From: OC GCP Questions
To: [redacted]
Cc: [redacted]
Subject: RE: Is this study FDA-regulated
Date: Wednesday, May 28, 2014 2:13:00 PM
Attachments:

Dear [Redacted]-

Thank you for your question. I'm sure you are aware of FDA's September 2013 guidance titled, "Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND", which can be found at the following link: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm229175.pdf.

At the top of page 4 of this guidance, section B states:

> **B. What Is a Clinical Investigation?**
>
> The IND regulations in § 312.3(b) define *clinical investigation*[7] as:
>
> . . . [an] experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of [the IND regulations], an experiment is any use of a drug [whether approved or unapproved] except for the use of a marketed drug in the course of medical practice.

7 Additional information on clinical investigations is available on FDA's Web site at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.

Based on the limited information provided, it appears that the study you describe would be considered a clinical investigation rather than the use of a marketed drug in the course of medical practice. It would appear that, if not for the study, participants would not be randomized to receive one delivery method over another (topical vs. oral antibiotics). While the current protocol may not dictate which product is used once randomized, the act of randomization to a particular route of administration in this case dictates what the physician administers to a participant, which may differ from what a physician may administer in the course of medical practice.

If needed, the sponsor, or sponsor-investigator if applicable, is welcome to inquire with the applicable review division at FDA with more specifics of the proposed study. Section VIII. of the guidance I mentioned above has contact information for the various centers at FDA and advises that if a sponsor or sponsor-investigator is uncertain about whether or not the IND regulations apply, they should contact the appropriate review division. I am also happy to assist in identifying the appropriate review division if needed.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [Redacted]
Sent: Thursday, May 22, 2014 12:48 PM
To: OC GCP Questions
Cc: [Redacted]
Subject: Is this study FDA-regulated

Janet,

This is a study where subjects are randomized into two groups: (1) topical antibiotics or (2) oral antibiotics. After that decision, the choice of which topical antibiotic or which oral antibiotic is up to the discretion of the treating physician. After than subjects have tests of their microbial flora genome sequences, complete a survey, and get clinical data collected.

The main issue is whether FDA considers this “the use of a marketed drug in the course of medical practice” and there for is not an “experiment” per 21 CFE 312.3(b) and therefore not a clinical investigation per 21 CFR 312.3(b).

My opinion is that this is a clinical investigation of a drug, that the drugs that might be prescribed need to be listed in the protocol, and that those drugs need an IDE or need to fall into an IND exemption category, specifically that dose, route, and population do not present increased risks, and that the drugs and their reasonably foreseeable risks and discomforts need to be disclosed to the subject. I am getting pushback from the investigator who says that there are hundreds of drugs that might be used and that these requirements are unreasonable.

I wanted to get your feedback on this. If this is FDA-regulated, no explanation is needed. If not, please let me know where my thinking is wrong.

Thank you,

[Redacted]