

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: RE: registration requirements for clinicaltrials.gov
Date: Monday, September 25, 2017 2:25:00 PM

Dear [REDACTED],

FDA cannot respond to specific questions about the registration of studies on the clinicaltrials.gov site. Any questions related to the following should be addressed to the ClinicalTrials.gov staff at the NIH at register@clinicaltrials.gov :

Regulations at 42 CFR Part 11
How to register studies and enter clinical trial results information
Technical issues related to submission of information to the ClinicalTrials.gov databank

Some general information about FDA's role in clinicaltrials.gov can be found at
<https://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/fdasroleclinicaltrials.govinformation/default.htm>

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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: Sunday, September 24, 2017 11:56 PM
To: OC GCP Questions
Subject: registration requirements for clinicaltrials.gov

Hello -

Can you please clarify requirements for registration of an investigational device study.

1. Must ALL secondary outcomes defined in the protocol be included in the registration or is this left to sponsor discretion, based on degree of significance?

2. Must ALL inclusion/exclusion criteria defined in the protocol be included in the registration or is this left to sponsor discretion, based on degree of significance?

Thank you for your help and I look forward to your reply.

Regards,

[REDACTED]

[REDACTED]