

From: OC GCP Questions
To: [REDACTED]
Subject: DSUR - Harmonization request to INDs
Date: Monday, May 08, 2017 6:31:00 AM
Attachments: [REDACTED]

Good morning –

This office cannot answer your questions. It is best to consult the FDA regulatory project manager (RPM) of the IND to obtain specific answers to your questions related to your specific IND.

Kind regards,

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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.

From: [REDACTED]
Sent: Friday, May 05, 2017 1:50 PM
To: OC GCP Questions
Subject: DSUR - Harmonization request to INDs

Dear FDA,

I am hoping you would be able to give us some direction on the following regarding DSUR and ARs for INDs:

- Do I need to send an Official Harmonization Request to the FDA after receiving Study Might Proceed to harmonize my DSUR in lieu of AR and any potential change of +1 day to following reporting periods? Do I need an official response from the Agency?
- If the DIBD of an IND is not in the US, but later I would like to "harmonize" the reporting dates and DIBD, Is it acceptable to do a "Notification" to FDA of the changing dates considering other regulatory agencies? Or Do I need an Official Harmonization Request and Official letter from FDA confirming the change of dates?
- If I am harmonizing my dependent IND reporting periods to an Anchor IND, Do I need to receive and official letter from FDA after submitting an official request to the IND? (considering reporting periods will differ in month and day).
- If I did not heard back from FDA regarding an harmonization request of a dependent IND to the Anchor IND, and we go ahead, and submit the DSUR in lieu of AR during the requested dates, Do I need to still submit an AR to the agency on the current DIBD?

Please let me know if you require further elaboration of the cases,

Thanks for your help,

[REDACTED]