conduct of the trial

Identifying Potential Noncompliance

- Potential noncompliance is assessed on a case-by-case basis
- Information that may be evaluated to identify potential noncompliance includes:
  - ClinicalTrials.gov National Clinical Trial (NCT) records, including archived information
  - Information collected as part of an FDA inspection
  - Related publications and media articles (e.g., journal articles, conference materials, trade press stories)



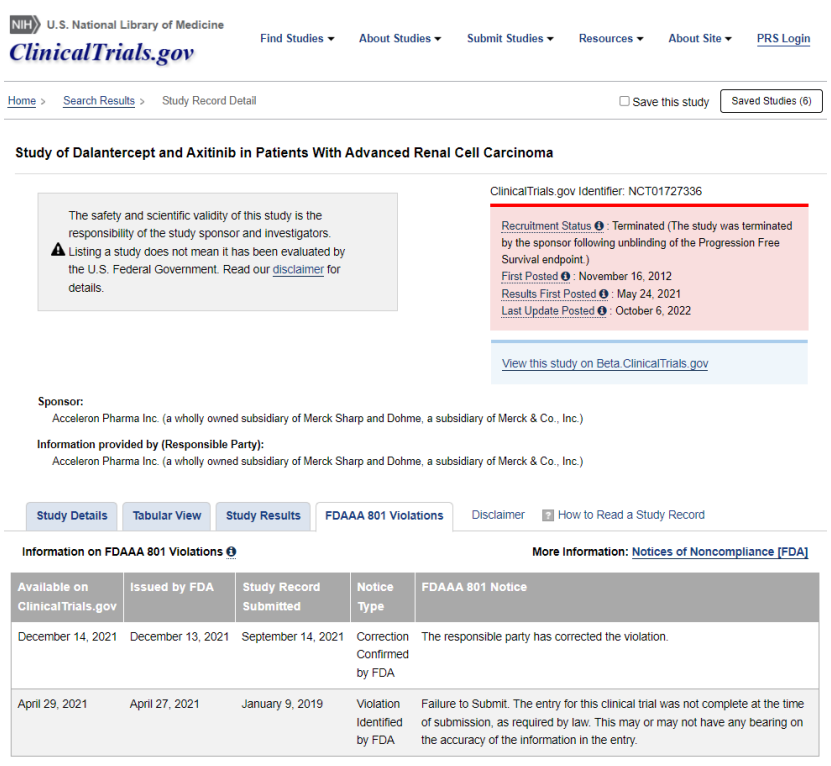
Preliminary Notice of Noncompliance Letter

- Identifies potential violation
- Provides responsible party an opportunity to address potential violation
- Notes FDA will further assess beginning 30 calendar days following receipt of the Preliminary Notice (Pre-Notice) of Noncompliance Letters

Notice of Noncompliance Letter

- Notifies the responsible party of the Center's determination
- Gives an opportunity to remedy noncompliance not later than 30 calendar days after the notification
- Posted on FDA's website
- Includes a link to the Notice of Noncompliance posting on FDA website

FDA



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Study of Dalantercept and Axitinib in Patients With Advanced Renal Cell Carcinoma

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT01727336

Recruitment Status : Terminated (The study was terminated by the sponsor following unblinding of the Progression Free Survival endpoint.)
First Posted : November 16, 2012
Results First Posted : May 24, 2021
Last Update Posted : October 6, 2022

View this study on Beta.ClinicalTrials.gov

Sponsor:
Acceleron Pharma Inc. (a wholly owned subsidiary of Merck Sharp and Dohme, a subsidiary of Merck & Co., Inc.)

Information provided by (Responsible Party):
Acceleron Pharma Inc. (a wholly owned subsidiary of Merck Sharp and Dohme, a subsidiary of Merck & Co., Inc.)

Study Details | Tabular View | Study Results | FDAAA 801 Violations | Disclaimer | How to Read a Study Record

Information on FDAAA 801 Violations — **More Information:** Notices of Noncompliance [FDA]

Available on ClinicalTrials.gov	Issued by FDA	Study Record Submitted	Notice Type	FDAAA 801 Notice
December 14, 2021	December 13, 2021	September 14, 2021	Correction Confirmed by FDA	The responsible party has corrected the violation.
April 29, 2021	April 27, 2021	January 9, 2019	Violation Identified by FDA	Failure to Submit. The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.

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TERMINATED
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Study of Dalantercept and Axitinib in Patients With Advanced Renal Cell Carcinoma

Information provided by Acceleron Pharma Inc. (a wholly owned subsidiary of Merck Sharp and Dohme, a subsidiary of Merck & Co., Inc.) (Responsible Party)
Last Update Posted: 2022-10-06

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.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read Learn About Studies.

Study record dates +

Study | Results Posted | Record History | FDAAA 801 Violations

Information on FDAAA 801 Violations

Notices of Noncompliance [FDA]

Available on ClinicalTrials.gov	Issued by FDA	Study Record Submitted	Notice Type	FDAAA 801 Notice
2021-12-14	2021-12-13	2021-09-14	Correction Confirmed by FDA	The responsible party has corrected the violation.
2021-04-29	2021-04-27	2019-01-09	Violation Identified by FDA	Failure to Submit. The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.

