**From:** OC GCP Questions
**To:** [redacted]
**Subject:** RE: Question about NCT number submission for new protocol
**Date:** Friday, April 06, 2018 10:09:00 AM
**Attachments:** image004.png
[redacted]
FDA-3674_instr supplmnt_508(2.13).pdf
[redacted]

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Good morning,

As you have described, phase I trials of a drug or biologic product are not "applicable clinical trials" as the term is defined in section 402(j) of the Public Health Service Act or its implementing regulations at 42 CFR part 11. Per the instructions for Form FDA 3674 (see attached), box 9. B. "should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies."

The NCT number requested in Field 10 of Form FDA 3674 may be left blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT number(s) for the "applicable clinical trial(s)" for which data is included, relied upon, or otherwise referred to in the application/ submission.

The absence of the NCT number on the Form FDA 3674 will not impact the review of the IND submission. Regarding providing the NCT number at a later date, should your firm submit a new protocol to the IND you can include the NCT number for the original protocol on the new Form FDA 3674.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

**Patrick J. McNeilly, Ph.D.**
*Senior Health Policy Analyst*

**Office of Good Clinical Practice**
**U.S. Food and Drug Administration**

[redacted]

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.

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**From:** [redacted]
**Sent:** Thursday, April 05, 2018 7:45 PM
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>
**Subject:** Question about NCT number submission for new protocol

Dear FDA,

I would like to clarify some cases related to Form FDA 3674 - Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions .

**First,** according to **section 402(j)(1)(A)(i) of the PHS Act (42 U.S.C. § 282(j)(1)(A)(i)) and at 42 CFR 11.10**, phase I trial (conducted in US) is not required to submit NCT number and checkbox B of 9 in Form 3674 will be marked when this certification is signed.

**Second**, for new protocol submission of other phases of clinical trials (applicable clinical trials) to IND, sometimes the NCT number might be not available if the Sponsor has not registered the study into clinicaltrials.gov yet or still under evaluation by PRS system.

In this case, according to **section 10 NCT numbers in " INSTRUCTIONS FOR COMPLETION OF FORM FDA 3674 – CERTIFICATION OF COMPLIANCE Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))"**,

*Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT number(s) for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.*

IND can be submitted with Form 3674 without NCT number. Please let me know if my understading is incorrect.

Third, if IND is submitted without NCT number, will  t impact FDA's review and approval timeline for the protocol?
Also, when is the appropriate time to submit NCT number for the Sponsor after getting NCT number?
-Just after having NCT number (no later than 21 days after first subject signed ICF)
-Next application/submission

Thank you for your time to read my question. Please forward my mail if you are not the right person or department for my questions.

Sincerely yours,
[redacted]

[redacted]