

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,

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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, 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]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]