From: OC GCP Questions
To: [redacted]
Subject: anonymized GCP inspection reports/findings
Date: Friday, January 31, 2014 1:01:20 PM

Good afternoon –

My office only has inspection metrics for FDA's BIMO program. FDA's Bioresearch Monitoring (BIMO) program is a comprehensive program of on-site inspections and data audits designed to monitor all aspects of the conduct and reporting of FDA-regulated research. The BIMO Program was established to assure the quality and integrity of data submitted to the agency in support of new product approvals, as well as, to provide for protection of the rights and welfare of the thousands of human subjects involved in FDA regulated research. .

Please see the link below to inspection metrics from 2007-2013. There is some international inspection information in these metrics.

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

From: [Redacted]
Sent: Friday, January 31, 2014 12:42 PM
To: OC GCP Questions
Subject: anonymized GCP inspection reports/findings

Dear All,

I am writing my master thesis in the field of clinical research management. The draft title is [redacted] In the course of my research I have found the very important "Annual Report of the Good Clinical Practice Inspectors Working Group" by EMA for the years 2008-2012 which will be part of my paper.

However, as I am to do a quantitative analysis I should have more figures. I would appreciate it if you could help me with more information on this point. I am interested in anonymized data from GCP inspections reports/findings by the FDA of the period 2008-2013.
Such data are of primary importance for my thesis. I should be most grateful if you could give me the respective information.

I am a chemical engineer working in a chemistry research lab.

Thank you.

Sincerely
[Redacted]