From: OC GCP Questions
To: [redacted]
Subject: RE: Question regarding listing of study sites on clinicaltrials.gov
Date: Friday, January 24, 2014 11:25:00 AM

Good morning,

I would point you to the description of the required fields for clinical trial registration which are outlined in section 402(j)(2)(A)(ii)(III)(cc) of the Public Health Service Act (42 U.S.C. § 282(j)). This section requires submission of location and contact information including "the facility name and facility contact information (including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location may be accessed)." The text of the statute can be found at http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf#page=82 .

Should you have other questions related to how to register your study or technical issues related to information in the ClinicalTrials.gov databank, you should contact the ClincialTrials.gov staff at the National Library of Medicine at NLM Helpdesk.

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

Patrick J. McNeilly, Ph.D., C.I.P.
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: Friday, January 24, 2014 8:17 AM
To: OC GCP Questions
Subject: Question regarding listing of study sites on clinicaltrials.gov

Hello,

I am trying to find specific guidance regarding the listing of individual study sites for a clinical trial on clinicaltrials.gov. Specifically, for a multi-site study, is it a requirement that all study sites participating in the trial be listed on the trial's clinicaltrials.gov page?

Thank you,

[REDACTED]