

**From:** OC GCP Questions  
**To:** [REDACTED]  
**Subject:** RE: Are all clinicaltrials.gov studies considered to be FDA registered trials?  
**Date:** Wednesday, September 30, 2015 8:42:00 AM

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Good morning,

I'm not clear what you mean by "FDA registered trials" in this context. Trials which are required to register with ClinicalTrials.gov under the [Food and Drug Administration Amendments Act of 2007](#) (FDAAA) are referred to as "applicable clinical trials" and defined in the statute. Not all trials listed in the ClinicalTrials.gov databank are "applicable clinical trials" and therefore may not be subject to the requirements of FDAAA. For example, there are many behavioral trials listed in ClinicalTrials.gov which are voluntarily submitted but are not required to meet the statutory requirements.

The NIH website contains the [Elaboration of Definitions](#) document which can be useful in making the determination of whether a trial is an applicable clinical trial and required to register and submit results to ClinicalTrials.gov.

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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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.

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**From:** [REDACTED]  
**Sent:** Tuesday, September 29, 2015 2:10 PM  
**To:** OC GCP Questions  
**Subject:** Are all clinicaltrials.gov studies considered to be FDA registered trials?

Dear Friend,

Are all clinicaltrials.gov studies considered to be FDA registered trials?

Thank you,

[REDACTED]