From: OC GCP Questions
To: [redacted]
Subject: inquiry regarding third party safety reports
Date: Monday, February 02, 2015 10:56:57 AM

Good morning –

Your question was forwarded to the Center for Drugs (CDER) Office of Medical Policy for a response. Please see their answer below.

Kind regards,

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

By "third party safety reports" we believe you mean IND safety reports sent by the sponsor to investigators for events that did not occur at the receiving investigator's site.

Your proposed approach to investigator review of IND safety reports is not acceptable. 21 CFR 312.32(c) requires sponsors to notify FDA and all participating investigators in an IND safety report of potential serious risks within 15 days. We expect investigators to promptly review the IND safety reports that sponsors are required to send to them in order to meet the investigator's responsibility for protecting the rights, safety, and welfare of subjects (21 CFR 312.60). Investigator review of a summarized list, quarterly, as you proposed, would not meet the regulatory requirement. In addition, investigators must promptly report to the IRB all unanticipated problems involving risk to human subjects or others (21 CFR 312.66). Investigator review of a summarized list, quarterly, as you proposed, would not allow the investigator to comply with this regulatory requirement.

The information provided in response to this inquiry does not address any specific product or trial. Follow up questions regarding specific products or trials should be directed to the appropriate FDA review division by the sponsor.

From: [redacted]
Sent: Monday, January 26, 2015 4:53 PM
To: Kassim, Sean
Cc: [redacted]
Subject: inquiry regarding third party safety reports

Hello Dr. Kassim:

As requested when we spoke earlier today, following is my email inquiry regarding third party safety reports.

We want to be sure we handle Third Party Safety reports correctly. As we are updating our SOP for handling of Third Party Safety Reports, remaining compliant yet judicious with staff time spent on these study related activities, we would like guidance as to if the following process would be acceptable. We would provide a listing of all Third Party Safety Reports to the PI for their review, and upon request, provide complete safety reports for their detailed review. (some studies have 1 safety report per quarter or less, others have 30 or more per month).

I appreciate your consideration of this question and await your reply. Thank you.

[redacted]

1) **Third Party Safety Reports** As part of IND safety reporting requirements, the sponsor will provide the investigator or research staff with third party safety reports via a website, facsimile, mail, or email.
    a. Research Coordinator/Clinical Research Specialist should have the capability to be notified and have access to third party safety reports as they become available.

        i. Research Assistant will submit a summarized list of all third party safety reports to the Principal Investigator for acknowledgement by signature, on at least a quarterly basis.
        ii. The summarized list will include values present in the report, including a number uniquely identifying each report (sometimes called a 'control number'), the date of the report, the date of the event onset, and a brief description of the event.
            1. This signed paper summarized list is stored with study files.
            2. The Form titled "Third Party Safety Reports, PI Review" (see below) will be utilized for this process.
                a. Working form is found on intranet.
                b. Any third party safety report accessible to study staff will be available to the PI upon request

Third Party Safety Reports, PI Review Listing

Date report prepared:

Short study name:
Full Study Title:

Principal Investigator (*typed or printed name*):

PI Signature: _____ Date of signature: _____

PI, If you wish to see the complete safety report of any events referenced below, please contact _____at _____.

{CRC or other appropriate study staff name} {Phone}

report cover	event onset	MFR control number	event description

letter date	date	or other unique event identifier	