

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Statistics on FDA Remote BIMO Inspections  
**Date:** Friday, January 31, 2020 2:39:31 PM  
**Attachments:** [REDACTED]

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Good afternoon –

Please see the email below from FDA's Office of Regulatory Affairs (ORA). ORA performs inspections for FDA.

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



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.

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**From:** [REDACTED]  
**Sent:** Friday, January 31, 2020 2:36 PM  
**To:** OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>  
**Subject:** RE: Statistics on FDA Remote BIMO Inspections

Hi Doreen,

You are correct, we don't conduct remote BIMO inspections. We have conducted (very infrequently) foreign inspections "domestically" when FDA is unable to travel to the foreign location due to security/safety concerns, but always in a site and never remotely. For example if we receive an assignment for a CI inspection in China (currently on "Do not travel" advisory) that we absolutely need to conduct, the foreign trip coordinator would contact the sponsor to identify a location domestically for us to go and conduct the inspection there. The foreign site (in this case China) would ship the records to the identified domestic site before the start of the inspection.

Regards,

[REDACTED]

[REDACTED]

[REDACTED]



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[REDACTED] OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>

**Sent:** Friday, January 31, 2020 1:37 PM

**To:** ORA BIMO Inspection POC <[orabimoinspectionpoc@fda.hhs.gov](mailto:orabimoinspectionpoc@fda.hhs.gov)>

**Subject:** Statistics on FDA Remote BIMO Inspections

Hi ORA –

Does FDA perform REMOTE BIMO inspections? See below. I didn't think so.

Thank, Doreen (OGCP)

**From:** [REDACTED]

**Sent:** Friday, January 31, 2020 1:17 PM

**To:** OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>

**Subject:** Statistics on FDA Remote BIMO Inspections

Hello,

I am interested in the number and outcome (NAI, VAI, OAI) of FDA remote BIMO (clinical investigator sites, sponsors, IRBs, and CROs) inspections conducted in 2017, 2018, and 2019. I have searched the FDA inspection statistics information posted on the FDA website. However, the posted information does not include inspections conducted remotely, where FDA is not onsite at the entity location.

Any assistance would be greatly appreciated.

Best regards,

[REDACTED]

[REDACTED]

