



Procedure DEE data export

Name:	Function:	Date:	Signature:
Author:			
Maritza Witteveen	Clinical data management consultant, ProCDM	15 SEP 2011	
Reviewed and approved by:			



REVISION HISTORY

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

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ABBREVIATIONS AND DEFINITIONS

DEE	Data Entry Export
csv	comma separated value
GCP	Good Clinical Practice (ICH-E6 Guideline)
SOP	Standard Operating Procedure
UM	User Manual

Clean dataset: a dataset of which is verified that there are no inconsistencies in the clinical research data it contains.

csv file: a file in which the data is separated by commas.

DEE: method to collect, structure and verify clinical research data with

Dataset: a file containing structured clinical research data with which analysis can be done.



Export: *the process of generating output ready for analysis, from the data captured.*

Macro: *a script with which to conduct multiple, repeating tasks regularly.*

Normalization: *the re-structuring of one row per subject to many rows per subject.
E.g. for adverse events and concomitant medications.*

Pdf file: *a file readable with Adobe Reader software.*

Transpose: *Normalization of datasets.*



1. INTRODUCTION

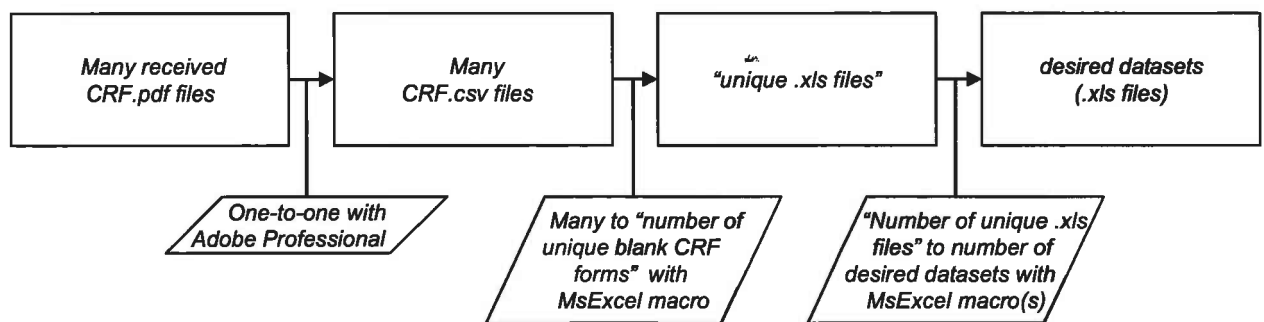
This SOP describes the export of collected study data in CRFs to grouped electronic files, so called datasets, ready for analysis. These (clean) datasets are considered the final product of data management. After delivery of the final datasets it is the Statistician's responsibility to further guarantee data integrity.

DEE data export is done by creating MsExcel macro's to re-structure data captured in CRFs to the desired format.

2. SCOPE

This SOP applies to study data captured in digital CRFs (pdf files).

Visually the procedure takes you from the received CRFs to the required datasets ready for analysis in the following order:



The SOP describes the transfer of data captured in CRF forms to MsExcel data and the creation & testing of necessary MsExcel macro(s) to re-structure data to desired datasets.

Out of scope are the data checks and the study data verification process to be able to deliver accurate, complete and reliable data (clean datasets). CRF data checks and data check specification are described in SOP CRF creation. Whereas study data verification is described in the corresponding study data verification SOP.

3. AIM

The aim is to deliver clinical study datasets in the desired format, with accurate, complete and reliable data, meeting requirements of traceability and reproducibility (GCP). A format with which statistical analysis can be done.

4. RESPONSIBILITIES

The Data Manager;

- creates necessary MsExcel macros
 - o for the transfer of .csv files to unique .xls files corresponding with the number of unique blank CRF forms
 - o for the re-structure of unique .xls files to required datasets (.xls), if needed
- tests study data export
 - o from dummy data captured in .pdf files to dummy data in corresponding datasets
- performs study data export
 - o from data captured in .pdf files to an equal number of .csv files



- from .csv files to unique .xls files corresponding with the number of unique blank CRF forms
- from unique .xls files to required datasets (.xls), if needed
- signs for formal data transfer and takes care that the Statistician signs for correct receipt,
- files any study documentation as generated by this procedure.

