



Clinical Trial Health Canada Audit Findings 2011

Detailed below is a list of recent findings and best practices from a Health Canada Audit conducted late this Spring. We hope by sharing this information we will enhance your knowledge pertaining to the federal regulations and reinforce Good Clinical Practices in all clinical studies.

FINDING #1: Calibration and maintenance of study equipment used in clinical trials

Site calibration and equipment maintenance procedure should address any equipment that might be used in a trial such as: scales, temperature probes, blood pressure monitors etc. It is expected that trial equipment be maintained and/or calibrated in accordance to their manufacturer's recommendations.

FINDING #2: Standard Operating Procedure (SOP) on reviewing SOPs

It is recommended sites to have a document outlining when SOPs are reviewed and how the review process is carried out.

FINDING #3: Site Drug Reconciliation Form

In addition to capturing the administration of study drugs given to subjects, a site should have a document which demonstrates all study drug received at a site. This document should include Investigational Product that has not yet been administered to subjects. This serves to provide a 'snapshot' of current drug activity at any given point in time. This can be addressed by using one form which combines both Accountability and Reconciliation, listing all Investigational Product sequentially received and signed off as each treatment number is administered.

FINDING #4: Documentation of fridge assessment prior to receiving Investigational Product

Ensure fridge assessment is completed and on file by all parties before receiving first shipment of Investigational Product. If fridge assessment is not available or unnecessary, there should be documentation confirming an exemption.

FINDING #5: Evidence each inclusion/exclusion criteria is met or not met

Blanket statements such as 'inclusion/exclusion criteria are met' are not acceptable. Ensure criteria are always fully recorded on the source document as asked and whether a yes or no answer. When asking participant questions about criteria/eligibility, the answer to the question must be clearly documented, for example: 'does not plan on becoming pregnant' should be documented. It is recommended to have space for comments at each exclusion statement.

FINDING #6: Documentation of time of Pregnancy test

Time of pregnancy test (and other study related procedures) should be written on the source document to ensure test was conducted before drug administered.

FINDING #7: Documentation of training of study personnel on Division 5 regulations

A general binder with up to date training documents should be maintained and available on site with the following training documents for ALL staff:

- GCP training
- Division 5 training
- Protocol Compliance training
- eCRF certificate of training (i.e. INFORM, system training)
- IATA training (Dangerous Goods by air transport)
- SOP training

Training documents should include at least a certificate identifying date of completion and agenda discussed at the training session.

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