From: OC GCP Questions
To: [redacted]
Subject: Question regarding End of Trial
Date: Friday, July 10, 2015 10:25:38 AM

Good morning –

There is no true FDA definition of "end of trial". It depends on the investigational product and the protocol. Please see the guidance document below that mentions primary variable or endpoint of a trial. (Page 6 of the document)

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073137.pdf

That said, FDA does not have a guidance document that provides details about how to close out a study. However, the following information is found in the "Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidance" (April 1996 ICH)
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf
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Trial master files should be established at the beginning of the trial, both at the investigator/institution's site and at the sponsor's office. A final close-out of a trial can only be done when the monitor has reviewed both investigator/institution and sponsor files and confirmed that all necessary documents are in the appropriate files.

Any or all of the documents addressed in this guidance may be subject to, and should be available for, audit by the sponsor's auditor and inspection by the regulatory authority(ies).

(See section 8.1, at http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf).

The activities a sponsor, CRO and investigator/site follow for a close out visit and any data query follow-up are usually addressed in Standard Operating Procedures (SOPs) of the sponsor, CRO, and site. The clinical investigator must ensure that any requirements to maintain IRB oversight per the regulations are met, and additionally, that any pertinent SOPs are followed.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Wednesday, July 08, 2015 3:16 PM
To: OC GCP Questions
Subject: Question regarding End of Trial

Hi,
I am looking for the end of trial definition in the US. Do you know where I can find the definition? It is not obvious form FDA site.

Kind Regards,

[redacted]