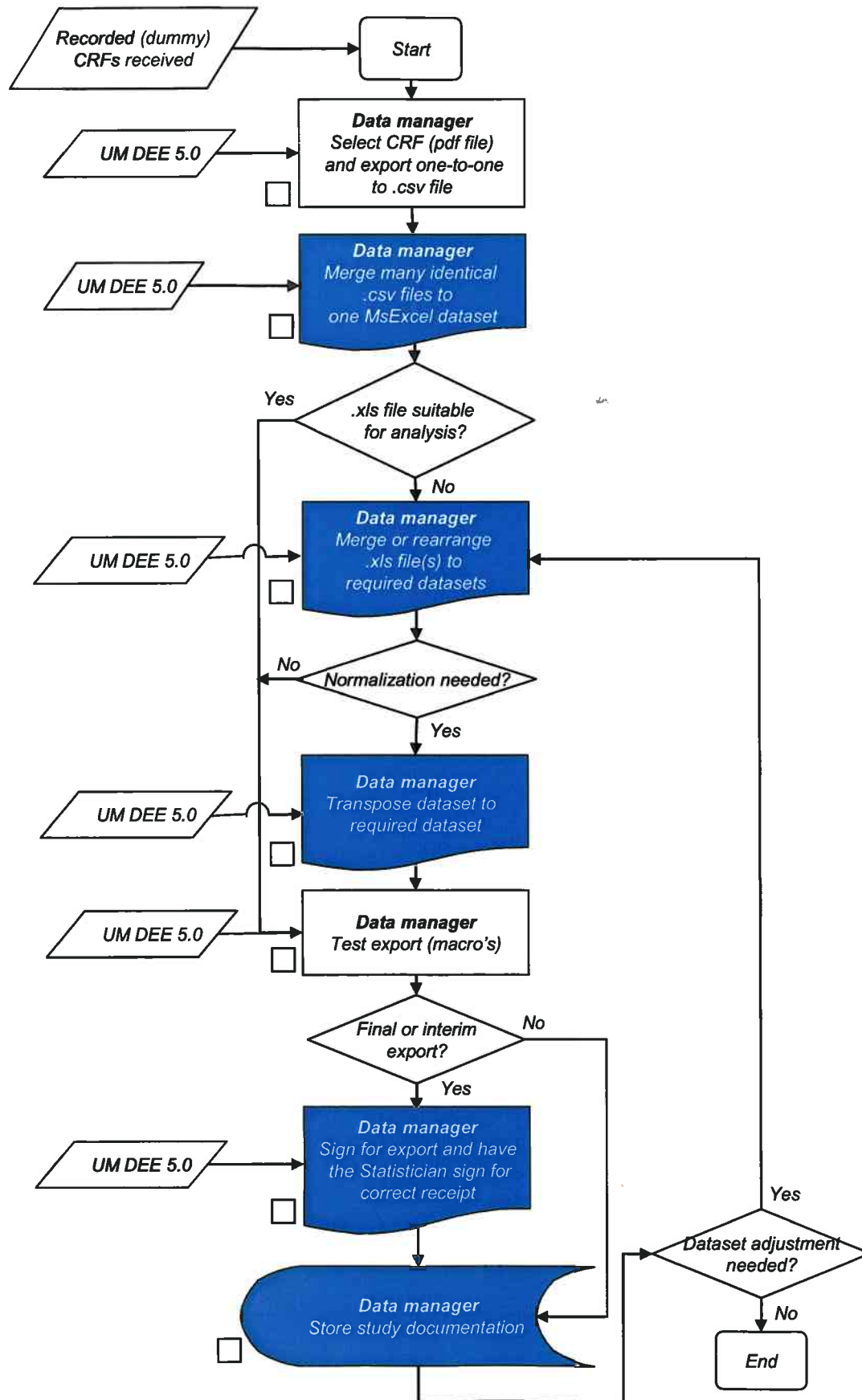
5. **TIMELINE**

Creation and testing of MSEXcel macros starts in the clinical study preparation phase. Actual performance takes place in the study conduct phase to the study close-out phase. From capturing electronic subject data to final, clean datasets.

The frequency of data export is depending on the study data flow. But at least recommended monthly, as centralized queries across CRF forms are generated up on the datasets made by this SOP.



6. ACTUAL PROCEDURE





7. CHANGES DURING THE STUDY

Changes in dataset requirements require adjustments to MsExcel macros.

8. REFERENCES

- *ICH-E6 Guideline*

9. APPENDICES

- *User manual DEE data export*