From: OC GCP Questions
To: [redacted]
Subject: RE: clinicaltrials.gov registration question
Date: Friday, March 10, 2017 9:10:00 AM
Attachments: [redacted]

Good morning,

There is no requirement to register a trial with ClinicalTrials.gov that does not meet the definition of an applicable clinical trial. Submitting a 510(k) to FDA does not alter the requirements for registration with ClinicalTrials.gov. FDA does require that Form FDA 3674 (certification of compliance with the requirements of the ClinicalTrials.gov databank) accompany 510(k) submissions that include information from a clinical trial. Attached is a link to Form FDA 3674, as well as the instructions for completing this form. You may wish to take note of the instructions for Item 9. when filling out the form.

Form FDA 3674
https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf
Instructions for Form FDA 3674
https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM354618.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.
Captain, USPHS

Senior Health Policy Analyst

Office of the Commissioner
Office of Good Clincial Practice
U.S. Food and Drug Administration

From: [redacted]
Sent: Thursday, March 09, 2017 11:49 AM
To: OC GCP Questions
Subject: clinicaltrials.gov registration question

Good morning. One of our clients has a question regarding clinicaltrials.gov registration of an a trial that was completed several years ago. Company A manufactured a device OUS and conducted a clinical study of that device entirely OUS. As this was not an 'applicable clinical trial' under the clinicaltrial.gov registration requirements, it was not registered. Company B has now purchased the device technology and associated data and plans to submit the clinical trial data in support of a 510(k) notice.

Questions:

- Does this completed trial now need to be registered as it is being submitted as part of a 510(k) notice? As noted above, at the time the trial was conducted, all entities and conduct were OUS and there was no plan to seek FDA clearance.
- If registration is required, is it appropriate for Company B to register the trial even though they were not the sponsor or otherwise involved with the study?

Thanks so much for your assistance.

Best regards,

[redacted]

[redacted]