

From: OC GCP Questions
To: [REDACTED]
Subject: RE: question regarding compliance and enforcement of NIH ClinicalTrials.gov databank requirements
Date: Monday, February 09, 2015 10:44:00 AM

Good morning,

Since passage of Title VIII of FDAAA, FDA has had certain implementation and compliance/enforcement responsibilities related to ClinicalTrials.gov. FDA continues to review records and contact individual responsible parties, as appropriate, when it appears from the ClinicalTrials.gov record and other information available to FDA that clinical trial information has not been submitted correctly or in a timely fashion. We expect that when the final regulations are promulgated as required under FDAAA, FDA be able will be able to pursue a more complete compliance/enforcement program. To date, no civil money penalties have been assessed under the statute.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

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Office of Good Clinical Practice
Food and Drug Administration

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [REDACTED]
Sent: Thursday, February 05, 2015 6:42 PM
To: OC GCP Questions
Subject: question regarding compliance and enforcement of NIH ClinicalTrials.gov databank requirements

Dear Sir or Madam,

I am interested in finding out the process regarding enforcement of noncompliance with registry of a clinical trial on clinicaltrials.gov website.

In particular, would the responsible party be notified, audited and how much time would be allowed from notification of noncompliance to updating trial information to become compliant with regulations?

Also, would fines be levied, and if so, at what point in time? That is, would any fine be retroactively applied from notification of noncompliance to becoming compliant?

In general, have responsible parties been fined for noncompliance with regulations?

Do you expect changes in enforcement/fines with regulations proposed under the notice of proposed rulemaking currently in process?

Thank you,

