From: OC GCP Questions
To: [redacted]
Subject: PRE INTIATION VISIT
Date: Monday, March 16, 2015 3:59:20 PM

Good afternoon ---

I am sorry from a FDA respective we cannot force the sponsor to provide an initiation visit. I suggest you work and communicate closely with the sponsor so that all parties that are involved in the clinical study are satisfied and are in compliance.

Kind regards,

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

From: [redacted]
Sent: Saturday, March 14, 2015 12:51 PM
To: OC GCP Questions
Subject: PRE INTIATION VISIT

Dear GCP experts:

A site to whom I am providing a training has an issue:
The sponsor requested to Site to receive a pre initiation visit. During this 6 hrs visit, they reviewed all the information related to an initiation visit . The site is prevented to initiate because they do not have yet the signed contract and the supplies are stoked on the customs.
The site asked to the sponsor to receive an initiation visit but the sponsor refused to provide it.
We know that pre initiation visits does not exist so we would like to know about a GCP support to request to sponsor a proper initiation visit.
Best Regards
[redacted]