5 Whys: Root Cause Analysis Guide

Purpose

The 5 Whys is a structured problem-solving technique used to identify the root cause of an issue by repeatedly asking "Why?" until the underlying cause is uncovered. In clinical research, this method supports a culture of continuous improvement and helps prevent protocol deviations, data errors, and process failures from recurring.

Step 1 — Define the Problem

Develop a clear, specific problem statement before the session begins. A good problem statement describes what happened, where, and when — without assumptions about cause.

Example: *"Three participants in Study XYZ missed their Week 8 visit window during Q1 2024."*

Avoid vague statements like "scheduling is a problem." Precision here shapes the quality of the entire analysis.

Step 2 — Assemble the Right Team

Include team members who have direct, hands-on knowledge of the processes and systems involved — not just managers or observers. In a clinical trial setting, this might include:

- The coordinator who manages participant scheduling
- The research nurse or clinical staff involved in visit conduct
- The data entry or EDC specialist
- The regulatory coordinator, if the issue involves documentation

Diverse perspectives from those closest to the work will produce more accurate and actionable findings.

Step 3 — Facilitate the Analysis

Designate a facilitator whose role is to guide the discussion, ask "Why?", and record the team's responses. The facilitator should remain neutral — their job is to draw out the team's knowledge, not to direct them toward a predetermined answer.

Begin with the problem statement and ask: "Why did this happen?" Record the team's response, then ask "Why?" again about that response. Continue this process iteratively.

Step 4 — Test Each Response as a Root Cause

After each response, the facilitator should prompt the team to apply this test:

"If we corrected this factor, is it likely the problem would still recur?"

- If yes — this is a contributing factor, not the root cause. Continue asking "Why?"
- If no — the team may have identified the root cause. Confirm there is group agreement before stopping.

This test prevents the team from stopping at surface-level fixes (e.g., "the coordinator forgot") and drives toward systemic causes (e.g., "there is no backup process when the primary coordinator is out").

Step 5 — Reach Agreement on the Root Cause

Continue asking "Why?" until the team reaches consensus that they have identified the true root cause. While the method is called the "5 Whys," it commonly takes 3 to 7 iterations depending on the complexity of the problem. Do not stop arbitrarily at five — keep going until the root cause is genuinely identified.

Understanding Branches: When Analysis Splits

A 5 Whys analysis does not always follow a single straight line. When different team members — or different lines of questioning — point to different answers, the analysis may branch into two or more separate paths. Each branch represents a distinct chain of causes that may lead to its own unique root cause.

For example, if you ask two experienced coordinators why participants missed visits, one may identify a communication breakdown while another identifies a tracking process failure. Both answers can be valid and worth pursuing. Stopping at one branch risks missing contributing root causes that could allow the problem to persist even after a fix is applied.

When branching occurs:

- Record and follow each branch independently through its own chain of whys
- Each branch may lead to a different root cause requiring its own corrective action
- Multiple root causes from different branches can all be addressed in a single CAPA plan
- Branching is a sign of a thorough analysis — not a sign that the process has gone wrong

Diagram 1: Single Branch (Linear) 5 Whys

This example shows a straightforward analysis that follows one line of inquiry to a single root cause.

Problem	Three participants missed their Week 8 visit window.
▼	
Why 1?	Participants were not contacted in time to reschedule.
▼	
Why 2?	The coordinator did not have reminder alerts set up.
▼	
Why 3?	There is no standard process for scheduling reminders in the study protocol.
▼	
Why 4?	The protocol was implemented without a visit tracking SOP.
▼	
Root Cause	No visit-tracking SOP was created or adopted during study startup.

Diagram 2: Two-Branch 5 Whys

This example shows how the same problem can branch into two distinct chains — each with its own root cause — when different perspectives are explored.

PROBLEM: Three participants missed their Week 8 visit window.

▼ Branch A		▼ Branch B	
Why 1?	Participants were not contacted in time.	**Why 1?**	Coordinator was unaware visits were overdue.
▼		▼	
Why 2?	No reminder alerts were configured.	**Why 2?**	The tracking spreadsheet was not being updated.
▼		▼	
Why 3?	No SOP existed for scheduling reminders.	**Why 3?**	Responsibility for updates was never assigned.
▼		▼	
Root Cause A	No SOP for visit reminders existed at study startup.	**Root Cause B**	No role was assigned to maintain the visit tracking log.

Tips for Clinical Research Settings

- Document each "Why" and response in writing during the session to create a clear audit trail.
- Focus on process and system failures — not individual blame. Root causes in research environments are usually upstream process gaps, communication breakdowns, or missing safeguards.
- If the team identifies multiple root causes through branching, that is expected and appropriate for complex problems.
- Completed 5 Whys analyses can support CAPA (Corrective and Preventive Action) documentation and sponsor or IRB reporting where required.
- Consider including people from different roles — a coordinator and a research nurse may surface entirely different branches of the same problem.

5 Whys Worksheet

Use this worksheet to document your team's analysis.

5 Whys Analysis Worksheet	
Study / Protocol	
Date	
Facilitator	
Team Members	
Problem Statement	
Why 1?	
Why 2?	
Why 3?	
Why 4?	
Why 5?	
Additional Whys (if needed)	
Root Cause(s) Identified	
Corrective Actions Planned	