From: OC GCP Questions
To: [redacted]
Subject: Question about GCP and ICH
Date: Friday, March 16, 2018 12:47:00 PM
Attachments: [redacted]

Good afternoon –

If a study is an FDA-regulated study, the FDA regulations must be followed by all parties. (Sponsor, investigator, and IRB).

ICH Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human subjects. Compliance with GCP assures that the rights, safety, and well-being of trial subjects are protected and that the clinical trial data are credible. This International Conference on Harmonization (ICH) guidance provides a unified standard for the European Union, Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in those jurisdictions.

Additionally, FDA has been part of the ICH process since its inception. When the E6 (GCP Consolidated Guideline) was developed, it was agreed that there might be differences in some national GCP requirements between the U.S., the EU, and Japan. In particular, ethics committee requirements were more detailed in the U.S. than the EU and Japan --- and EU and Japanese representatives did not believe at that time that they were able to adopt all U.S. regulatory requirements for IRBs/IECs as part of ICH.

The bottom line, then, is that ICH E6 has been adopted as guidance in the U.S. U.S. regulatory requirements (i.e., FDA regulations) must be met for studies conducted in the United States; in some areas, these are more detailed [and, in fact, in a few areas less detailed --- for example, FDA regulations do not address clinical trial auditing] than ICH E6.

For studies conducted outside of the U.S. but in ICH regions, compliance with the provisions of ICH E6 ensure that that the studies will be accepted for review by FDA as non-U.S., non-IND studies (under FDA regulations for accepting such non-U.S., non-IND studies).

Our recent proposed rewrite of regulations for accepting non-U.S., non-IND studies reinforces this position. We are requiring that studies meet internationally accepted GCP standards (citing ICH E6 as one such internationally accepted GCP standard; there may be others, including ICH-similar standards under development by WHO and PAHO) --- no matter where in the world the study is conducted (i.e., not just in ICH regions, but anywhere in the world).

Please see FDA's guidance document below.

https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm294729.pdf

Please also see FDA regulations and ICH links below.

Clinical Trials and Human Subject Protection > Regulations

Guidance Documents (Including Information Sheets) and Notices > ICH Guidance Documents

ICH Official web site : ICH

https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf

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.

From: [redacted]
Sent: Friday, March 16, 2018 10:37 AM
To: OC GCP Questions <OCGCP.Questions@fda.hhs.gov>
Subject: Question about GCP and ICH

Hello,
Thank you in advance for your help. I would like help understanding the difference between FDA GCP and ICH GCP. Or is there not a difference?
Thanks again,

[redacted]

[redacted]

[redacted]