From: OC GCP Questions
To: [redacted]
Subject: Questions on clinical trial protocols
Date: Friday, April 22, 2016 8:58:59 AM

Good morning –

Please see the web link below.

Questions and Answers on FDA's Adverse Event Reporting System (FAERS)

If this is not what you are looking for please contact FDA's Office of Medical Policy directly. CDEROMP@fda.hhs.gov. CDER OMP is the expert on AE reporting and patient safety outcomes as this office issued the final rule and guidances.

I hope this information is helpful. 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

From: [redacted]
Sent: Thursday, April 21, 2016 4:19 PM
To: OC GCP Questions
Subject: Questions on clinical trial protocols

Hello, I'm writing on behalf of a client who is running a clinical trial overseas.

Do you have a set of protocols for how the FDA publicly releases information regarding patient safety investigations and their outcomes?

Kind regards,
[redacted]

[redacted]