

Q-BITES

THE QUARTERLY NEWSLETTER BY



The Curious Case of the Missing Delegation Log

Case study

It was noticed during a monitoring visit on 18 Dec 2019 that the delegation log for study LIGHT* was missing from the ISF. The SC was requested to search for the missing delegation log and the PI was informed of this. However, after the main and backup SC have gone through all the ISF multiple times, the delegation log could not be found. Members of the study team was also asked if they had removed the delegation log, but none had removed it.

Corrective action

- A copy of the signed delegation log that was kept by the Sponsor was provided to site and PI signed as certified true copy
- If a copy was not available, to sign a new delegation log with current date
- Note-to-file to document the event that has occurred

Preventive action

- ISF to be kept in safe and secured cabinet with limited access only to study team
- SC to ensure immediate or weekly basis filing is done
- CRA to check ISF regularly to ensure essential documents are in place
- Training for the study team on the importance of essential documents

6 months later, the delegation log was found lodged in the corner of the filing cabinet, underneath a pile of ISF.

*Names have been changed



Diamond at Fifteen Feet

A Shaman awoke one day and predicted there are diamonds buried in the village lands. Believing the words of the Shaman, every villager started digging their lands.

Peter, who was one of villager started digging too. On the first day, few of the villagers had found diamonds on their land after digging a few feet. As the days passed by, one by one the villagers found diamonds on their land. Some found it at 6 feet and some at 8 feet. But Peter was still unlucky.

By the tenth day almost the whole village had found diamonds on their land. None of them had to dig beyond ten feet except for Peter. He went on digging and by the time he reached twelve feet he was being laughed at and ridiculed by others. But Peter did not give up, he continued digging.

At fifteen feet, Peter's shovel hit something hard and solid. He had found his diamond; the biggest piece of diamond the village has ever seen. All his hard work finally rewarded.

Though everyone else found their diamond early, Peter did not give up. He kept digging until he found his diamond.

As we pre-screen patients, we might get demotivated when we don't find a suitable patient. Other sites might screen and randomize a patient within a week. Some sites might reach their target within a few months. But don't give up. As long as the recruitment period is open, keep on searching. You may never know, but you might even find your "diamond" on the last day of recruitment.