From: OC GCP Questions
To: [redacted]
Subject: RE: Research
Date: Friday, March 21, 2014 9:37:00 AM

Good morning,

Only applicable clinical trials are required to be registered on ClinicalTrials.gov. Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) [please see http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf#page=82] further defines an applicable drug clinical trial as a controlled clinical investigation, other than a Phase I clinical investigation, of a drug subject to section 505 of the FD&C Act or section 351 of the PHS Act. As you can see, certain trials would fall outside this definition. For example, Phase I studies would not be required to be registered on ClinicalTrials.gov, even if they were submitted to FDA and an investigator signed a 1572. However, trials may be submitted voluntarily to ClinicalTrials.gov. It is not uncommon that trials which are not required to be submitted under FDAAA actually are registered by the responsible party for a variety of reasons, such as to assist with recruitment for the trial.

Additionally, there is no direct link between a 1572 and a ClincialTrials.gov registration. The investigator signing the 1572 may not be the responsible party who is required to register the trial. The responsible party may fail to register an applicable clinical trial. This could also explain why a trial being conducted by at a particular site does not appear in the ClincalTrials.gov databank.

Simply put, just because an investigator signs a 1572 does not mean the trial will necessarily be registered with ClincialTrials.gov.

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: Thursday, March 20, 2014 5:09 PM
To: OC GCP Questions
Subject: Research

Dear FDA,

Can you tell me if a form 1572 is filled out, does that mean the clinical trial it is connected to will be found on www.clinicaltrials.gov? Or can a 1572 be filled out and the trial it is connected to not be listed on www.clinicaltrials.gov.

Thank you
[REDACTED]