

<b><u>Signën Clinical Discoveries LTD</u></b>	
Affiliate Location: Jeddah, Saudi Arabia Date: 26 February 2009 (ver 2 -20 August 2008)	
Title: <b>SOP- Data Management-</b> Data Release 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 releasing data for analysis on completion of all data management processes and unlocking a database that were the data has been previously released for analysis, when changes are required.

## 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. Data Release

The DM will confirm that the data is ready to be released for analysis once:

- ❖ all data queries have been resolved and the database updated
- ❖ any issues identified from Quality Control (QC checks) have been addressed
- ❖ the data has passed an error-rate audit, if applicable

The DM will document the release of the data, usually via email to the statistician and other members of the study team. A copy of the data release documentation (email) will be filed in the Study Master File (SMF).

If the clinical data management system used for the study has a data-lock functionality the DM will lock the database. If there is no data-lock functionality the DM will ensure the data cannot be altered by restricting access to the database by its location or password protection.

## 2. Data changes post data release

Occasionally it may be necessary to correct previously missed data errors or inconsistencies after data has been released for analysis. A database will only be unlocked once released if the data to be changed would have a significant affect on the statistical outcome of the analysis.

For studies where the data has been released in order to conduct an interim analysis it is acceptable for the database to be unlocked to continue data entry for the remainder of the trial. A copy of the datasets used to conduct the interim analysis must be maintained.

The Project Statistician must document their authorisation to unlock the database and the reason for the requested change (the affect on the statistical outcome), usually via email to the data manager and other members of the study team. A copy of this documentation must be filed in the SMF.

The DM will unlock the database and ensure that only the requested change(s) is made. Changes to data must be documented as part of the audit trail. The DM will confirm that the data is ready to be released for analysis once again, re-running any validation and QC steps as necessary.

The DM will document the re-release of the data, usually via email to the statistician and other members of the study team. A copy of the data re-release documentation (email) will be filed in the Study Master File (SMF).

## 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**=====