From: OC GCP Questions
To: [redacted]
Subject: RE: clinicaltrials.gov
Date: Monday, March 12, 2018 7:34:00 AM

Good morning,

The submission of summary results information under the Food and Drug Administration Amendments Act of 2007, including information for primary and secondary outcomes, for applicable clinical trials has been required since September 27, 2008. The requirements for submission of clinical trial registration and results information were further clarified and expanded under the HHS regulations at 42 CFR part 11 which went into effect on January 18, 2017.

Clinical trials which meet the definition of an "applicable clinical trial" must register and submit results information, as required under 42 CFR part 11. Please see the HHS final rule at https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission

I hope this information is helpful. Should you have additional questions about interpretation of the HHS regulations at 42 CFR part 11, please contact the ClinicalTrials.gov staff at the NIH at register@clinicaltrials.gov .

Patrick J. McNeilly, Ph.D.
Senior Health Policy Analyst

Office of Good Clinical Practice
U.S. Food and Drug Administration

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [redacted]
Sent: Thursday, March 08, 2018 5:58 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: clinicaltrials.gov

Would you please tell me the date that the primary and secondary outcome of the study went into effect (the date it was mandated)? Additionally, does a firm have to report primary and secondary outcomes in exploratory studies on the clinicaltrials.gov website?

Thank you,

[redacted]