From: OC GCP Questions
To: [redacted]
Subject: We met at MAGI- Interested in Feedback on Investigator Oversight
Date: Monday, August 28, 2017 6:25:00 AM
Attachments: [redacted]

Good morning –

You email was forwarded to my office for a response. FDA does not have a standard number of studies for investigators to maintain in order to ensure proper oversight.

FDA regulations require sponsors of clinical investigations to select only investigators qualified by training and experience to investigate the test article (see 21 CFR §§ 312.53 and 812.43). FDA considers this to include the investigator meeting any licensing requirements of the jurisdiction where the trial takes place. The regulations further require investigators to supervise the testing (for investigations of drugs, including biological products, under 21 CFR Part 312, investigators commit themselves to personally conduct or supervise the investigation; for investigations of medical devices, under 21 CFR Part 812, investigators commit themselves to supervise all testing of the device involving human subjects). Investigators may delegate a task to individuals who are qualified to perform the task, including being appropriately licensed.

FDA has a guidance document for industry titled, "Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects" that can be found at www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm187772.pdf . Please see question #3 on page 4.

The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task. Appropriate delegation is primarily an issue for tasks considered to be clinical or medical in nature, such as evaluating study subjects to assess clinical response to an investigational therapy (e.g., global assessment scales, vital signs) or providing medical care to subjects during the course of the study. Most clinical/medical tasks require formal medical training and may also have licensing or certification requirements. Licensing requirements may vary by jurisdiction (e.g., states, countries). Investigators should take such qualifications/licensing requirements into account when considering delegation of specific tasks. In all cases, a qualified physician (or dentist) should be responsible for all trial-related medical (or dental) decisions and care.

Kind regards,

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Wednesday, August 23, 2017 8:03 AM
To: [redacted]
Cc: OC GCP Questions
Subject: RE: We met at MAGI- Interested in Feedback on Investigator Oversight

Hi [redacted] –

How nice it is to hear from you! My apologies for not replying until now.

Unfortunately, I am not able to answer the question directly as there is a formal process within the FDA to answer a query that comes directly to an FDA employee. I can direct you to the Office of Good Clinical Practice (OGCP), and more specifically, their website where you can send in questions and/or view the repository where all questions to the agency are housed.
https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm

https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

I've included the Office of Good Clinical Practice (OGCP) email as a recipient so that they may address your question.

I wish you the very best with finding the answer to your question.

Kind regards,

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

From: [redacted]
Sent: Monday, August 21, 2017 10:10 AM
To: Hewett, Jan
Cc: [redacted]
Subject: We met at MAGI- Interested in Feedback on Investigator Oversight

Good morning, [redacted]

I hope you're doing well. We met at the MAGI conference (we ate lunch together) and I apologize for not following up sooner.

I'm extremely eager to pick your brain regarding investigator oversight if you have a few minutes to spare. I'm asking the same questions to our study sponsors and hope to receive guidance from the FDA point of view as well.

Does the FDA have a standard number of studies that is too many studies for investigators to maintain in order to ensure proper oversight? I assume there is no perfect number but rather based on each investigator, type of study, and how much time each investigator is able to dedicate to research but I am interested in obtaining your feedback.

Thank you for your help. I look forward to hearing from you soon.

Best,
[redacted]

[redacted]