From: OC GCP Questions
To: [redacted]
Subject: RE: E-Binder Naming Conventions/FDA Audit
Date: Friday, October 26, 2018 12:18:00 PM
Attachments: [redacted]

Good Afternoon,

FDA does not define the term "regulatory binder" in regulation, and, thus, there are no requirements regarding the types of documents that should be filed in a clinical study site's "regulatory binder," nor any requirements as to how the "regulatory binder" should be organized.

You may want to review FDA's Compliance Program Guidance Manual (CPGM) for the FDA inspection of clinical investigators during a bioresearch monitoring (BIMO) inspection of a clinical study site, available at: www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133562.htm. In particular, you may want to review Part III, Inspectional, which identifies some of the things an FDA investigator will look for during a clinical investigator site inspection.

The guidances listed below might be helpful to you:

Part 11 -Electronic Records
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf

Computerized Systems Used in Clinical Investigations
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Electronic Source Data in Clinical Investigations
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

You may also find helpful advice with respect to the types of documents that should be retained, in FDA's official guidance, the ICH E6, "Good Clinical Practice: Consolidated Guidance." Section 8.1, "Essential Documents for the Conduct of a Clinical Trial," states:

> Essential documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements... Filing essential documents at the investigator/institution and sponsor sites in a timely manner can greatly assist in the successful management of a trial by the investigator, sponsor and monitor. These documents are also the ones that are usually audited by the sponsor's independent audit function and inspected by the regulatory authority(ies) as part of the process to confirm the validity of the trial conduct and the integrity of data collected. (ICH E6, 8.1)

Section 8 contains a very thorough list of essential documents, with recommendations as to who should maintain a copy of them.

You may view the ICH E6 guidance in its entirety on FDA's GCP website (www.fda.gov/oc/gcp). Once there, click on "Guidances and Information Sheets," and scroll down the list.

Best Regards,

Karena Cooper
Senior Regulatory Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

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[redacted]
Sent: Wednesday, October 24, 2018 2:22 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: E-Binder Naming Conventions/FDA Audit

Good Afternoon,

I hope this e-mail finds you well. I wanted to know if there is a guidance document that can be viewed in regards to preparing an electronic regulatory binder for an FDA Audit, I am specifically seeking guidance on the structure of the e-binder's folders and naming conventions for the documents within the binder.

Is there a specific order in which the Auditors may want to see the binder, and/or a specific naming convention that they may be seeking? Any guidance you could provide would be appreciated and helpful.

Thank you in advance,

[redacted]