From: OC GCP Questions
To: [redacted]
Subject: RE: FDA IDE and trial registration question
Date: Wednesday, June 10, 2015 9:35:00 AM

Good morning,

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. FDAAA defines an "applicable device clinical trial" as:

(1) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the FD&C Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); or

(2) a pediatric postmarket surveillance as required under section 522 of the FD&C Act.

Device trials which do not meet this definition would not be required under FDAAA to register with ClinicalTrials.gov. It is possible that device a trial being conducted under an IDE may not meet this definition, for example, because it is not studying a health outcome or may not be comparing an intervention against a control in humans.

FDA would not be able to opine on whether such a trial would be required to register with any other public trial registry.

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, June 09, 2015 3:45 PM
To: OC GCP Questions
Subject: FDA IDE and trial registration question

Hello,

If a study has been registered as an FDA approval study under an investigational device exemption number, should it also be registered as a clinical trial on ClinicalTrials.gov? We had asked one of our authors to register their trial in a public trial registry such as ClinicalTrials.gov and they responded that it was registered as an FDA IDE approval study. Would this be acceptable, or should they have also registered separately in a public trial registry?

Thank you very much for your input.

Best,
[redacted]