

From: OC GCP Questions
To: [REDACTED]
Subject: RE: Clinical Trial Registration Timeline Questions
Date: Wednesday, July 26, 2017 11:14:00 AM
Attachments: [REDACTED]

Good morning,

Applicable clinical trials must be registered with ClinicalTrials.gov no later than 21 days after the enrollment of the first subject. There is no prohibition from registering a trial prior to that time. Should the recruitment status or other required information related to the trial change, the ClinicalTrials.gov information may need to be updated, as necessary. Registration of a trial on ClinicalTrials.gov does not affect the review process for an IND and clinical trials which require an IND must follow the requirements under 21 CFR 312.

Per the ClinicalTrials.gov website, "After you release a record and it is accepted by review staff for publication, the record, including its NCT Number, will be available on ClinicalTrials.gov within 2–5 business days." Please see <https://clinicaltrials.gov/ct2/manage-recs/how-register>

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
U.S. 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: Tuesday, July 25, 2017 6:31 PM
To: OC GCP Questions
Subject: Clinical Trial Registration Timeline Questions

Hello,

I have two questions regarding clinicaltrials.gov registration timelines:

- 1) I understand that a clinical trial must be registered within 21 days of enrolling the first subject; can the entry be submitted prior to the IND effective date?
- 2) Once the trial is submitted/entered, how long is it under review before it goes live/enters recruitment?

Thanks so much for your help in answering these questions. Please don't hesitate to ask me any follow-ups.

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