




## Procedure DEE database lock

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## REVISION HISTORY

Version number	Description	Date
9.0	New SOP	23FEB2009
8.1	SOP in English language New numbering One user manual instead of several forms, templates and examples	14SEP2011

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## ABBREVIATIONS AND DEFINITIONS

CSV	Computerized System Validation
DEE	Data Entry Export
GCP	Good Clinical Practice (ICH-E6 Guideline: GCP 1997)
SOP	Standard Operating Procedure
UM	User Manual

/ or

DEE: a method to collect, structure and verify clinical research data with using Adobe Professional combined with MsExcel or SAS.



## 1. INTRODUCTION

To prevent modifications, including additions and deletions to (part of) the study data after clean database declaration; when the database is ready for locking, the database is locked. A database lock checklist is used to assure that all the necessary steps are taken before the database is locked. When locking the database all users are revoked access, except the Data Manager who keeps read only access.

## 2. SCOPE

This SOP describes the steps to lock the database. The procedure also outlines the steps to unlock the database, if necessary and requested.

In case of an interim lock for analysis, no updates to study data due to queries and/or data conventions are allowed to take place. In fact, signed consent from the Clinical Study Manager is needed to allow for continued cleaning of the database.

Out of scope is the delivery of interim datasets or final datasets for analysis which is described in SOP 5.1 DEE data export.

## 3. AIM

This SOP assures that the quality and integrity of the study data in the final product is continuously guaranteed as unchanged, meeting clinical research requirements (GCP).

## 4. RESPONSIBILITIES

The Data Manager,

- checks that the database is ready for locking (e.g. does a signed clean database declaration exist for the study),
- signs and collects signatures for the Request for Database Lock form,
- assures no updates to study data due to queries and/or data conventions are take place during an interim analysis
- signs the database lock form,
- updates and signs for the User Access Log (21CFR11),
- signs and collects signatures for the Request for Database Unlock form,
- signs the database unlock form,
- files study documentation.

The IT Representative;

- (un)locks the database,
- revokes user access,
- signs for the updated user access log ,
- signs the database (un)lock form.



*The Clinical Study Manager;*

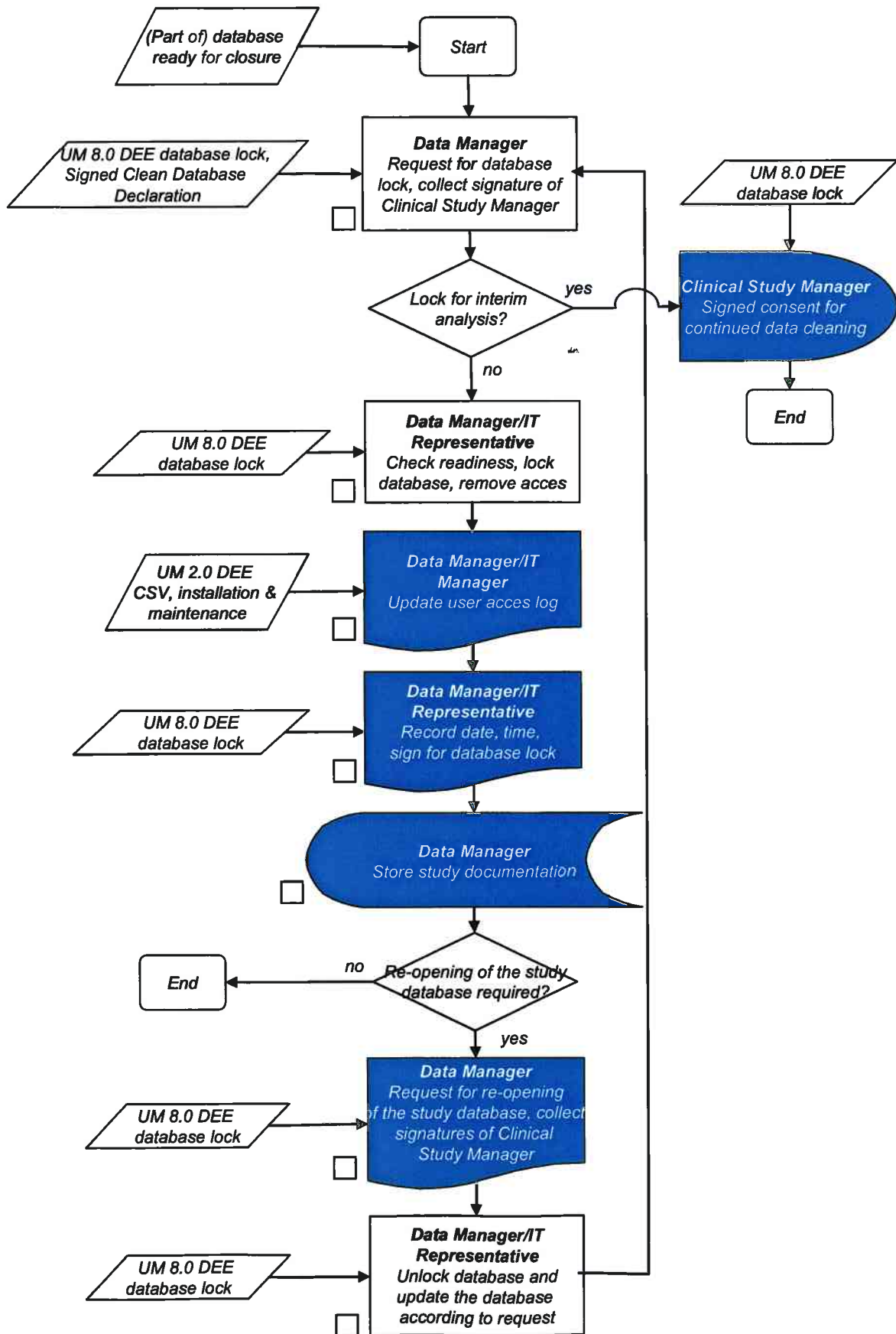
- *gives signed consent for continued study data cleaning after study data delivery for interim analysis.*

## 5. *TIMELINE*

*During the study close-out phase of the data management process for a clinical study. From declaration clean database to a locked database. Or for the duration of an interim analysis (for part of the database).*



6. ACTUAL PROCEDURE





**7. CHANGES DURING THE STUDY**  
**Not applicable.**

**8. REFERENCES**

- FDA – 21CFR11
- ICH-E6 Guideline

**9. APPENDICES**

**UM 8.0 DEE database lock**

**UM 2.0 DEE computerized system validation, installation & maintenance**