

CORRECTIVE ACTION PLAN GUIDELINES

NON-CONFORMITIES THAT MAY REQUIRE A CORRECTIVE ACTION PLAN

May include but not limited to:

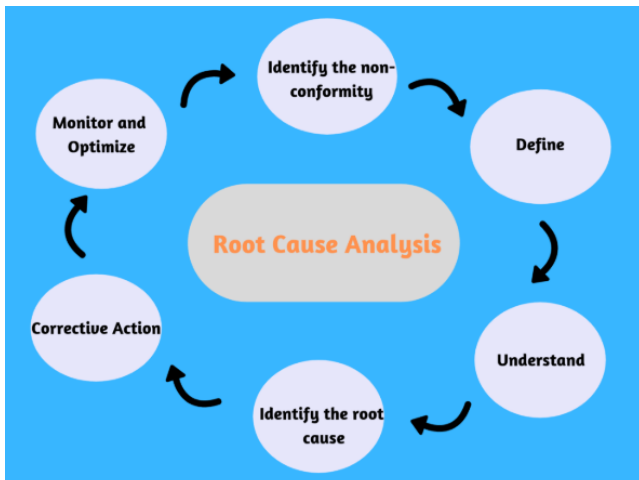
- Protocol deviations / violations
- Internal audit / Monitoring (findings / reports)
- Study staff complaints
- Monitoring visit findings (sponsor)
- Operational issues
- Research participant complaints
- Adverse events

STEPS TO COMPLETE CORRECTIVE ACTION

- **Define the problem**
- **Immediate Corrective/Containment Action** – define extent of problem and try to limit it
- **Root Cause Investigation***
- **Corrective Action Plan**
- Name the **Responsible Parties** to carry out corrective actions
- **Reporting Accountability**- Who needs to know?
- Tasks to be completed (**Implementation**)
- Know and meet **Regulatory / IRB requirements**
- Establish **Goals and Deadlines**
- Determine How to **Monitor**
- Organize **Supporting documents**

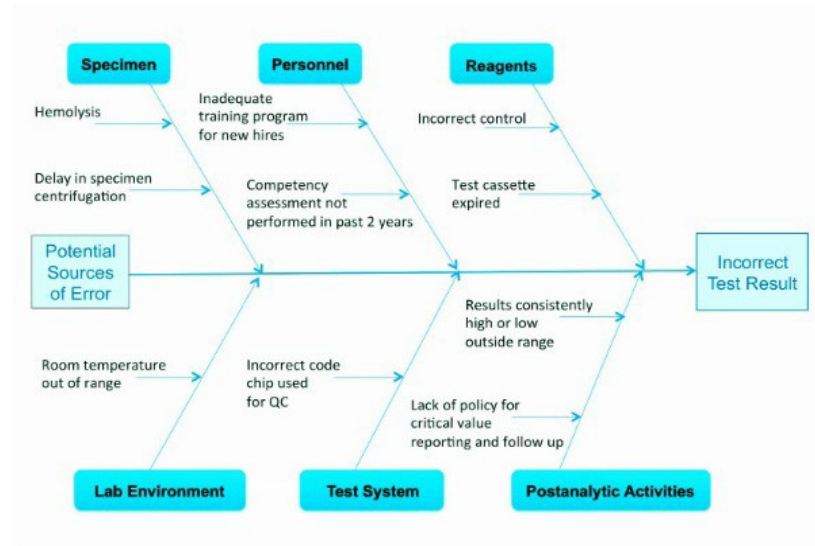
ROOT CAUSE ANALYSIS

An approach used to identify the underlying causes of why a problem/nonconformity occurred so that the most effective corrective action can be identified and implemented



FISHBONE DIAGRAM*

The Fishbone Diagram, also known as an Ishikawa diagram, identifies possible causes for an effect or problem.



5 WHY'S*

By repeatedly asking the question “Why” (five is a good rule of thumb), you can peel away the layers of symptoms which can lead to the root cause of a problem.

