

# Q-BITES

THE QUARTERLY NEWSLETTER BY



## Creating a CAPA for PD

Protocol Deviation is something that we try our best to avoid. But once it happens, it must be reported. When submitting a PD report, one of the challenges faced is addressing the CAPA.

### What is a CAPA?

Corrective Actions (CA) are steps taken to eliminate the causes of existing deviation. Consequently, Preventive Actions (PA) are steps taken to prevent the re-occurrence of the deviation. In short it means making the wrong right and making sure it doesn't happen again.

### Creating a CAPA

- Determine the problem - Review the finding and the evidence to pinpoint the nature of the deviation. Every finding should have accompanying evidence.
- Determine the corrective action - Identify the action to be taken to rectify the problem and the person responsible for implementing it. If the deviation cannot be corrected or reversed, document the deviation accordingly (patient's note, note to file, PD report).
- Conduct a root cause analysis - Determine the root cause of the finding, particularly to establish if it is a systematic or isolated problem. A systematic problem could mean other studies may also be affected. Example of a systematic problem is PI's lack of understanding on consenting process.
- Determine the preventive measure - Propose solution to address the root cause of the problem, consider existing regulations, guidelines and resources. An accountable person should be appointed to oversee the process.
- Set realistic deadlines - Consider the manpower and resources to implement the corrective and preventive measures within a realistic timeframe.

### A Collective Effort by the Study Team

Completion of CAPA should not be a lone effort. Study team should always collaborate to address the findings.

### Points to Remember

- Root cause analysis can be done using 5W1H or Fishbone Diagram technique.
- Do not wait for CRA to find the PD. Once aware, report.
- PD reporting is not to assign blame but to improve the conduct of study and a learning process for all.

Source: Modified from <https://www.research.nhg.com.sg>

## That's How You Carry A Milk Bottle

A small boy was trying to remove a bottle of milk from the refrigerator with one hand when he lost his grip on the slippery bottle and it fell, spilling its contents all over the kitchen floor.

When his mother came into the kitchen, instead of yelling at him, giving him a lecture, or punishing him, she smiled, "Well, the damage has already been done. Let's try to clean this up. So, how would you like to do that? We could use a sponge, a towel, or a mop. Which do you prefer?"

He chose the sponge and together they cleaned up the spilled milk.

His mother then said, "You know, what we have here is a failed way of carrying a milk bottle. Let's see if we can get it right."

The mother then placed another bottle of milk in front of the boy and asked him how he carried it the first time. He said he did it with a single hand.

"Now try using both your hands," said the mother.

By using both his hands he was able to carry the milk bottle.

We sometimes do mistakes in our line of work. It is not something to worry about as mistakes are just opportunities for learning something new.

But do remember that it is our duty to clean up the mess (mistake) and ensure we learn how not to repeat it again.

Also remember, learning from a mistake together (two hands) is always better than learning it alone (single hand). Because that's how you carry a milk bottle.

