

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: REMOTE CLOSE OUT VISIT
Date: Tuesday, March 10, 2015 1:00:10 PM

Good afternoon –

FDA regulations do not specifically address “remote” close out” visits. However, I would think that this would be difficult to do given the requirements listed below.

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.

Clinical investigators are responsible for the control of the investigational drug as per 21 CFR 312.61 and to maintain adequate records concerning the disposition of the drug under 21 CFR 312.62(a). The regulations state that if the investigation is terminated or discontinued, the investigator will return or provide the sponsor the disposition of the unused supplies of the drug as per 21 CFR 312.59. In addition to supplying the sponsor with routine progress reports during the investigational study (21 CFR 312.64(a)), the clinical investigator is required to provide the sponsor with adequate information in the form of a final report shortly after the completion of the investigator’s participation in the study (21 CFR 312.64(c)).

As per 21 CFR 312.62(c), clinical investigators are required to retain records for a period of two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified. If investigational records are transferred off-site to a third party (e.g., CRO), the sponsor and FDA should be notified by the associated clinical investigator in the form of a final report.

When study enrollment and subject follow-up have been completed at a given site, the clinical investigator will often (usually for FDA-regulated studies) send the required final report to the IRB, thus closing out the study at the site.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov .

Kind regards,

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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: Thursday, March 05, 2015 12:50 PM
To: OC GCP Questions
Subject: REMOTE CLOSE OUT VISIT

Dear FDA GCP experts:

An investigational site asked to me if it is advisable to allow a "Remote close out visit". The status of the site is as follows:

There are study medication pending to be reconciled by the CRA

There are a lot of extra copies of essential documents out of the investigator's binder

We would like to check with you if these kind of remote close out visits are common in these days.

Regards

[REDACTED]