

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** PRE INITIATION VISIT  
**Date:** Monday, March 16, 2015 3:59:20 PM

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Good afternoon ---

I am sorry from a FDA perspective 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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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**From:** [REDACTED]  
**Sent:** Saturday, March 14, 2015 12:51 PM  
**To:** OC GCP Questions  
**Subject:** PRE INITIATION 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]