From: OC GCP Questions
To:
Subject: CRA audit findings

Date: Thursday, June 19, 2014 2:49:49 PM

Good afternoon-

We don't have audit finding per say. We have BIMO inspection findings or metrics. Please see the link below to the BIMO inspection metrics by year.

Clinical Trials and Human Subject Protection > BIMO Inspection Metrics

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

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: [redacted]

Sent: Thursday, June 19, 2014 1:33 PM

To: OC GCP Questions **Subject:** CRA audit findings

Dear Sir or Maam,

I am looking into collecting data around the top 10 audit findings for CRAs. My goal is to ensure CRA training is focused on current as well as past trends. Is it possible to get this data from your office?

Respectfully, [redacted]