

## Data storage

Excerpt from South African Good Clinical Practice Guidelines, second edition, Department of Health 2006

### 4.8 TRIAL MANAGEMENT, DATA HANDLING, AND RECORD KEEPING

The sponsor should utilize appropriately qualified individuals to supervise the overall conduct of the trial, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports. The sponsor may consider establishing an independent data monitoring committee (IDMC) to assess the progress of a clinical trial, including the safety data and the critical efficacy endpoints at intervals, and to recommend to the sponsor whether to continue, modify, or stop a trial. The IDMC should have written operating procedures and maintain written records of all its meetings. When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should: (a.) Ensure and document that the electronic data processing system(s) conform(s) to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation). (b.) Maintains SOPs for using these systems. (c.) Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e. maintain an audit trail, data trail, edit trail). (d.) Maintain a security system that prevents unauthorized access to the data. (e.) Maintain a list of the individuals who are authorized to make data changes. (f.) Maintain adequate backup of the data. (g.) Safeguard the blinding, if any (e.g. maintain the blinding during data entry and processing). If data are transformed during processing, it should always be possible to compare the original data and observations with the processed data. The sponsor should use an unambiguous **participant** identification code that allows identification of all the data reported for each **participant**. The sponsor, or other owners of the data, should retain all of the sponsor-specific essential documents pertaining to the trial. The sponsor should retain all sponsor-specific essential documents in conformance with the applicable regulatory requirement(s) of South Africa. If the sponsor discontinues the clinical development of an investigational product (i.e. for any or all indications, routes of administration, or dosage forms), the sponsor should maintain all sponsor-specific essential documents for at least 15 years after formal discontinuation or in conformance with the applicable regulatory requirement(s). If the sponsor discontinues the clinical development of an investigational product, the sponsor should notify all the trial investigators/institutions and all the regulatory authorities. Any transfer of ownership of the data should be reported to the appropriate authority(ies), as required by the applicable regulatory requirement(s). **The sponsor specific essential documents should be retained for not less than 15 years or until, at least, two years after the last approval of a marketing application and until there are no pending or contemplated marketing applications or at least 15 years have elapsed since the formal discontinuation of clinical development of the investigational product. (Same for Investigators)** These documents should be retained for a longer period however if required by the applicable regulatory requirement(s) or if needed by the sponsor. The sponsor should inform the investigator(s)/institution(s) in writing of the need for record retention and should notify the investigator(s)/institution(s) in writing when the trial related records are no longer needed.