

**From:** OC GCP Questions  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Results Publication enforcement on clinicaltrials.gov  
**Date:** Monday, May 05, 2014 8:15:00 AM

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Good morning,

Thank you for your inquiry. There can be many reasons why a particular trial may not have results posted. Only trials which meet the definition of an “applicable clinical trial,” as defined under [Title VIII of the Food and Drug Administration Amendments Act of 2007](#) (FDAAA), are required to register with ClinicalTrials.gov. So, if the trial you referred to in your inquiry does not meet that definition, there may not be a requirement to submit results, even if it is registered.

FDAAA also only requires the submission of results for approved products and also has provisions for the delay in submission of results for manufacturers seeking a new use of a drug or device. In addition, FDAAA also allows for the Director of NIH to grant an extension of the deadline for submission of results to ClinicalTrials.gov. This type of information may not be apparent when reviewing the ClinicalTrials.gov record.

Many of the items I have mentioned are very detailed and specific to the product and trial in question. As a result, it would not be uncommon to see trials which are registered with ClinicalTrials.gov which do not have results posted.

I hope this information is helpful. Please contact us again at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) should you have additional questions.

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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:** Friday, May 02, 2014 8:47 AM  
**To:** OC GCP Questions  
**Cc:** [REDACTED]  
**Subject:** Results Publication enforcement on clinicaltrials.gov

Hello;

I am very interested in the results of the trial [REDACTED].

I have no experience in interpreting the status information on the website so there may very well be a perfectly reasonable reason as to why the study results have not been published. May I ask that you look into it, and if they are not publishing as required please see what you can do to persuade them.

Thank you

Yours truly

[REDACTED]