From: OC GCP Questions
To: [redacted]
Subject: Questions about SUSAR
Date: Monday, March 30, 2015 10:02:05 AM

Good morning –

Thank you for your patience. I sent your question to the Center for Drugs (CDER) Office of Medical Policy. 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

From: CDER OMP
Sent: Monday, March 30, 2015 9:09 AM
To: OC GCP Questions
Subject: RE: Questions about SUSAR

FDA's *Safety Reporting Requirements for INDs and BA/BE Studies* guidance includes the following which addresses your question (page 16):

- "Until the investigator brochure is updated to include a new serious, suspected adverse reaction, subsequent occurrences of similar serious, suspected adverse reactions must be submitted expeditiously in IND safety reports (21 CFR 312.32(c)(1)(i)) to FDA and all participating investigators. There is more than one acceptable approach for updating the investigator brochure with new safety information. For example, adding a new serious and unexpected suspected adverse reaction to the investigator brochure as an addendum, rather than reissuing the entire brochure, is an acceptable approach for keeping investigators informed of new observations. Sponsors should ensure that any addenda are incorporated into the next full revision of the investigator brochure."

Link to FDA's *Safety Reporting Requirements for INDs and BA/BE Studies* guidance:
http://www.fda.gov/downloads/Drugs/.../Guidances/UCM227351.pdf

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: Tuesday, March 24, 2015 2:19 AM

To: OC GCP Questions
Subject: Questions about SUSAR

Good afternoon,
This is [redacted] from [redacted], I'm the IRB analyst.
I have a question about reporting of unexpected serious adverse drug reactions (SUSAR).

The neutropenia was occurred ongoing clinical trial and the investigator/sponsor considered it, SUSAR, because the neutropenia is not the adverse event stated on the IB (& protocol).
The sponsor has proceed the IB update to pertain neutropenia as the adverse event and it will take about 3 months for update.
During the IB update, the neutropenia has been occurred continuously.
I wonder in this case, these neutropenia should be still considered "SUSAR" until the IB update, because it is not stated on the IB.
Or it can be considered 'expected' event, because investigator/sponsor already knew this event from their experience.

It would be very helpful for me, if you answer my question.