From: OC GCP Questions
To: [redacted]
Subject: OSI Reports Previous Years
Date: Sunday, March 16, 2014 12:42:38 PM

Good afternoon –
I am not sure what you mean by "characteristics" of an investigator. However you may find the link helpful. As it states in the link… "The slides accessed through the links below provide annual bioresearch monitoring (BIMO) inspection metrics by fiscal year (FY). The inspectional data cover all aspects of FDA's BIMO program (i.e., clinical investigators, IRBs, sponsors, bioequivalence, and good laboratory practices) for all Centers, as applicable."

The website and slides do show clinical investigator deficiencies from a compliance perspective per year. In addition, the slides show CDER (OSI) inspections per year as well.

Clinical Trials and Human Subject Protection > BIMO Inspection Metrics

As far as characteristics of an investigator, the expectation is that investigators and sub-investigators will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc. Sponsors have discretion in determining what qualifications will be needed to conduct a study.

Additionally, the regulations require that sponsors choose investigators qualified by training and experience (see 21 CFR 312.53(a)). The regulations also require that investigators commit themselves to personally conduct or supervise the investigation (see 21 CFR 312.53(c)(1)(vi)(c)). FDA's guidance on Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf) states that, "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."

I hope this information is helpful. 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

From: [Redacted]
Sent: Friday, March 14, 2014 6:39 PM
To: OC GCP Questions
Subject: Fw: OSI Reports Previous Years

Dear Team:
In absence for my request below, I would like to know if you can let me know where this is information is posted, therefore I can get it.

I was unable to find it at FDA website. Maybe I am not searching well.

I appreciate your support

Regards
[Redacted]

On Monday, March 10, 2014 8:04 PM,[Redacted] wrote:
Good Morning
My name is [redacted].
I am located in [redacted].

I am currently a MSc Clinical Research student at [redacted] I am in the process to prepare my dissertation and I am working to identify the potential characteristics that an investigator should have to ensure clinical trial compliance.

I would like to compare the results obtained by OSI accross the years. I was searching but I only could find the current report. (January 2014), and I would like to know where I can find those results.

I appreciate your help

Regards

[Redacted]