

**From:** [Kezer, Doreen M](#)  
**To:** [REDACTED]  
**Subject:** Foreign/International BIMO Inspections  
**Date:** Friday, April 06, 2018 10:02:00 AM  
**Attachments:** [REDACTED]

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Good morning –

Please see the responses to your questions from FDA's Office of Regulatory Affairs. The answers are typed in red below in addition to the two templates attached above. ORA answers our BIMO inspection questions.

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.

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**From:** [REDACTED]  
**Sent:** Thursday, April 05, 2018 4:28 PM  
**To:** OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>  
**Subject:** Foreign/International BIMO Inspections

Dear FDA Representative,

I believe these are simple questions and appreciate your input regarding BIMO inspections conducted outside of the U.S. (OUS).

1. Does the FDA request or require a Sponsor representative to attend the OUS Clinical Investigator inspection?
  - a. Foreign-speaking location (e.g., France, Belgium)? **No**
  - b. English-speaking location (e.g., England, Scotland)? **No**
2. If the answer to #1 is No, can the Clinical Investigator allow a Sponsor representative to attend their inspection? **Yes**
3. Can the FDA prohibit a Sponsor representative from attending an OUS Clinical Investigator inspection if the Clinical Investigator would like to have them attend? **No**
4. Can you please share the template notices and requests for information that are sent to Clinical Investigators and Sponsors for inspections of foreign Clinical Investigators who are located outside of the U.S.? **Please see the attached documents**
5. Can you please share the template notices and requests for information that are sent to

Sponsors/U.S. agents for inspections of foreign Sponsors who are located outside of the U.S.? **There are no templates for domestic communications.**

Your attention to these questions is greatly appreciated.

Kind Regards,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]