From: OC GCP Questions
To: [redacted]
Subject: RE: Question Related to FORM FDA 3674
Date: Monday, September 17, 2018 10:53:00 AM
Attachments: [redacted]

Good morning,

Questions related to the regulations related to clinical trial registration and summary results information submission should be addressed by the NIH/National Library of Medicine at register@clinicaltrials.gov . In general, per 42 CFR 11.24, an applicable clinical must be registered no later than 21 days after the enrollment of the first subject.

There may be a delay between submitting registration information and the receipt of an NCT number. NIH/NLM would be in a better position to provide specifics on how much of a delay there would be.

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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Office of Good Clinical Practice
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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: Thursday, September 13, 2018 1:30 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>

Subject: Question Related to FORM FDA 3674

Hello,

I have a client who is asking what is the latest date that a clinical trial (per Item 9c of the FORM FDA 3674) can be registered at ClinTrials.gov? The protocol has already been submitted to the sponsor's IND (with a FORM FDA 3674 and a statement in the cover letter they will provide the NCT number at a later date via an updated FORM FDA 3674), however "ramp up" to initiating the study is taking more than a few months. I have reviewed FDA's webpage (Form FDA 3674). Please let me know what the regulations are for timing of registering the clinical trial and obtaining the NCT number (which would then immediately be provide to the IND).

For example:

Prior to initiation of the study?
Within 30 days of initiation the study?
Other?

Thanks!

Best Regards,

[redacted]

[redacted]

[redacted]

[redacted]