From: OC GCP Questions
To: [redacted]
Subject: Biometrics for start-up question
Date: Monday, May 18, 2015 12:15:59 PM

Good morning –

It is best to send your question directly to the Center for Drugs (CDER) as they are knowledgeable about treatment clinical trials. Their email address is druginfo@fda.hhs.gov

Additionally, please see the links below that might be helpful to you.

Search for FDA Guidance Documents > Treatment Use of Investigational Drugs - Information Sheet

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351261.pdf

Code of Federal Regulations

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, May 18, 2015 9:59 AM
To: OC GCP Questions
Subject: RE: Biometrics for start-up question

Hello,

On the FDA website, I am looking for recommendation or guidance on a site's start-up time for a treatment clinical trial. For example, some pharmaceutical sponsors have said the industry standard is 90 days which includes completion of budget, contract, and IRB approval.

Any information you can provide in a document or from a FAQ source would be appreciated.

Best Regards,

[redacted]