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.

PROBLEM

Our client is refusing to pay for leaflets we printed for him

Why?

The delivery was late, so the leaflets couldn’t be used

Why?

The job took longer than we expected

Why?

We ran out of printer ink

Why?

The ink was all used on a large, last-minute order

Why?

We didn’t have enough ink in stock, and couldn’t order new supplies in time

COUNTER-MEASURE

Find an ink supplier who can deliver at short notice, so that we can continue to minimize inventory, reduce waste, and respond to customer demand.