From: OC GCP Questions
To: [redacted]
Subject: CDRH Domestic and Foreign Clinical Investigator routine BIMO Inspections
Date: Thursday, June 05, 2014 12:01:24 PM

Good afternoon –

We had to reach out to the office of regulatory affairs. Please see the response below.

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.

From: Colon, Hector J.
Sent: Wednesday, June 04, 2014 4:51 PM
To: OC GCP Questions
Subject: RE: : CDRH Domestic and Foreign Clinical Investigator routine BIMO Inspections

Hi Doreen,

We don't keep metrics on "lead time" as described in the message below. For Domestic EIs the field investigator should keep the time span between initial contact and actual inspection as short as possible; most Investigators usually pre-announce with one week in advance. For Foreign inspections is very different because of all the different requirements for foreign travel (i.e. trip planning, visas, foreign government notification, etc.). Foreign inspections are preannounced by the Trip Planning Branch and not by the Investigator who will be conducting the inspection. This has to be like this because the Agency needs to have the inspection dates set with the firm before announcing the trip for volunteers. For these and other reasons, foreign inspections are preannounced approximately eight weeks (and sometimes more) in advance.

Thanks,

Héctor J. Colón Torres, MPH
LCDR, US Public Health Service
CSO, BIMO Program Expert
FDA/ORA/Office of Operations
Office of Medical Products and Tobacco Operations

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From: OC GCP Questions
Sent: Wednesday, June 04, 2014 11:38 AM
To: Colon, Hector J.
Subject: : CDRH Domestic and Foreign Clinical Investigator routine BIMO Inspections

Good morning Hector –

Can you assist with this question? I checked with Jean Toth-Allen and she thought the question should be answered by ORA as we don't have the information.

Thank you!
Doreen

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

From: [redacted]
Sent: Wednesday, June 04, 2014 10:35 AM
To: OC GCP Questions
Subject: CDRH Domestic and Foreign Clinical Investigator routine BIMO Inspections

Dear Staff:

Does the Agency keep metrics on the lead time of routine BIMO domestic and foreign clinical investigator inspections? By "lead time" I am refering to the approximate number of days between first contact with a clinical research site to schedule an inspection and Day 1 of the inspection for both U.S. and OUS Clinical Investigator BIMO inspections.

I would appreciate any information you may have to share or to be directed to an information source where I may be able to research this question on my own.

Thanks in advance for your time and attention to my question.
Sincerely,
[Redacted]