

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Remote FDA Inspections
Date: Wednesday, May 06, 2020 11:46:27 AM
Attachments: [REDACTED]

Good morning [REDACTED] –

I reached out to ORA. ORA coordinates and performs FDA inspections. Please see David's answer below.

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



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From: [REDACTED]
Sent: Wednesday, May 06, 2020 11:30 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>; ORA BIMO Inspection POC <orabimoinpectionpoc@fda.hhs.gov>
Cc: [REDACTED]
Subject: RE: Remote FDA Inspections

Hi, Doreen.

FDA has done a few remote BIMO inspections during the pandemic response. These have been done when it is critical to perform an inspection related to the review of an application, but has not been possible to be on-site at the establishment. There has not been any guidance issued on this. For these critical inspections, the FDA investigator contacts the site to preannounce an inspection. If informed it is not currently possible for the site to host an on-site inspection, the investigator will discuss the situation with their supervisor. ORA management and center management will determine if a remote inspection option should be pursued. The availability of responsible site staff, records and data as well as logistics are all considered.

FDA uses WebEx for communications including the opening meeting (if that cannot be done in person), interviews with responsible staff, reviews of records and the closing meeting. FDA has used Box as a secure solution to receive electronic copies of records needed for the inspection. FDA doesn't currently use Zoom or Microsoft Teams for communications and collaboration and we haven't used SharePoint outside of our firewall with industry. Thus far, WebEx and Box have met our needs. We have also used read-only access to a web portal to view subject records and documents.

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David K. Glasgow

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From: OC GCP Questions <gcpquestions@fda.hhs.gov>

Sent: Wednesday, May 06, 2020 9:19 AM

To: ORA BIMO Inspection POC <orabimoinspectionpoc@fda.hhs.gov>

Subject: Remote FDA Inspections

ORA –

Can you assist with this inspection question?

Thanks Doreen (OGCP)

From: [REDACTED]

Sent: Wednesday, May 06, 2020 9:05 AM

To: OC GCP Questions <gcpquestions@fda.hhs.gov>

Subject: Remote FDA Inspections

Hello,

I understand that the FDA is conducting remote sponsor and site inspections.
Is there any guidance on this?

I also understand that Box has been used for document sharing and that Zoom has been used

for interviews. Is this correct?

Can Microsoft SharePoint and Teams also be utilized for inspections by sponsors?

Many thanks,

