From: OC GCP Questions
To: [redacted]
Subject: Support at FDA/DSMICA Re:Response is in-progress: Clinical Database AE Cut-off Dates
Date: Wednesday, February 26, 2014 1:23:02 PM

Good afternoon –

The additional information below was sent to us from CDRH.

Kind regards,

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

From: noreply@salesforce.com [mailto:noreply@salesforce.com] **On Behalf Of** "DSMICA" <industry devices@fda.gov>
Sent: Wednesday, February 26, 2014 1:12 PM
To: OC GCP Questions
Subject: Support at FDA/DSMICA Re:Response is in-progress: Clinical Database AE Cut-off Dates

Hello OC GCP Questions and CDER OMP,

The details of study start dates, acceptability criteria, etc. are generally items that should have been agreed upon by the Sponsor, Clinical Investigator, and Investigational Review Board (IRB) prior to study initiation (i.e., during the drafting of the Protocol) per 21 CFR 812.25:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.25

The CDRH Investigational Device Exemption (IDE) Staff (301-796-5640) can give official comments on details involving medical device clinical investigations. Their intra-FDA email address (not public) is cdrhide@fda.hhs.gov.

If the stakeholder needs additional information on IDE specifics, they can visit the following site:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm

For specific questions and issues associated with IDE requirements - or to discuss study specifics for an IDE (especially those occuring outside of protocol bounds) - the stakeholder should contact the IDE Staff at the phone number listed above (301-796-5640).

They can also examine Good Clinical Practice (GCP) and BIoresearch Monitoring (BIMO) group information at the following link (I think this ultimately leads back to the CDRH OC GCP group):

http://www fda gov/scienceresearch/specialtopics/runningclinicaltrials/ucm160670 htm

Stanley Liu
Consumer Safety Officer

Sincerely,
Division of Small Manufacturers, International and Consumer Assistance (DSMICA)
Center for Devices and Radiological Health
Food and Drug Administration