

<u>Signën Clinical Discoveries LTD</u>	
Affiliate Location: Jeddah, Saudi Arabia	
Date: 26 February 2009 (Previous version 20 August 2008)	
Title: SOP- Data Management - Data Validation VER 2	
Authorized Signature:	Date: 26 February 2009
Third Party Approval:	Date: 26 February 2009

Background

Signën Clinical Discoveries LTD (SCD) Standard Operating Procedures (SOPs) are designed to ensure that clinical research, and its supporting activities, is conducted to the principles of Good Clinical Practice (GCP)(1) and Good Data Management Practices (GDMP) (2). GCP is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of trials that involve the participation of human subjects. Compliance with GCP provides assurance that the data and reported results are credible and accurate, and that the rights, wellbeing and safety of participants are protected.

GCP states that all clinical trial information shall be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification. Clinical Data Management is concerned with the collection, validation, and presentation of clinical data according to the principles of GCP in order to support statistical analysis and subsequent reporting.

Purpose

To define a procedure for the validation of computerised clinical trials data. The identification of data checks to be performed on the database. The programming and testing of the validation checks on 'example' data. The validation check process on the study database to test the consistency and accuracy of the database.

Scope

This SOP applies to all SCD clinical trials where SCD is responsible for the data management and where the trial data is stored electronically on a database

Procedure

The Data Manager (DM) or person(s) responsible for the data management for the trial will be referred to as the DM for the purpose of this SOP.

1. Specifying data validation checks

- Once the protocol and Case Report Form (CRF) are finalised the DM will agree the validation checks required with appropriate representatives of the trial team.
- The DM will specify the checks in a validation document. The validation document will contain all checks (manual and computerised) to be carried out to test the consistency of the data.

2. Programming and testing data validation checks

- The computerised validation checks specified in the validation document will be programmed.
- The DM will produce “dummy” CRF data in order to test the electronic validation checks. The “dummy” data will be based on the study CRF and database design and contain example data that will trigger all the validation checks documented in the validation document. The data must also contain a ‘clean’ CRF to ensure checks do not fire inappropriately.
- Any errors or findings will be noted and amendments made to the program(s) as necessary. When the DM is satisfied with the validation checks program it can be run on project data.

3. Performing data validation

- On completion of data entry the DM will run/perform the validation checks on the project database. The timing of when the validation checks are run/performed will be decided at the start of the study and documented in the validation document.
- Discrepancies, identified during the review of the validation output or following manual checks, which require resolution will be sent to the appropriate member of the research team for resolution.
- The method for the sending, return and tracking of discrepancy queries will be decided at the start of the study and documented in the validation document.
- Changes made to the database following resolution of a discrepancy will be documented as part of the audit trail.
- Following any data changes the DM will re-run the data validation until no further discrepancies are identified.
- In circumstances where discrepancies are not able to be resolved, the DM will document this as part of the database release documentation (cross ref Database release SOP when it has a number).

References

1. Medicines for Human Use (Clinical Trials) Regulations 2004, Schedule 1, Part 2 (<http://www.uk-legislation.hmso.gov.uk/si/si2004/20041031.htm>)
2. Good Clinical Data Management Practices, Society for Clinical Data Management, July 2008,US

Attachments

Not Applicable

=====**End of Document**=====