From: OC GCP Questions
To: [redacted]
Subject: Regarding sample size and study duration for multi- centric clinical trial
Date: Wednesday, January 08, 2014 8:12:52 AM

Good morning –
By "multicentric" I assume you mean multi-center studies. The number of sites, and the number of subjects (sites and total) would depend on the protocol and whether your research is a phase 1, 2, or 3 study. Please see 21 CFR 312.23. Protocol requirements and phases are described in this section.
CFR - Code of Federal Regulations Title 21

Please see 21 CFR 312.21 (Phases of an investigation).
CFR - Code of Federal Regulations Title 21

Additionally requirements for an IND
CFR - Code of Federal Regulations Title 21

For more specific guidance on a particular study, you may contact the Center for Drugs (CDER) directly at druginfo@fda.hhs.gov or by phone 1-888-463-6332.

You may wish to review a few FDA guidances on multi-center studies, study monitoring, and protecting the rights, safety and welfare of research subjects. Please see the links below.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127013.pdf

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

Kind regards,

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

From: [Redacted]
Sent: Tuesday, January 07, 2014 2:28 AM
To: OC GCP Questions
Subject: Regarding sample size and study duration for multi- centric clinical trial

To,
Office of Good Clinical Practice
US FDA

Respected,

We request assistance in clarifying the following queries regarding USFDA guidelines with respect to multicentric clinical trials in diabetic subjects.

To conduct a multicentric study on drugs intended for *long term treatment of non-life threatening conditions*:

- What is the minimum number of sites required to conduct a multicentric trial?
- What should be the total number of patients in each site?
- What should be the total number of patients for entire study?

As we could not get clarification for our above mentioned queries from the website, we request your guidance in this regard.

TWith regards
[Redacted]