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

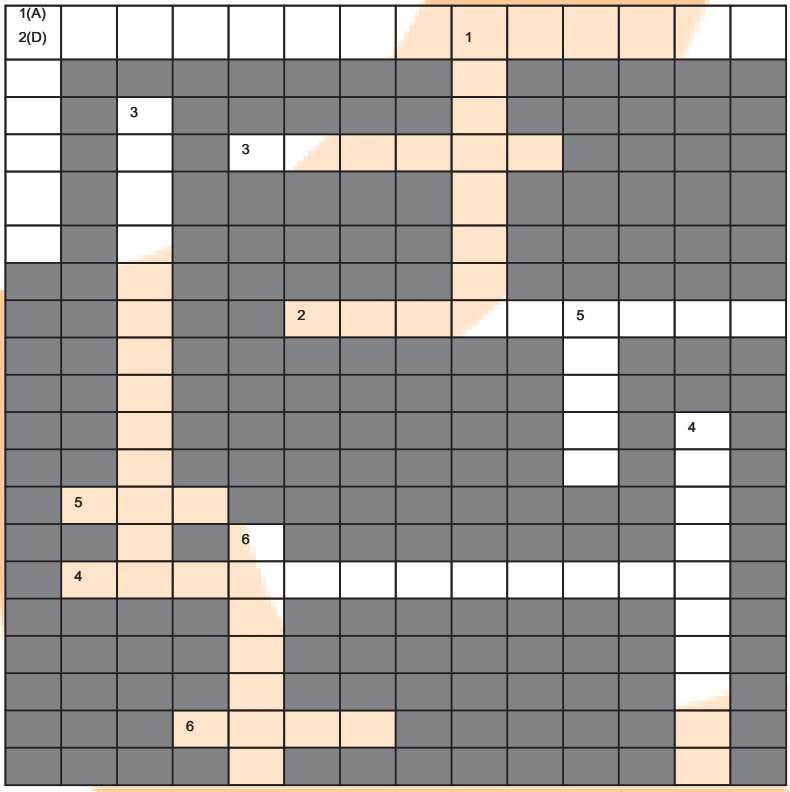
Quality Crossword Puzzle - Check Your Understanding

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

Essential documents and documentation

Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements.

Essential Documents also serve a number of other important purposes. Filing essential documents at the investigator/institution and sponsor sites in a timely manner can greatly assist in the successful management of a trial by the investigator, sponsor and monitor. These documents are also the ones which are usually audited by the sponsor's independent audit function and inspected by the regulatory authority (ies) as part of the process to confirm the validity of the trial conduct and the integrity of data collected.

Documentation are all records, in any form (including, but not limited to, written, electronic records, and scans, x-rays, and electrocardiograms) that describe and record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

Source data can be defined as all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in original source documents.

Filing of Essential documents

The list of essential documents that is required in the investigator site file can be found in SGGCP Section 8.

Common Findings

Investigator File – The most common observation in site study reviews was non compliance with essential documents requirements in Proper Conduct of Research SOPs and SGGCP Guidelines. Essential documents were either not filed or were outdated. The commonly missing / outdated documents in the Investigator File were:

Study Team – It is important to maintain up to date study team logs to ensure that the roles and responsibilities of all the study team members are documented and are always current. This is important so that any study team member would know whom to contact and how to contact other team members for enquiries or emergencies. In addition to the Curriculum Vitae of the Principal Investigator, it is good practice to maintain CVs of all study team members to ensure that the study team collective has sufficient education, training and experience to conduct the research study.

Protocol / Participants Information Sheet and Informed Consent – It is very important to maintain current approved copies of the study protocol, consent document, investigator's brochure, data collection forms, advertisements and any other study document that is used. A common finding was not all documents were filed. Moreover, when there were amendments, there was inadequate version control.

DSRB Documentation – Most Investigator Files contained important DSRB documents such as approval letters. However, it was a common finding that for most research studies, an audit trail was not maintained making it difficult to understand what changes were made and why they were made. Important documents that were commonly missing were signed copies of initial DSRB Application Form and DSRB Correspondences.

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References:

NHG PCR SOP-501-B05
SGGCP Sections 4 and 8