

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)(II) 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.

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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: 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]