**From:** [redacted]
**To:** [redacted]
**Cc:** CDER DRUG INFO
**Subject:** Marketing during a clinical trial
**Date:** Thursday, July 12, 2018 8:11:00 AM
**Attachments:** [redacted]

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Good morning –

FDA is not familiar with the term “Continuity Program”. You state the research participants are enrolled in a phase 3 trial but the investigational product has not yet been approved by FDA. This is what we have stated in the past regarding IND start-up and approval although it may not totally apply to the situation that you describe.

This question, when previously raised, was discussed by our office, the Office of Good Clinical Practice (OGCP), in conjunction with others in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). We did not consult with the Center for Devices and Radiological Health (CDRH) because the regulations at 21 CFR 812.110(a) are clear and state:

"An investigator may determine whether potential subjects would be interested in participating in an investigation, but shall not request the written informed consent of any subject to participate, and shall not allow any subject to participate before obtaining IRB and FDA approval."

For drugs and biologics, the regulations at 21 CFR 312.20(b) state:

"A sponsor shall not begin a clinical investigation subject to 312.2(a) until the investigation is subject to an IND which is in effect in accordance with 312.40."

FDA's interpretation is that recruitment, obtaining informed consent, and screening subjects for a specific study that is subject to an IND is considered "beginning the clinical investigation" and such activities cannot be performed until an IND is in effect (30 days after FDA receives the IND, or earlier if the sponsor is so notified by FDA). Recruiting subjects, obtaining informed consent, and screening subjects for a specific IND study prior to the IND being in effect is not in compliance with the FDA regulations.

OGCP believes that no study activities (which include consenting and screening) of subjects should begin on any study prior to ensuring that all regulatory requirements are met (whether that be an effective IND in place or whether that means the innovator product is approved by FDA for marketing. The IRB can go ahead and review and even approve a study, but no study activities should begin prior to all requirements being met. We liken this to ensuring that "all green lights are lit" prior to proceeding.

Please see FDA’s information sheet on Recruiting Study Subjects --Search for FDA Guidance Documents > Recruiting Study Subjects - Information Sheet

Please  contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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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.

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**From:** [redacted]
**Sent:** Wednesday, July 11, 2018 4:49 PM
**To:** [redacted] CDER DRUG INFO <DRUGINFO@fda.hhs.gov>
**Subject:** Marketing during a clinical trial

Hello,
We are asking for input on how to approach a request from a drug sponsor to provide what they term "Continuity Program" materials to research participants. The participants are enrolled in a Phase 3 trial of the drug product. The company would like to begin the process of collecting patient information and getting "paperwork" such as authorizations in place so they can begin working with subjects to transition them to the commercial product  if it is approved. The materials indicate that they have submitted to the FDA, but do not yet have approval for the drug.

We are concerned that this is beginning a marketing process prior to IRB approval and though they are not charging, may be inappropriate in the context of the ongoing study. However, we wanted to understand if this was a common process and acceptable during the drug approval review process.

Thanks.

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[redacted]

[redacted]