From: OC GCP Questions
To: [redacted]
Cc: [redacted]
Subject: RE: Registration of an IVD study on clinicaltrials.gov
Date: Monday, June 08, 2015 11:34:00 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. FDA cannot make that determination for any party. You may wish to discuss this issue with your legal counsel.

Since your trial appears to be involve a device, some important considerations when making such a determination relate to whether the study (i) is looking at a health outcome; (ii) is looking at a prototype device or studying the feasibility of a device and not related to health outcomes; or (iii) involves a control in human subjects?

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: Monday, June 08, 2015 4:02 AM
To: OC GCP Questions
Cc: [redacted]
Subject: Registration of an IVD study on clinicaltrials.gov

Dear Sir/Madam,

I'm writing to understand whether a clinical study with an in vitro diagnostic device (IVD) needs to be registered on clinicaltrials.gov.

The study in question is an IDE exempt, method comparison study where test and predicate devices (both IVDs) will be tested on prospectively collected human blood specimens. Study data will be used in support of a 510(k) application.

I have reviewed in detail the Document available on the FDA website entitled " ELABORATION OF

DEFINITIONS OF RESPONSIBLE PARTY AND APPLICABLE CLINICAL TRIAL" dated 9 Mar 2009 but am unable to come to a definite conclusion on this matter.

Thanks in advance and best regards

[redacted]