From: OC GCP Questions
To: [redacted]
Subject: Safety Database Issue
Date: Wednesday, June 24, 2015 8:44:59 AM

Dear [redacted] –

I consulted CDER's Office of Medical Policy for an answer to your question. Please see their response below.

OMP's Response:
FDA regulations pertaining to investigational new drugs and marketed products do not prohibit having one safety database for multiple clinical trials.

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.

I hope this information is helpful. As to your second question, I told CDER that the answer is time sensitive. You should hear from them shortly.

Kind regards,

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

From: [redacted]
Sent: Thursday, June 04, 2015 9:43 AM
To: OC GCP Questions
Subject: Safety Database Issue

Hi,

We would like your opinion on the composition of safety databases in clinical trials.
We have reviewed current FDA regulations and have been unable to find this issue addressed.

We have purchased licensing to use the safety database software from [redacted] recently to record documentation associated with each SAE in our clinical trials. This safety database will list each SAE separately but will be co-mingling safety data from multiple clinical trials in the one database. In other words there will not be a separate safety database created for each study as we are used to with our clinical databases.

We will however be able to filter by Sponsor and by product to produce reports and listings specific to a product.

Are their any federal regulations that would prohibit having one safety database for multiple studies?

Thanks so much for your insight in this matter!

Take care,

[redacted]