From: OC GCP Questions
To: [redacted]
Subject: Con Meds
Date: Thursday, April 09, 2015 11:07:20 AM

Good morning –

FDA regulations do not specifically address your questions regarding concomitant medication logs. However based on the limited information in your email if the stop dates are left blank for the course of the clinical it might make it difficult to accurately record the medication stop dates.

That said FDA regulations require investigators to "...prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes..." See 21 CFR 312.62(b). http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62 Because the regulations do not specifically address data discrepancies, it is left to the sponsor's and/or clinical investigator's discretion to create their own procedures for the individual study sites. When, the regulations are not specific, sponsors/sites have the flexibility to develop procedures that make the most sense to them.

Typically, it is the investigator or a member of his/her staff who would be responsible for entering information into the subjects' charts, medical histories, and case report forms (CRFs). If during the course of monitoring a study, the sponsor's monitor discovers a discrepancy between information in the source documentation (i.e., a subject's medical records) and what was reported on a CRF, the sponsor's monitor may bring it to the attention of the clinical investigator. Any change to a CRF should be endorsed by the investigator, per the advice in FDA's official guidance and well documented, the ICH E6 "Good Clinical Practice: Consolidated Guidance:" [http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf]. If data is changed to address a discrepancy and the change is complex, a note to file would also be appropriate.

Additionally, you may also be interested in reviewing information found within the FDA guidance on Investigator Responsibilities: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf .

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional information.

Kind regards,

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

From: [redacted]

Sent: Wednesday, April 08, 2015 3:11 PM
To: OC GCP Questions
Subject: Con Meds

Hello,

My questions is about concomitant medications.

A log is kept of all the con meds the subject is taking during the trial. The stop dates are left blank on the log because the subjects change medication so often during a trial. Once the subject has completed the trial, the coordinator goes and either marks the entry as ongoing or adds a stop date.

This means that the stop date/ongoing box will be left blank until the subject completes the trial or withdraws, etc..

Would this be acceptable to an FDA auditor?

Thanks!