



FDA's Enforcement of ClinicalTrials.gov Reporting

Clinical trial sponsors, including sponsor-investigators who are academic researchers, have been required by law to register and report results on applicable clinical trials¹ in the ClinicalTrials.gov database for more than a decade. Events that occurred over the last year, and those occurring more recently, indicate the FDA's intention to exercise its enforcement authority. In April of 2021, the FDA sent a [Notice of Noncompliance](#) to Acceleron Pharma, an industry sponsor of a clinical trial, for failing to submit required results to ClinicalTrials.gov on time. If Acceleron fails to submit the required data within the mandated reporting timelines, the FDA warns of possible civil monetary penalties, which could reach more than \$10,000 per day, per study.

Now, more than ever, it is important for study teams to comply with the federal laws and regulations that require registration and results reporting in ClinicalTrials.gov. Per [Washington University's policy](#), it is the responsibility of Principal Investigators for any investigator-initiated applicable clinical trials to register, update and report results in the ClinicalTrials.gov database in a timely fashion.

The FDA will continue to encourage voluntary compliance with these requirements, but will pursue enforcement action when necessary to ensure that information is available on ClinicalTrials.gov as required by law for the benefit of clinical trial participants and public health.

Notices of Noncompliance are preceded by a "Pre-Notice of Noncompliance," and both are delivered in writing. Notices of Noncompliance are posted to the FDA's website, and noncompliance are posted on the study record on ClinicalTrials.gov by the National Institutes of Health (NIH). The NIH will continue to update ClinicalTrials.gov records with information regarding whether the clinical trial's noncompliance has been corrected, and the amount of civil money penalties assessed, if any.

If you receive a Pre-Notice or Notice from the FDA regarding ClinicalTrials.gov, immediately contact Michelle Jenkerson at jenkerson_m@wustl.edu or (314)-362-5626.

For more information about Pre-Notice or Notice of Noncompliance, Civil Monetary Penalties or Frequently Asked Questions, see the links below:

- [FDA Takes Action for Failure to Submit Required Clinical Trial Results Information to ClinicalTrials.gov](#)
- [NOTICE OF NONCOMPLIANCE ISSUED PURSUANT TO 42 U.S.C. 282\(j\)\(5\)\(C\)\(ii\)](#)
- [ClinicalTrials.gov - Notices of Noncompliance and Civil Money Penalty Actions](#)
- [FDA Guidance on Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank](#)
- [Frequently Asked Questions: ClinicalTrials.gov \(National Institutes of Health\)](#)

¹The FDA defines an [Applicable Clinical Trial \(ACT\)](#) as follows: Trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation. Trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance.