From: OC GCP Questions
To: [redacted]
Subject: RE: Registration question
Date: Wednesday, July 02, 2014 7:58:00 AM

Good morning,

Please be aware that the determination of whether a trial is an applicable clinical trial has to be made by the sponsor/responsible party associated with that trial and familiar with all aspects of the clinical trial. The NIH website does contain the Elaboration of Definitions which can be referred to as well as various FAQs. FDA cannot make that determination for any party.

Your e-mail appears to indicate that you are studying a drug. You may wish to consider the following, along with a review of the NIH Elaboration of Definitions document. Is your study a clinical investigation, as defined under 21 CFR 312.3? Is it controlled? Is the study something other than a Phase 1 study? Is it being conducted in at least one site in the United States? The answers to these questions should help in making a determination of whether the trial is an applicable clinical trial and required to be registered with ClinicalTrials.gov.

FDA does have guidance related to the requirements at 21 CFR 50.25(c) which includes a description of the definition of an applicable clinical trial. You may wish to review the guidance at the link below.
www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf

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

From: [REDACTED]
Sent: Tuesday, July 01, 2014 1:38 PM
To: OC GCP Questions
Subject: Registration question

Hello,

I was wondering if I am required to register my study on clinicaltrials.gov.

Study Information:
Non Inferiority Study
Non absorbed, local acting drug
Compared to RLD
Healthy adult volunteers

Thank you,

[REDACTED]