

## How to Create an Effective CAPA Plan

### The event is identified

The study personnel are made aware of an unexpected event or deviation from the protocol. In order to protect the rights, welfare, and safety of participants and the integrity of the research data, a Root Cause Analysis (RCA) is conducted, and a Corrective and Preventative Action (CAPA) plan is created.

### Root Cause Analysis

An RCA is a structured process to help identify the underlying reason or reasons why a problem occurred. The goal is to find the true cause, so the CAPA addresses the right issue. The 5 whys is an easy and effective RCA tool.

### Creating the CAPA

1. Describe the Event
  - a. Provide a brief summary of the event that triggered the need for the CAPA. What occurred and when it occurred (including dates).
2. Corrective Action
  - a. Describe the actions taken or planned by study personnel to address this event. Describe who (roles, not names) is responsible for these changes. This is the reaction to the event or deviation.
  - b. Note: It is not acceptable to state that an event cannot be corrected due to staffing changes. There is always a way to correct the problem.
3. Preventative Action
  - a. Describe the actions taken or planned by study personnel to prevent recurrence in the future. Describe who (roles, not names) is responsible for these changes. This is the action to eliminate the cause of a potential problem or situation.

### Implementation and Monitoring

- b. Follow the CAPA that was created to avoid future unexpected events or deviations.
- c. Regularly perform self-assessments to ensure that the CAPA created is effectively preventing the event from occurring again.