

From: OC GCP Questions
To: [REDACTED]
Subject: RE: Registering Clinical Trials
Date: Thursday, March 05, 2015 1:14:00 PM

Good afternoon,

Thank you for your inquiry. Under [Title VIII of the Food and Drug Administration Amendments Act of 2007](#) (FDAAA), only certain “applicable clinical trials” are required to register with ClinicalTrials.gov. You may wish to refer to the NIH [Elaboration of Definitions](#) document for more information regarding which trials are required to submit information to ClinicalTrials.gov.

Hospitals and other organizations which are the “responsible party” for an “applicable clinical trials” would be required to register their trial with ClinicalTrials.gov. Please bear in mind that trials that do not fall under the definition of an “applicable clinical trial” are not required to with ClinicalTrials.gov databank but may submit information related to the trial on a voluntary basis.

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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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: Wednesday, March 04, 2015 2:29 PM
To: OC GCP Questions
Subject: Registering Clinical Trials

Hello,

I am a librarian in [REDACTED] and have been asked to look into alternatives to clinicaltrials.gov for locating current clinical drug trials. We found centerwatch.com and research-match.org along with the NIH Clinical Research Studies databases, but would like to know if there are any other ways to find out about studies.

Are hospitals or other research institutions required to post information about trials? If yes, is there a central location for this?

Thanks,

