

From: OC GCP Questions
To: [REDACTED]
Subject: CAPAs
Date: Thursday, May 18, 2017 8:12:00 AM

Good morning --

FDA does not have a specific form or format to be used for a CAPA. However, I can offer the following information.

Corrective and preventive action (CAPA) programs are not a specific regulatory requirement in FDA's regulations related to clinical trials (21 CFR parts 50, 56, 312 and 812) but are discussed in the quality system regulation for medical devices (21 CFR part 820).

FDA would expect an investigator, the investigational site and/or the sponsor to take corrective actions when issues arise during a clinical investigation and to document the actions taken. Several FDA guidance documents indicate this. See for example:

- "Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects" (available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf) includes as a possible element for an investigator's plan to supervise and oversee a clinical trial "A procedure for the timely correction and documentation of problems identified by study personnel, outside monitors or auditors, or other parties involved in the conduct of a study."
- "IRB Continuing Review after Clinical Investigation Approval" (available at www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf) indicates that, when an IRB notes a pattern of non-compliance with the requirements for continuing review, "the IRB should determine the reasons for the non-compliance and take appropriate corrective actions."
- "Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring" draft guidance (available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf), when discussing possible components of a monitoring plan to address management of noncompliance, "Processes to ensure that root cause analyses are conducted where important deviations are 456 discovered and that appropriate corrective and preventive actions are implemented to address issues identified by monitoring."
- "FDA Inspections of Clinical Investigators" (available at www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf) indicates that an FDA investigator may inspect records to ascertain "corrective actions in response to previous FDA inspections, if any"; that if significant violations of FDA regulations are found, a warning letter may be issued and "include a request for correction and a written response to the agency"; and that "If, in response to the NIDPOE (notice of initiation of disqualification proceedings and opportunity to explain), the investigator provides an explanation that is accepted by the agency and the disqualification is not warranted, alternatives such as a detailed corrective action plan may be considered."

These guidance documents indicate that FDA review of records may include CAPA plans specific to a problem that occurred during a trial and CAPA plans that are part of trial monitoring or quality assurance. If an establishment has a GCP CAPA plan that is separate from the ongoing monitoring and quality assurance programs, it would seem unlikely that FDA would review those records. If, however, the establishment references those plans as a means of addressing problems found during an FDA inspections, than I believe the CAPA plans would be subject to FDA review.

I hope this information is helpful. Please contact us again should you have additional GCP questions.

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.

-----Original Message-----

From: [REDACTED]
Sent: Wednesday, May 17, 2017 8:27 PM
To: OC GCP Questions
Subject: CAPAs

Hello,

I am trying to write a CAPA for a medication error. Is there an FDA form or format that should be used for a CAPA? I want to make sure everything is included.

Thank you so much for your assistance.

[REDACTED]