From: OC GCP Questions

To:

Subject: Number of IRB, CI & sponsor inspections in calendar year 2014 and 2015

Date: Thursday, October 08, 2015 10:55:33 AM

Good morning ---

We don't have the 2015 BIMO inspection metrics yet. They are generally not published until the first quarter of the next year. Please see the link below that gives you BIMO metrics from 2007-2014.

Clinical Trials and Human Subject Protection > BIMO Inspection Metrics

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:

Sent: Thursday, October 08, 2015 10:35 AM

To: OC GCP Ouestions

Subject: Number of IRB, CI & sponsor inspections in calendar year 2014 and 2015

Can you provide me with the total number of FDA inspections conducted in calendar year 2014 & 2015 for the following?

IRB inspections in 2014; irb inspections in 2015 Clinical Investigator inspections 2014; CI inspections 2015 Sponsor inspections 2014; sponsor inspections 2015.

Thanks!