

# Q-BITES

THE QUARTERLY NEWSLETTER BY



## PDPA 2010



### What is PDPA?

The Personal Data Protection Act (PDPA) 2010 came into force in Malaysia on 15 November 2013. The PDPA regulates the processing of personal data regarding commercial transactions. It was gazetted in June 2010. There is a penalty of RM100,000 to RM500,000 and/or imprisonment between 1 to 3 years for non-compliance. But what does this mean for clinical trials?

### PDPA in Clinical Trials

Personal data refers to any data that is used to identify a certain individual. These data include unique identifiers (NRIC number) and any sets of data such as name, address, telephone number, etc. Do take note that scope of PDPA only applies to identifiable data and not data used in anonymous form.

### Study Coordinator Role in PDPA

Study Coordinators manage high volume of personal data whether it is patients, investigators, or study team members. It is highly important for study coordinators to take note of certain aspects of personal data such as:

- What type of personal data is being managed?
- Where are the personal data stored?
- Who has access to the personal data?
- Whom are the personal data shared with?

Once the type of data is identified, manage the storage location accordingly. Whether it is in the patient notes, kept in the cabinet, stored in the laptop, etc do ensure that it is under lock and key or with password protection. If the data should not be stored in certain devices such as personal laptop or phone, kindly delete the data accordingly.

When sharing the data, whether it is reporting SAE or a CRA requesting investigator contact details, ensure the personal data is protected. For SAE, kindly blind all personal data accordingly. For sharing contact details do seek permission from the relevant individual before releasing it.

If personal data breach does occur do report it (to line managers, PI, etc) immediately. It is not only important to record the incident, but corrective actions and preventive actions needs to be implemented immediately. Let's uphold integrity and protect personal data accordingly.

## Elephant and the Rope

Once a man went to a circus. There were many exciting shows but the man loved the elephant show the most. The elephant could carry huge things and push heavy objects. The elephant's strength was unmatched.

Once the show was done, the man took a walk on the circus ground. When he was walking he saw the huge elephant that had performed before. What surprised the man was the elephant was only tied to a pole using a rope. There were no cages. The elephant using its size and strength could easily break the rope and escape, but the elephant did not do so. The man looked around and found the elephant's trainer.

"The elephant is tied using a small rope, how come it doesn't break the rope and escape?" asked the man curious.

The trainer explained, "When the elephant is young, it is tied using the same rope. Being small it could not break free from the rope. As the elephant grows up, it is conditioned to believe that it cannot break away from the same rope. The elephant believes that the rope can hold it, hence it never tries to escape."

The man understood that the elephant doesn't try to escape not because it couldn't escape, but only because the elephant believes it cannot escape.

Sometimes, we are faced with situations that hold us back. Sometimes we face failures in our attempts. Doesn't matter how much anyone tries to hold us back, or how many failures that come our way, always believe in your potential. Always believe that whatever the circumstances, you can do it and you can be successful.

Believe in yourself and your potential, put the effort needed and it will give you the strength to break the rope that holds you back. Let's break our ropes and bring the best out of ourselves together.

