

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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 occurring 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

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