From: OC GCP Questions
To: [redacted]
Subject: RE:
Date: Wednesday, January 22, 2014 11:10:00 AM

Good morning,

A description of the required fields for clinical trial registration are outlined in section 402(j)(2)(A)(ii)(I)(ll) of the Public Health Service Act (42 U.S.C. § 282(j)). This section requires descriptive information regarding the clinical trial, including "outcomes, including primary and secondary outcome measures." The text of the statute can be found at http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf#page=82 .

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, January 20, 2014 1:20 PM
To: OC GCP Questions
Subject:

If a protocol includes both a primary and secondary outcome, must both the primary and secondary outcome be included when registering a trial under clinical trial.gov. I am working with a client who believes the secondary outcome is optional (even when in protocol). Can you clarify and provide appropriate reference.

thank you -

[REDACTED]