From: OC GCP Questions
To: [redacted]
Subject: Inquiry - GCP Audits
Date: Friday, July 17, 2020 1:23:47 PM
Attachments: [redacted]

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,

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Office of Clinical Policy and Programs
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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?