

# Q-BITES

THE QUARTERLY NEWSLETTER BY



## Good Clinical Practice: A Guide to Archiving

Archiving is the long-term storage of essential documents that provide evidence a clinical study was conducted in accordance with the principles of Good Clinical Practice (GCP). The storage system used during the trial and for archiving (irrespective of the type of media used) should provide for document identification, version history, search and retrieval. Oftentimes study team are aware number of years study information should be archived but unsure of how it should be done to ensure its' credibility. Principal Investigator (PI) and named individuals should ensure archive facilities are secure with appropriate environmental control and adequate protection from physical damage. Archiving of clinical study information includes essential documents and source documents. This article lists the steps in ensuring clinical study information is recorded, handled and stored in the most suitable manner.

### Archiving of essential documents

- Identify personnel responsibilities and check requirements of archiving
- Identify all study documents that are required for archiving and prepare a checklist
- Store documents in labelled archive boxes and generate an inventory checklist
- Seal the archive boxes with archive cable tags provided or packing tape
- Arrange for personnel to transfer archive boxes to storage facility and sign off the transfer
- Inventory checklist, archiving agreement and documents for each study are to be kept in a confidential folder by respective personnel
- Review archiving documents when disposal date is due to arrange for disposal or to be kept for longer period

### Archiving of source documents

- Retrieves source documents referring to the study requirements for archiving
- Label/tag the selected source documents identifying the protocol information, personnel responsible and duration of archiving
- Maintain a list of patients that were recruited into the study in a confidential folder
- Identify and inform the archiving officer of the requirements of source document archiving
- Review the archiving documents when disposal date is due to arrange for disposal or to prolong the period
- It is crucial that if PI and/or Archiving Officer is leaving the facility, a proper handover should be conducted to ensure continuity of archiving requirements.

## The Starfish Story

One fine morning a young man was walking on the beach. As he was walking, he saw a person from afar walking, stopping, bending down, standing up and then continue walking. The person kept repeating this action. The young man was curious with what the person was doing. He quickened his pace and caught up to the person.

The person was an old lady. She walked a few steps, stopped, picked up a starfish that was washed up on the beach, threw it back into the ocean, and continued walking. She kept repeating her actions. Still curious, the young man asked what she was doing.

"I'm saving the starfish," she replied.

Starfishes gets washed up on beaches and they can't go back to the ocean. Once the sun gets high, the starfishes will die.

The young man felt her actions were futile, "There are hundreds of starfishes on this beach and thousands of beaches around the world. You can't save them all. You can't make a difference."

The old lady bent down, took a starfish and said to the young man, "It makes a difference to this one." She threw the starfish into the ocean and continued walking.

Throughout the world, they are billions of people with diseases and we can't save them all. But you are making a difference in the life of your patients.

The oncology study you do can prolong a patient's survival, the asthma study you do can improve a patient's quality of life, the paediatrics study you do can bring tears of joy to the parents.

**2020 has been a challenging year but remember that the work you do makes a difference to the "starfish" in your studies. Well done to all of you.**