

Q-BITES

THE QUARTERLY NEWSLETTER BY



Knowing Your SAEs

Serious Adverse Events (SAE) are crucial events that need to be captured within a specific timeline. GCP defines the SAE reporting to be done immediately.

“All serious adverse events (SAEs) detected or being notified should be reported immediately to the sponsor...”

Usually sponsors have stricter timeline where all SAEs must be reported within 24 hours of awareness of the event. Awareness here refers to any member of the study team, which includes the SC. So, it is an added advantage when SCs can identify SAEs for timely reporting.

GCP lists five criteria as identification for SAE - Any untoward medical occurrence that at any dose:

- results in death,
- is life-threatening,
- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability/incapacity, or
- is a congenital anomaly/birth defect.

Scenario 1

Study patient is admitted for Hyperglycemia. Patient is stable on the 2nd day with treatment modification. Before being discharged, patient develops respiratory symptoms and is diagnosed with Nosocomial Pneumonia. Patient is kept in the ward, treated and discharged after 5 days. How many SAEs need to be reported?

Two SAEs need to be reported.

- ✓ *Initial SAE (Hyperglycemia) that caused hospitalization.*
- ✓ *Second SAE (Nosocomial Pneumonia) that prolonged existing hospitalization.*

Scenario 2

Study patient complains of loss of hearing in one side of his ears. Upon examination it is confirmed that patient has developed total hearing loss on his right ear (it is not related to IP but might be related to patient's loud working environment). Is this a SAE?

- ✓ *Yes, the hearing loss is a SAE as it is a significant disability.*

It is important that SCs are always aware of the SAE criteria and be alert on patient's condition that might fit any of the criteria. Though the responsibility of identifying SAE belongs to the investigators, SCs can play the role of detecting the SAE earlier and contribute to real-time reporting.



What? What?

A group of frogs living in the pond decided to climb a tall tree and gathered around it. So did all the other animals in the forest. The other animals were discouraging and making fun of them.

“You are too small; you can't climb that tree!”

“It's going to be so funny when you drop one by one. It's going to be raining frogs.”

With all the discouragement, half of the frogs decided not to climb the tree. The other half started climbing. As the other animals spewed more negativity, one by one the frogs stopped climbing. Halfway to the top, all the frogs had stopped except for one frog; the smallest one.

Seeing there was still one frog continuing to climb, the other animals screamed more discouragement; taunting that it will fall and die. But the lone frog kept going. No amount of discouragement was stopping this frog.

Finally, the frog reached the top. All the other frogs jumped in joy. The other animals surprised, started applauding it too. The small frog stood at the top with pride and then slowly came down.

As soon as the frog reached the ground, it said “Thank you so much for all the encouragement.”

One of the animals replied, “But we were not encouraging you, we were discouraging you.”

“What?” the small frog asked.

“We discouraged you,” the animal said louder.

“What?” the small frog asked again loudly.

The small frog was deaf. It did not hear any of the discouragement. It kept going thinking everyone was encouraging it and reached the top.

2021 has been a tough year for everyone and 2022 is yet to be explored. But whatever challenges, discouragement or negativity that might come our way, let's be like the small frog and turn it into encouragements and motivation. Let's leap to the top of the tree together once again in 2022.