From: Brown, Sheila (OGCP)
To: [redacted]
Subject: RE: Question regarding clinicaltrials.gov registration
Date: Friday, May 12, 2017 11:27:00 AM
Attachments: [redacted]

Dear [redacted],
Please be advised that FDA cannot provide legal advice regarding whether your trial is an "applicable clinical trial." Under Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and 42 CFR 11 certain applicable clinical trials are required to register and submit results information to the ClinicalTrials.gov databank. The determination of whether a trial is an "applicable clinical trial" has to be made by the sponsor/responsible party associated with that trial and familiar with all aspects of the clinical trial. FDA cannot make that determination for any party.

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.

From: [redacted]
Sent: Thursday, May 11, 2017 4:09 PM
To: OC GCP Questions
Subject: Question regarding clinicaltrials.gov registration

Dear FDA,
We have a question regarding our need to register our clinical trials on clinical trial.gov. On page 65011

of Vol 81 No. 183 of the Federal Register (https://www.gpo.gov/fdsys/pkg/FR-2016-09-21/pdf/2016-22129.pdf) it states that 4 conditions must be met in order to require registration. The 4 conditions are listed on page 65011 (third column) include:

(1) It is a prospective clinical study of health outcomes;
(2) it compares an intervention with a device against a control in human subjects;
(3) the studied device is subject to section 510(k), 515, or 520(m) of the FD&C Act; and
(4) it is other than a small clinical trial to determine the feasibility of a device or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes.

QUESTION: Our question relates to the fact that our clinical trials, which are [redacted] do not meet criteria 2 above. There is no intervention and the [redacted]

Can you confirm that in this scenario, that we do not need to register our clinical trials on www.clinicaltrials.gov? We did correspond with the National Library of Medicine who agreed that we do not need to register (see email below), however, it would be great if we could receive confirmation from FDA.
Thanks!
[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]NIH / NLM / NCBI - NCBI Support [mailto:info@ncbi.nlm.nih.gov]
[redacted]

If the patient is receiving an intervention that they normally don't receive through standard of care, then it should be

registered.

ClinicalTrials.gov