From: OC GCP Questions
To: [redacted]
Subject: Question on ex-US sites and converting them from IND sites to non-IND sites
Date: Thursday, May 10, 2018 7:28:00 AM
Attachments: [redacted]

Good morning –

For a non-US study to be considered an IND study, the sponsor has to have chosen to include it under the IND and the non-US site(s) needs to be compliant with all requirements of 21 CFR Part 312, the IND regulations. Clinical investigators at many non-US sites are refusing to sign a Form FDA 1572 (1572) and so sponsors have been conducting more of the studies at these non-US sites outside of the IND. The data from these sites can be submitted for review in support of an NDA or BLA if the sponsor follows the requirements in 21 CFR 312.120. It is not necessary to inform the review division during the course of the study that these non-US non-IND sites exist, but it is useful information to share with them.

Just to be sure, you should consult the FDA regulatory project manager of the IND to obtain their advice on switching a IND site to a non-IND site. Or you can email or call the Center for Drugs (CDER) at druginfo@fda.hhs.gov or Phone: 855-543-3784 or 301-796-3400.

Please see the guidance below.

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf

Kind regards,

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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, May 09, 2018 8:04 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question on ex-US sites and converting them from IND sites to non-IND sites

Dear FDA,

A number of EU Regulatory Authorities have recently taken a strong position that EU Investigators should not sign Form FDA 1572. Many sponsors of global clinical trials no longer collect a signed Form FDA 1572 for ex-US clinical investigators participating in a clinical trial submitted to an IND. The requirements for acceptability of data from clinical investigation sites that do not have a signed Form FDA 1572 (i.e., "non-IND sites") are described at 21 CFR 312.120.

Question - Is it possible to change an ex-US "IND site" to an ex-US "non-IND site"? That is, if a signed Form FDA 1572 (and PI CV) has been submitted to an IND, initially identifying the site as an "IND site", can the sponsor of the clinical trial change the designation for such an ex-US site from "IND site" to "non-IND site", and, as a result, no longer be required to submit minor changes to the initial signed Form FDA 1572?

Please note that we have already reviewed FDA Guidance on Frequently Asked Questions – Statement of Investigator (Form FDA 1572) and was not able to find the answer to this question.

Many thanks in advance and I look forward to hearing from you.