NHG RESEARCH QUALITY ASSURANCE PROGRAM: The program with a mission to ensure and enforce the responsible conduct of research meeting high ethical standards

QUALITÉ

Issue 2009/01

Essential Documents and Documentation. What are they?

Essential Documents are those documents which individually and collectively permit evaluation of the conduct of the trial and the quality of the data produced.

Documentation are ALL records, in any form, that describes and record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken...

To read the entire article, please click here

Audit Survival Kit- Tip #1

- ✓ Check that all documents are concise, legible and accurate.
- ✓ Check that all data are accurate, complete, accessible, organized and verifiable.
- ✓ Check that the informed consent process is recorded and documented in the medical records.

Remember: If it is not written, it is not done!

References: NHG PCR SOP-501-B05 , SGGCP Sections 4 + 8

In This Issue

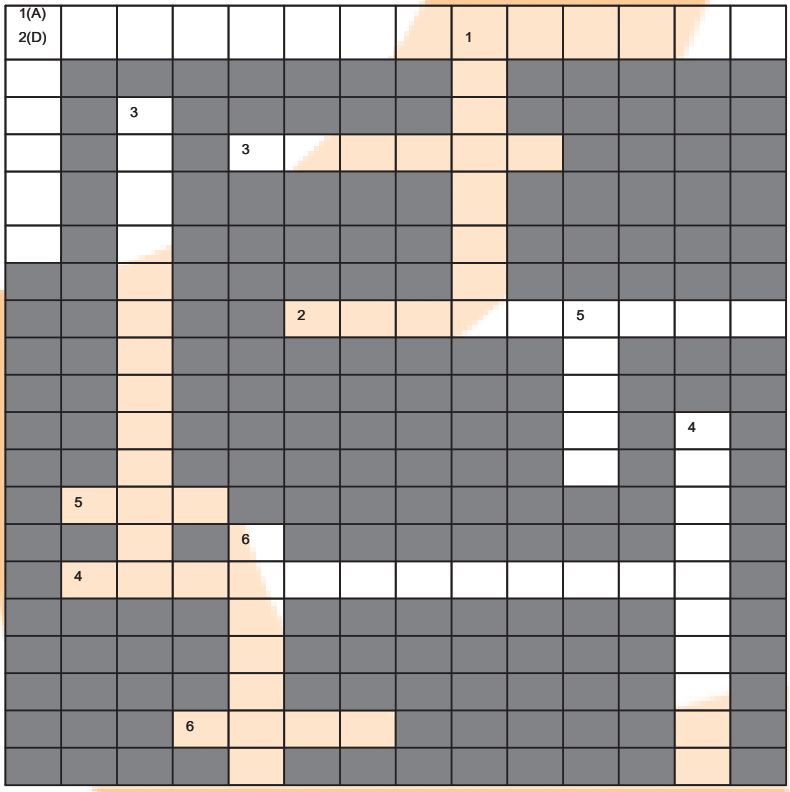
Quality Crossword Puzzle - Check Your Understanding

Across (A)

1. A Study ____ log captures the roles of study staff.
2. Documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced are called ____ documents.
3. ____ documents are original documents that data were first captured.
4. An ____site file is where the essential documents are filed.
5. Study essential documents should be retained ____ years after completion of the clinical trial.
6. Source document verification is necessary to ensure integrity of study _____.

Down (D)

1. An Investigator's ____ is an example of an essential document.
2. Case ____ form usually contains transcribed information and has no subjects' identifiers.
3. NHG PCR SOP: NHG PCR SOP-501-B05 is on ____.
4. Once a new up version of study document is approved by DSRB and HSA (if applicable), the previous document should be ____.
5. Clinical ____Certificate is required for research involving medicinal products.
6. _____notes is a source document.



Please send your completed puzzles to rdo-qa@nhg.com.sg by (Date) to participate in a lucky draw