



Building a Clinical Trial Transparency Coalition

Universities Allied for Essential Medicines



FDA Amendments Act of 2007

- ▶ Requires public reporting of certain clinical trial results
- ▶ Goals: ensure patient/physician access to information, prevent scientific fraud, avoid duplication of efforts
- ▶ FDA Commissioner Califf: "If you do an experiment on a person and get consent, you really have the obligation to make the results known. This is fundamentally an ethical issue."

2019 Transparency Report

Key findings:

- ▶ **27 of the 40** top research universities were in violation of reporting requirements under FDAAA.
- ▶ **140 clinical trials** from the cohort studied had results missing from ClinicalTrials.Gov.

Impact of 2019 Transparency Report

Soon after publication, Columbia University and Northwestern University improved compliance from rates of **16.7% and 30% respectively to 100%**.

nature

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NEWS | 26 March 2019 | Correction [27 March 2019](#)

Top US institutes still aren't reporting clinical-trial results on time

PHARMALOT

Many leading universities are still failing to report clinical trial results



By [Ed Silverman](#) [Twitter](#) March 25, 2019

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2021 Transparency Report

Within the cohort UAEM focused on:

Total number of research institutions legally compliant under FDAAA (100% of clinical trials reported)

increased from

13 to 17 ↑

(from March 2019 to February 2021)

The number of institutions with

rates above 80%
increased from

16 to 36 ↑

(from March 2019 to February 2021)

Scope of the problem

FDAAA
TrialsTracker

US Govt could have imposed fines of at least

\$34,427,990,427



Fines claimed by US Govt

\$0



Total trials: 14,686

Results overdue: 3,549

Results reported late: 4,365

Percentage not in compliance: 60.5% (DeVito and Goldacre 2021)

Focus on FDA/NIH Enforcement & FOIA

FDA ENFORCES CLINICAL TRIAL TRANSPARENCY FOLLOWING UAEM'S WORK

FOR IMMEDIATE RELEASE

Food and Drug Administration Takes First-Ever Enforcement Action to Ensure Clinical Trials Transparency, Follows UAEM's Work

A huge win in the battle for transparency and honoring biomedical R&D best practices

April 28, 2021--Washington, D.C--Universities Allied for Essential Medicines North America (UAEM) applauds the Food and Drug Administration (FDA) for sending a **Notice of Noncompliance to Acceleron Pharma, Inc.** after the company failed to submit legally required clinical trial results to the public ClinicalTrials.gov database. This marks **the first time the agency has ever taken such action** against a trial sponsor. In July of 2020, the FDA had requested the manufacturer to promptly submit Phase 2 clinical trial results for their experimental kidney cancer treatments, which the company failed to do.

April 2022 Letter to FDA Commissioner

“The FDA should... establish an actionable prioritization framework for enforcement of FDAAA, and demonstrate an intent to begin more rigorous enforcement.”

ENDPOINTSNEWS

Meanwhile, the pressure is on FDA to do more in this area. A group known as the Universities Allied for Essential Medicines is calling on FDA commissioner Rob Califf to help the agency do its job of enforcing these trial publishing requirements.

“Although violations of the law have been so frequent and so flagrant that they could have generated over \$30 billion in fines to date, the FDA has historically neglected its duty to enforce FDAAA,” the UAEM wrote in a letter to Califf last week. “The FDA should therefore establish an actionable prioritization framework for enforcement of FDAAA, and demonstrate an intent to begin more rigorous enforcement.”

January 2023 E&C Committee Letter

ONE HUNDRED EIGHTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE
WASHINGTON, DC

Majority (202)
Minority (202)

January 1

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The Honorable Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Pallone pushes NIH and FDA to disclose steps being taken to ensure clinical trial results are reported

Dear Commissioner Califf and Director Tabak,



By [Ed Silverman](#) and [John Wilkerson](#) Jan. 19, 2023

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I write regarding concerns about the lack with requirements to report certain clinical trial results information to the ClinicalTrials.gov database. The law requires that certain clinical trial sponsors report results to ClinicalTrials.gov to expand the knowledge base, support additional research, and provide important safety and efficacy information to health care providers and researchers. These important goals depend on adequate compliance with applicable requirements and appropriate enforcement.

Questions include...

1. How many Pre-Notices and Notices of Noncompliance has FDA sent?
2. For NIH-funded trials, what compliance and enforcement actions has NIH taken?
3. How does FDA most commonly assess compliance?
4. Please explain how FDA's compliance and enforcement actions to date have aligned with prioritization [based on product risk, public health need, compliance history, and whether there are additional violations of clinical investigation requirements, as listed in the 2020 guidance].
5. Has FDA approved or cleared premarket submissions that do not include the certification of ClinicalTrials.gov compliance required by section 402(j)(5)(B) of the Public Health Service Act? If so, what is the basis for taking such action?

Pediatric Trials Report & FDA Response

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Many pediatric drug study results were never posted to a U.S. government database

FDA: “The agency’s goal is to achieve voluntary compliance... provide the opportunity for responsible parties to take voluntary corrective actions before the agency proceeds with a civil or criminal enforcement action... We will continue to monitor compliance with the ClinicalTrials.gov requirements and will take appropriate action as warranted.”

Next Steps: Petition & Letters of Support

- ▶ Petition filing date: **February 27th**
- ▶ The petition calls for:
 - ▷ More enforcement
 - ▷ Prioritization framework (emphasis on trials of public interest)
 - ▷ Publicizing of preliminary notices