
From: OC GCP Questions
Sent: Wednesday, January 14, 2015 2:05 PM
To: [REDACTED]
Subject: BIMO

Good afternoon –

Generally if an international FDA BIMO inspection were to take place it would be pre-announced as international travel is involved.

Kind regards,

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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.

From: [REDACTED]
Sent: Wednesday, January 14, 2015 11:14 AM
To: OC GCP Questions
Subject: BIMO

To whom it may concern:

If a BIMO is going to take place in Europe clinical sites that were included in support of a PMA, does FDA provide an advance notice to the investigators?

Thank you,

[REDACTED]