Excerpts from an article in “The Bridge” (revised to include all regions)

Thinking About a Corrective Action Plan
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When is a Corrective and Preventive Action Plan (CAPA) needed?

During the conduct of a research study, protocol violations may occur that are identified and reported by the Principal Investigator to the IRB. In this reporting requirement, the need to develop a corrective and preventive action plan may be required in order to identify the primary cause (root cause) of the problem and assess what if any changes need to be developed and implemented to prevent future events.

What is a CAPA?

A CAPA or corrective and preventive action plan is a step-by-step process to identify and assess the causes of a problem in a process or system and the development and implementation of an improvement plan to alleviate the actual identified problem and proactively prevent recurrences.

How detailed should a CAPA be?

The extent of the CAPA will depend on the seriousness of the problem identified. A CAPA must contain several essential components:

- A description of the plan to address the cause of the problem (as outlined in the protocol violation description reported)
- The individuals responsible for implementing the long-term corrective and preventive action plan
- The specific timeframe and process for initial implementation
- The plan for determining effectiveness of the solution(s) implemented (in other words, what evaluation was done to verify that the problem has not reoccurred?) This often encompasses ongoing internal quality monitoring activities within the research group to thoroughly assess periodically the effectiveness of the CAPA.

The key to an effective CAPA is to identify and eliminate the primary cause rather than fixing only the identified result. For instance, if there is more than one problem identified, different individuals may be assigned to investigating different parts of the problem and more than one solution may be required. Depending on the protocol violation, a CAPA may require both short-term and long-term solutions to be developed and implemented.

A simple example is a series of multiple missed protocol-required blood tests at the research site. A group of the research staff directly involved with the trial site should be organized, their responsibilities and timelines established, and an investigation begun. It is critical that the group set a timeline for the investigation and to come together again to evaluate the results and discuss potential solutions.

In this example, it is identified that the same blood test has been missed on four research participants during the third protocol-required clinic visit, with all visits occurring within a few days of each other. Further research indicates that all of the visits occurred in the evening at one site only. The same laboratory staff members were on at the time of each missed test. The source documents indicate that the laboratory staff had been informed of the testing requirement. Discussion with the laboratory manager, however, indicated that a specific piece of equipment necessary for running the test was being repaired during the timeframe. With this information in mind, we know it affected:
- four research participants at their third protocol visit in the same week
- at only one site
- on evening shift
- with the same trained staff
- equipment was being repaired

The investigator and research staff then must determine the answer to why the issue had not occurred on day shift. Had the day shift found an alternative method for doing the test? What was the alternative? Had no study participants come in for the third protocol visit on day shift? Since the equipment was being repaired, had the day shift sent the blood to a different laboratory for results? What was the difference in the two shifts? These are just a few examples of questions that would need to be answered when determining the “root cause or primary reason” and developing an effective corrective and preventive action plan.

Once all these questions are answered, the group is ready to determine possible solutions. Potential solutions as examples could include ensuring all laboratories are sent out to a central laboratory or a second piece of equipment is on hand to run the test at all times, the laboratory staff are retrained on protocol requirements, a tracking system is put in place in the laboratory and with the study group with designated responsible individuals overseeing as part of documentation. A timeframe for implementation and evaluation is then established with a responsible person designated for each. The solutions that work the best are those solutions developed by the study staff having comprehensive knowledge of their sites and their protocol.

What are some of the issues identified with existing IRB reported written CAPAs associated with Protocol Violations?

- Inadequate clear and thorough outline of the problem, resolution and planned corrective and preventive action(s) implementation with specific timelines
- Inadequate clear and thorough description of how and when the effectiveness of the resolution will be determined
- Failing to address, in the CAPA, the “root cause or primary cause” of the protocol violation

What does the IRB look for in a CAPA?

To be able to adequately evaluate a CAPA, the IRB needs one that contains a thorough analysis of the problem, with potential causes identified, and outlined solution implemented. The CAPA breaks the solution into discrete actions and assigns responsibilities for each action to a member of the research team under the direction from the PI. The CAPA always must set a deadline for achieving specific results and identify what post-solution implementation evaluation occurred to verify that the problem has, indeed, been appropriately addressed.

A well-planned CAPA does require the PI and research staff time for the initial evaluation plan, implementation, and follow-up evaluation to be fully addressed; however, with this additional effort, quality of care, patient safety and integrity of research data may be maintained.