



Procedure DEE computerized system validation, installation & maintenance

Name:	Function:	Date:	Signature:
Author:			
Maritza Witteveen	Clinical data management consultant, ProCDM	15SEP2011	
Reviewed & approved by:			



REVISION HISTORY

Version number	Description	Date
3.0	New SOP	23FEB2009
2.1	SOP in English language New numbering One user manual instead of several forms, templates and examples	13SEP2011

CONTENT

ABBREVIATIONS AND DEFINITIONS	2
1. INTRODUCTION	4
2. SCOPE.....	4
3. AIM	4
4. RESPONSIBILITIES.....	4
5. TIMELINE	5
6. ACTUAL PROCEDURE.....	6
7. CHANGES DURING THE STUDY	7
8. REFERENCES.....	7
9. APPENDICES.....	7

ABBREVIATIONS AND DEFINITIONS

CDM	Clinical Data Management
CDMS	Clinical Data Management System
CFR	Code of Federal Regulations
csv	Comma separated files
CSV	Computerized System Validation
DEE	Data Entry Export
GCDMP	Good Clinical Data Management Practices
GCP	Good Clinical Practice (ICH-E6 Guideline: GCP 1997)
IT	Information Technology
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
QA	Quality Assurance
SOP	Standard Operating Procedure
UM	User Manual
URS	User Requirements Specification



/ or

Adobe Professional: *Adobe Acrobat Pro version 9 or Adobe Acrobat X software.*

Audit trail: *automatically, computerized, independent storage of time-stamped data modifications by whom.*

Computerized system: *computer hardware, software and corresponding documentation (e.g. user manual) to capture, modify, maintain, archive, provide, export or transform digital clinical data with.*

Decommissioning: *de-installation of the DEE method when decided not longer to be used by the companies management*

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

IQ: *Testing and documenting that the system is installed correctly*

OQ: *Testing and documenting that the system is operating as it is intended by its Supplier*

PQ: *Testing and documenting that the system behaves as intended by the users that acquired the system*

(Software) validation: *confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through the software can be consistently fulfilled (Guidance for Industry: Computerized Systems Used in Clinical Trials 1999, outdated. The current Guidance for Industry: Computerized Systems Used in Clinical Investigations 2007 doesn't list this definition anymore).*

URS: *All user requirements listed to help acquiring a suitable CDMS with for the company. The user requirements are graded as e.g. must have, should have, would have, could have.*



1. INTRODUCTION

This SOP describes installation, (re-)validation and maintenance of the acquired DEE method which is used to capture, verify and structure clinical research data with. In particular for (re-)validation, the SOP describes the steps to create a validation plan (PQ protocol), to validate the method accordingly and to document the validation results. This procedure meets clinical research requirements for reproducibility, quality assurance and quality control (GCP, 21CFR11).

2. SCOPE

This SOP applies to the installation, validation and maintenance of the DEE method for the collection, verification and structuring of clinical research data by its users. The DEE method uses software, hardware and operating system(s) to manage and store clinical study data as required. The necessary software is installed and maintained under supervision of the IT Manager, including modifications and access to the system. The DEE method is validated under supervision of the CDM Director. In order to test that DEE operates like it is expected to operate.

This SOP also provides guidance in creating a User Requirements Specification with which a suitable clinical data management system can be chosen. The SOP provides guidance towards the company's validation approach, including risk assessment, using the DEE method for collection, verification and structuring of clinical study data. In other words, the company's validation policy for DEE. And finally, decommissioning of the DEE method is described.

Outside the scope of this SOP is the study specific validation. E.g. CRF testing for correct data capture and storage, testing of correct data checks programming and testing of correct data export to desired data files. This study specific validation is described in SOP DEE CRF creation, SOP DEE data export and SOP DEE study data verification.

3. AIM

Goal of this procedure is to get and maintain the DEE method under subject in an ongoing validated state. Testing and correspondingly documenting that the method is capable to consistently deliver reliable data which is reproducible. In fact, proof that the system does what it is expected to do.

4. RESPONSIBILITIES

Data manager:

- *create User Requirements Specification for CDMS to be acquired*
- *writes the company's policy with regards to validation of the DEE method for collection, verification and structuring of clinical study data*
- *creates and signs for the validation plan (where needed in cooperation with the IT Officer),*
- *creates and signs for the test scripts (where needed in cooperation with the IT Officer),*
- *conducts the test scripts (where needed in cooperation with the IT Officer),*
- *writes and signs for the validation report.*
- *logs modifications to DEE method in cooperation with the IT Manager*
- *logs DEE problems in cooperation with the IT Manager*
- *logs DEE access rights in cooperation with the IT Manager*



IT manager, operating according to IT guidances and/or IT company procedures:

- *installs necessary DEE software and hardware*
- *maintains DEE software and hardware:*
 - o *logs modifications to DEE method in cooperation with the Data Manager*
 - o *logs DEE problems in cooperation with the Data Manager*
 - o *logs DEE access rights in cooperation with the Data Manager*
- *takes care of regular clinical study data and study specific programming back-ups*
- *takes care of restricted, registered access to the DEE method*
- *takes care of read-only storage for directories with csv files*
- *de-installs DEE software and hardware*
- *partly creates and signs for the validation plan, if needed,*
- *partly creates and signs for the test scripts, if needed,*
- *partly conducts the test scripts, if needed,*
- *signs for the validation report, if partly written and/or executed.*

QA officer:

- *reviews User Requirements Specification for clinical data management to be acquired*
- *reads the company's policy with regards to CDMS validation*
- *reviews and signs for the validation plan,*
- *functions as independent witness during the execution of the test scripts,*
- *reviews and signs for the validation report.*

The CDM director,

- *reviews User Requirements Specification for suitable CDMS*
- *reviews the company's policy with regards to CDMS validation and has the company's management team sign for it too*
- *assigns the Data Manager, IT manager and QA officer,*
- *reviews and signs for the validation plan,*
- *reviews and signs for the validation report.*

To comply with applicable regulations, test script authors are not allowed to function as independent witness during the execution of these test scripts.