Consequences of Noncompliance

- Civil money penalties (amounts adjusted annually; see 45 CFR 102.3)
  - Up to $10,000 for all violations adjudicated in a single proceeding
  - If a failure to register or failure to submit results information violation is not corrected within 30-day period following receipt of Notice of Noncompliance, shall be subject to civil monetary penalties of up to $10,000 **per day** until violation corrected
- Grant funding actions
- Injunction and/or criminal prosecution

Notices of Noncompliance and Civil Money Penalty Actions

ClinicalTrials.gov - Notices of Noncompliance and Civil Money Penalty Actions

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Federal law requires responsible parties to submit registration and summary results information to the ClinicalTrials.gov data bank for certain applicable clinical trials. The law also requires a submitter of certain applications/submissions to FDA certify that all the above-referenced requirements have been met for applicable clinical trials referenced in such applications/submissions. FDA has the authority to issue a Notice of Noncompliance to a responsible party for failure to comply with certain requirements, including:

- Failing to submit required clinical trial information
- Submitting false or misleading clinical trial information

FDA also has the authority to issue a Notice of Noncompliance to a submitter who has failed to submit or knowingly submitted a false certification to FDA.

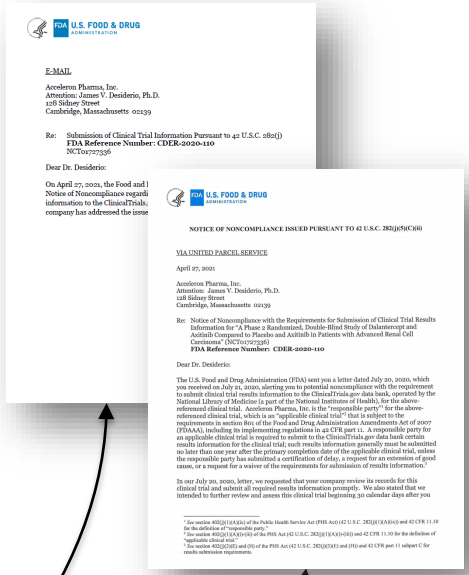
FDA has authority to assess civil money penalties for these violations. If a responsible party does not take adequate corrective action within 30 days after receiving a Notice of Noncompliance regarding failure to submit required information, that responsible party may be subject to additional civil money penalties.

FDA will take into consideration any corrective action that is taken by a responsible party after receiving a Notice of Noncompliance when considering civil money penalties. See Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank and 21 CFR part 17 for more information.

Notices of Noncompliance

The table below lists the Notices of Noncompliance sent by FDA and the amount of civil money penalties assessed, if any, for each responsible party or submitter listed.

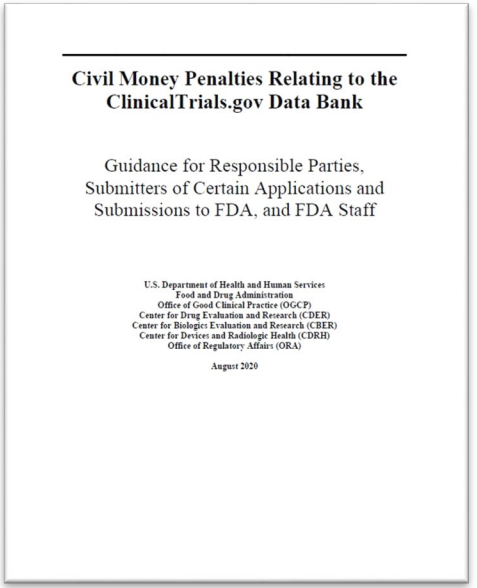
Responsible Party/Submitter	NCT Number	Notice of Noncompliance	Response Letter (if any)	Civil Money Penalty Amount (if any)
Ocugen	NCT03785340	4/15/2022	08/01/2022	
Petrikovets, Andrey M.D.	NCT03052816	8/31/2021	12/20/2021	
Accuitis Inc.	NCT03064438	7/26/2021	05/26/2022	
Acceleron Pharma, Inc.	NCT01727336	4/27/2021	12/13/2021	



Civil Money Penalty Guidance

The guidance addresses, among other things, how FDA intends to identify:

- Whether **responsible parties** have failed to submit required clinical trial registration and/or results information to ClinicalTrials.gov or submitted false or misleading information
- Whether **applicants** or **submitters** have failed to certify compliance or knowingly submitted a false certification


Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank

Guidance for Responsible Parties, Submitters of Certain Applications and Submissions to FDA, and FDA Staff

