From: OC GCP Questions
To: [redacted]
Subject: Inquiry - GCP Audits (2)
Date: Monday, July 20, 2020 2:13:55 PM
Attachments: [redacted]

Good afternoon –

Please see second email answered below by ORA.

The first question of whether FDA would accept a remote GCP audit by the sponsor is a question for the centers. If a sponsor wanted to provide a report of this kind, I don't know why a center wouldn't accept it as additional information, but we would not accept a sponsor conducted remote audit in lieu of an FDA conducted inspection. FDA does have information sharing agreements in place with many of our international counterparts and may take the findings of another country's agency into consideration when selecting sites for inspection.

Please see the contact information below for the FDA Centers.

Center for Drugs (CDER) - druginfo@fda.hhs.gov

Center for Biologics (CBER) - ocod@fda.hhs.gov

Center for Devices (CDRH) – DICE@fda.hhs.gov

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

From: [redacted]
Sent: Monday, July 20, 2020 10:12 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>

Subject: RE: Inquiry - GCP Audits

Hello Ms. Kezer,

Thank you for this information. The Sponsor has an additional inquiry, that I hope you can provide feedback on.

1. Will the FDA accept a remote GCP audit by the Sponsor for the clinical site(s)?
2. Will the FDA accept the remote GCP audit by the Sponsor in lieu of an FDA GCP audit of the clinical site(s)?
3. Will the FDA accept a GCP audit report performed by another Health Authority (e.g. from [redacted] or [redacted]), in lieu of an FDA GCP audit of the clinical site(s)?

Thank you in advance for your review and guidance.

[redacted]

[redacted]

From: OC GCP Questions <gcpquestions@fda.hhs.gov>
Sent: Friday, July 17, 2020 10:24 AM
To: [redacted]
Subject: Inquiry - GCP Audits

Good afternoon –

Thank you for your email. I contacted FDA's Office of Regulatory Affairs (ORA). ORA performs FDA

inspections for the agency. Please see their response below.

FDA continues to perform a limited number of high priority on-site GCP inspections, where the health and safety of site employees, patients and agency employees can be safeguarded. While FDA does not conduct remote inspections, we have begun conducting remote regulatory assessments for high priority assignments where an on-site inspection cannot be conducted. These are voluntary activities that allow for FDA to remotely review clinical trial records and data to assist in the review of applications. These may be conducted for both domestic and foreign locations.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

From: [redacted]
Sent: Thursday, July 16, 2020 2:04 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Inquiry - GCP Audits

Hello,

I have an inquiry for current practices, that I hope you can answer.

During the COVID-19 where most people are on stay at home orders, are GCP audits currently being performed? If they are being performed, are they performed remotely via video conference/teleconference? If they are not being performed during this time, are they being postponed? This inquiry is for both existing and new clinical trials under IND. Also, how does this impact foreign Sponsors? Some foreign regulators are performing virtual GCP audits, is this something the FDA is offering?

Kind regards, [redacted]