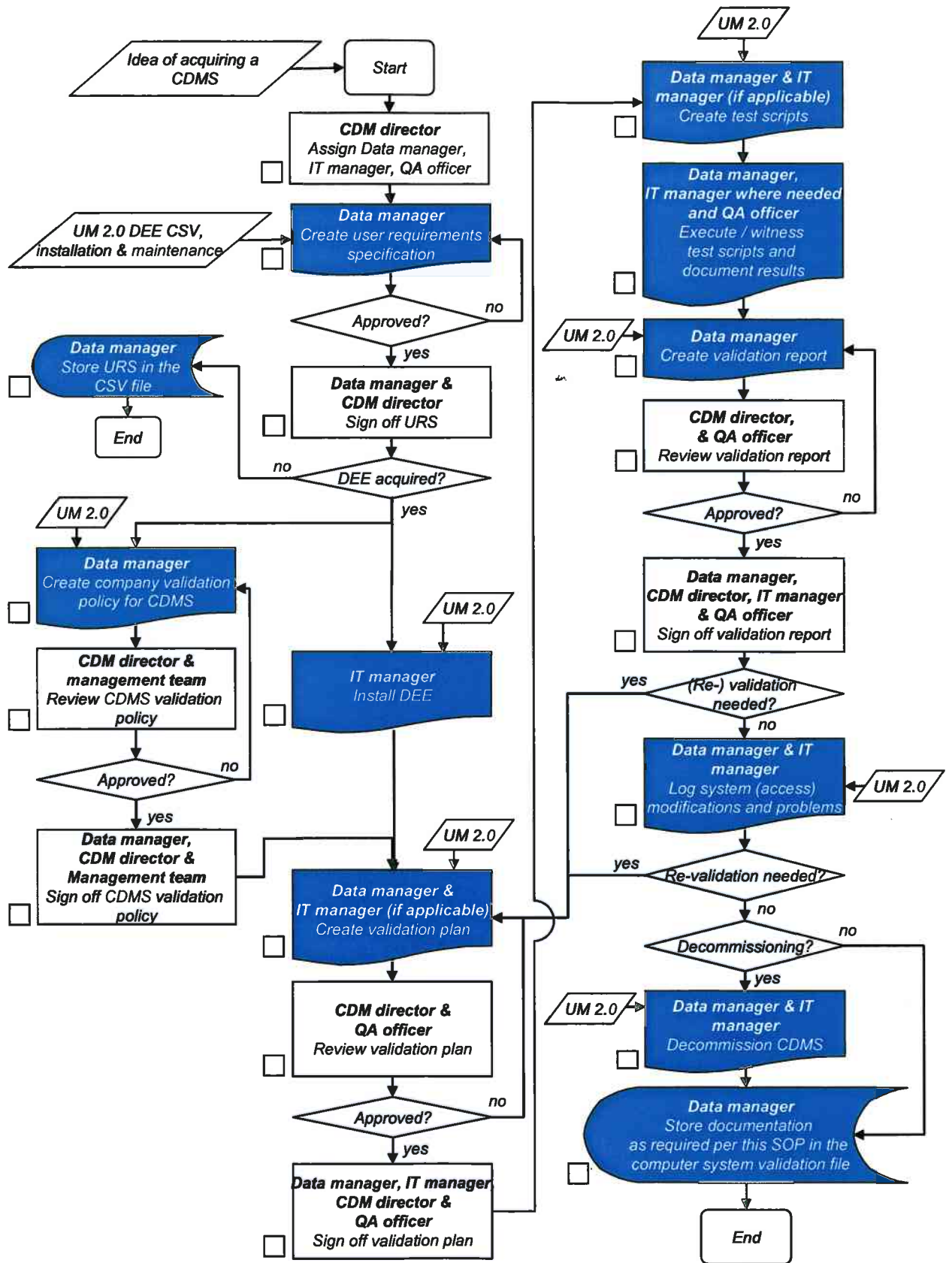
Also, an independent witness should not be directly involved in DEE or the collection, verification and structuring of data with DEE. Preferred as independent witness is an QA officer.

5. TIMELINE

Starting with the initial idea of acquiring a CDMS up till decommissioning of DEE.



6. ACTUAL PROCEDURE





7. CHANGES DURING THE STUDY

(Access) modifications to the DEE method and problems with the DEE method need to be logged.

Re-validation of (part of) the DEE method, e.g. as a consequence of a software upgrade, requires impact judgement of the modification upon the method's validated state.

8. REFERENCES

- ICH-E6 Guideline
- FDA – 21CFR11
- *Guidance for Industry: Computerized Systems Used in Clinical Investigations 2007*

9. APPENDICES

UM 2.0 DEE computerized system validation, installation*and maintenance