From: OC GCP Questions
To: [redacted]
Subject: Clinical Study Reports (CSR)
Date: Monday, May 08, 2017 6:14:00 AM
Attachments: [redacted]

Good morning –

Sponsors often prepare a clinical study report for submission to regulatory agencies in marketing applications (e.g., a New Drug Application (NDA)). Such reports describe the objectives of the study, the study design, results from the study, and conclusions (among other things). The most complete guidance on the content of clinical study reports is found in the ICH E3, Structure and Content of Clinical Study Reports.

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073113.pdf

It appears you are the sponsor and I assume the study was conducted under an IND. It is best to consult the regulatory project manager of the IND to see if a CSR is required.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, May 05, 2017 3:52 PM
To: OC GCP Questions
Subject: Clinical Study Reports (CSR)

Good afternoon,

I hope my message finds you well.

I am reaching out to you today in order to receive bit of a clarity in regards to Clinical Study Report (CSR) requirement. Would you be so kind to let me know if Sponsor is required to submit CSR to the FDA if decision is made not to move forward with a marketing application?

Thank you so very much!
Have a lovely day and weekend!

Kind regards,
[redacted]