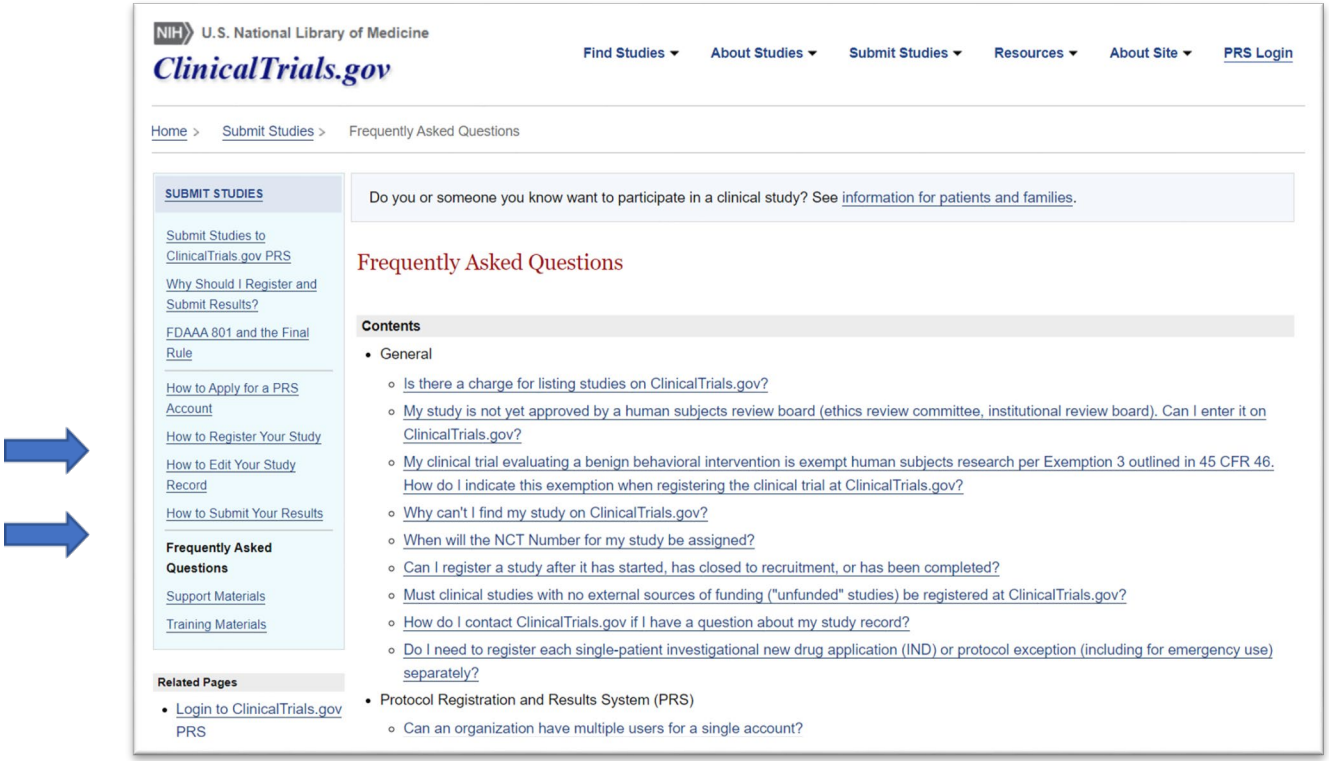
U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice (OGCP)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiologic Health (CDRH)
Office of Regulatory Affairs (ORA)

August 2020

CDER Compliance Activities

- Numerous Pre-Notices of Noncompliance issued
- Notices of Noncompliance issued and posted on FDA.gov
  - Information regarding the noncompliance is included in the associated ClinicalTrials.gov study records
  - Advanced search feature added to ClinicalTrials.gov that allows users to find study records with a Notice of Noncompliance
- No civil money penalties assessed to date

Resources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Why Should I Register and Submit Results?
FDAAA 801 and the Final Rule
How to Apply for a PRS Account
How to Register Your Study
How to Edit Your Study Record
How to Submit Your Results
Frequently Asked Questions
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Training Materials
Related Pages
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Do you or someone you know want to participate in a clinical study? See information for patients and families.
Frequently Asked Questions
Contents
General
Is there a charge for listing studies on ClinicalTrials.gov?
My study is not yet approved by a human subjects review board (ethics review committee, institutional review board). Can I enter it on ClinicalTrials.gov?
My clinical trial evaluating a benign behavioral intervention is exempt human subjects research per Exemption 3 outlined in 45 CFR 46. How do I indicate this exemption when registering the clinical trial at ClinicalTrials.gov?
Why can't I find my study on ClinicalTrials.gov?
When will the NCT Number for my study be assigned?
Can I register a study after it has started, has closed to recruitment, or has been completed?
Must clinical studies with no external sources of funding ("unfunded" studies) be registered at ClinicalTrials.gov?
How do I contact ClinicalTrials.gov if I have a question about my study record?
Do I need to register each single-patient investigational new drug application (IND) or protocol exception (including for emergency use) separately?
Protocol Registration and Results System (PRS)
Can an organization have multiple users for a single account?

Key Messages

- Clinical trial transparency is important
- FDA is responsible for ClinicalTrials.gov compliance and enforcement activities
- Sponsor or designee (responsible party) must ensure applicable trials are in compliance
- To ensure compliance, clear understanding of the responsible party's responsibilities for clinical trials reporting requirements (e.g., registration and results information reporting and deadlines) is essential

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