

# Q-BITES

THE QUARTERLY NEWSLETTER BY



## Impartial Witness For ICF

One of the components of ICF is the Impartial Witness. So, when does the section of Impartial Witness gets signed and who can sign it? Below are a few examples.

### Who is an Impartial Witness?

According to GCP, Impartial Witness is a person, who is independent of the trial, who cannot be unfairly influenced by people involved in the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

### When does an Impartial Witness sign the ICF?

- Patient A comes for consenting process. Patient A is illiterate. Is an Impartial Witness needed?
  - ✔ Yes, as explained in GCP, "if the subject cannot read".
- Patient B comes for consenting process. Patient B can only read in Chinese. ICF in Chinese language available, but investigator does not read Chinese. Investigator and patient able to converse in a mutual language. Is an Impartial Witness needed?
  - ✘ No, the presence of an Impartial Witness is related to the ability of the subject or subject's representative to read, not the investigator.
- Patient C comes for consenting process. Patient C has Alzheimer's Disease (loss of memory) and is unable to give consent. Is an Impartial Witness needed?
  - ✘ No, the presence of an Impartial Witness is related to the ability to read, not the patient's ability to give consent. The patient's Legally Acceptable Representative (LAR) is needed.
- Patient D comes for consenting process. Patient D is illiterate. Can Patient D's son be the Impartial Witness?
  - ✔ Yes, the patient's son is independent of the trial and cannot be unfairly influenced by the people involved in the trial.
- Patient E comes for consenting process. Patient E is illiterate. Can the Study Nurse be the Impartial Witness?
  - ✘ No, study nurse is part of the trial and can be influenced by the people involved in the trial.

### Points to Remember

- Always refer to GCP on the definition and need for an Impartial Witness.
- Presence of Impartial Witness is related to the ability to read.
- Impartial Witness should not be related to study or study team.
- Impartial Witness should be present throughout the consenting process.



## The Toothpaste Boxes

A toothpaste factory had a problem. They sometimes shipped empty toothpaste boxes without the tube inside and started getting complains from the shop owners. They decided to hire an external engineering company to solve the empty boxes problem.

They solved the problem by using a high-tech precision weighing scale that would sound a bell and flashlights whenever a toothpaste box was empty and weighed less than it should. The line would stop, the Supervisor would walk over, remove the defective box, and then press another button to re-start the line. As a result of the new package monitoring process, no empty boxes were being shipped out of the factory.

With no more customer complaints, they felt happy with their solution. When the company checked the line statistics report, they discovered the number of empty boxes picked up by the scale in the first week was 20 boxes per day. However, the next three weeks were zero. The estimated rate should have been at least 12 boxes a day. The engineers check the equipment and verified the report as accurate.

Puzzled, they travelled down to the factory, viewed the part of the line where the weighing scale was installed, and observed just ahead of the new scale was a desk fan blowing the empty boxes off the belt and into a bin. They asked the supervisor what that was about.

"Oh, that," the supervisor replied, "I put it there because I was tired of walking over to restart the line every time the bell rang."

In our work, we are often faced with complicated issues with the studies, the study team and so forth. But a complicated issue doesn't need a complicated solution. When an issue arises talk to everyone involved. The solution might come from an unexpected person and might be a very simple solution. Even as simple as switching on a fan.