From: OC GCP Questions
To: [redacted]
Subject: Question Regarding Clinical Trials
Date: Monday, May 22, 2017 8:07:00 AM
Attachments: [redacted]

Good morning –

FDA-regulated studies conducted in the US must follow FDA regulations. (CFR 312 for drugs and biologic studies and CFR 812 for device studies)

Clinical Trials and Human Subject Protection > Regulations

Generally foreign clinical studies follow ICH E-6 and CFR 312.120

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

CFR - Code of Federal Regulations Title 21

Please see some guidance documents that might be helpful for you to review.
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM328855.pdf

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf Please see page 7.

See also 21 CFR 314.106, Foreign data:

(a)General. The acceptance of foreign data in an application generally is governed by 312.120 of this chapter.

(b)As sole basis for marketing approval. An application based solely on foreign clinical data meeting U.S. criteria for marketing approval may be approved if: (1) The foreign data are applicable to the U.S. population and U.S. medical practice; (2) the studies have been performed by clinical investigators of recognized competence; and (3) the data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means. Failure of an application to meet any of these criteria will result in the application not being approvable based on the foreign data alone. FDA will apply this policy in a flexible manner according to the nature of the drug and the data being considered.

(c)Consultation between FDA and applicants. Applicants are encouraged to meet with agency officials in a "presubmission" meeting when approval based solely on foreign data will be sought.

Kind regards,

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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 19, 2017 12:51 PM
To: register@clinicaltrials.gov; OC GCP Questions
Subject: Question Regarding Clinical Trials

Good morning from the East Coast!

I've been searching through the website trying to understand the difference between a foreign clinical trial and a U.S. clinical trial. I see that foreign trials can be conducted in the U.S. or abroad and that many U.S. clinical studies are conducted in the U.S. and abroad as well. Could one of you please provide me with some type of document or article that would distinguish the two?

Best,

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