From: OC GCP Questions
To: [redacted]
Subject: RE: question about disclosing FDA-funded trial results on ClinicalTrials.gov
Date: Friday, January 02, 2015 10:07:00 AM

Good morning,

FDA does not presently have a policy similar to that being proposed in the draft NIH policy. I am not in a positon to comment on whether FDA would adopt such a policy. However, clinical trials which are funded by FDA and meet the definition of an applicable clinical trial, as defined under Title VIII of FDAAA, would be required to register and submit results to ClinicalTrials.gov, as appropriate.

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

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.

From: [redacted]
Sent: Wednesday, December 31, 2014 12:15 PM
To: OC GCP Questions
Subject: question about disclosing FDA-funded trial results on ClinicalTrials.gov

Hello,

I hope this finds you well and enjoying a pleasant day.

Since [redacted], I have been involved in clinical trial disclosure in the pharmaceutical industry and the academic research arenas. Recently, the NIH has submitted for public comment a proposed change to their clinical trial registration and results reporting requirement for NIH-funded trials:

> "NIH is proposing to issue a policy to ensure that all NIH-funded clinical trials are registered and have **summary results**, including adverse event information, submitted to ClinicalTrials.gov. Compliance with this policy will be a term

> and condition in the Notice of Grant Award and a contract requirement in the Contract Award. This proposed policy supports the NIH mission to advance the translation of research results into knowledge, products, and procedures that improve human health."
>
> "This Policy applies to all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by NIH, regardless of study phase, type of intervention, or whether they are subject to the FDAAA registration and results submission requirements set forth in Section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)). For purposes of this Policy, a clinical trial is defined as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

This newly proposed rule would require summary results posting to ClinicalTrials.gov and also more clearly defines what is meant by "clinical trial."

Because I advise both industry and academic researchers on the requirements for disclosing both protocol and results information to ClinicalTrials.gov, could you please advise as to whether the FDA might also move forward with a similar policy for FDA-funded trials? I have attached a copy of the NIH policy for your convenience.

Best wishes for a peaceful and prosperous new year.

Kind regards,

[redacted]