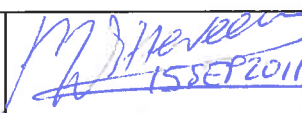




# Procedure DEE clinical study documentation

Name:	Function:	Date:	Signature:
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<b>Reviewed &amp; approved by:</b>			



## REVISION HISTORY

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

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## ABBREVIATIONS AND DEFINITIONS

CRF	Case Report Form
DEE	Data Entry Export
GCP	Good Clinical Practice (ICH-E6 Guideline: GCP 1997)
SOP	Standard Operating Procedure
UM	User Manual

**CRF:** a printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.

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



## 1. INTRODUCTION

*For the reproducibility of the study and to show compliance with SOPs, documented evidence of the data management conducted is required. Therefore data management documentation should bear at least; the document name, date last modification, study code, version number and page x of y on every page. To be able to actually store documentation as documented evidence, the document should be signed for either in the reserved space within the document, or on the first page of the document with initials, action performed and date.*

## 2. SCOPE

*The steps in this SOP concern documenting and filing of clinical data management documentation; study documentation as well as clinical data management system documentation. In summary, this SOP assures that documented evidence is created and stored throughout the study, meeting clinical research requirements (GCP).*

## 3. AIM

*This SOP describes the steps to assure documented data management evidence for clinical studies.*

## 4. RESPONSIBILITIES

*The Study Data Manager,*

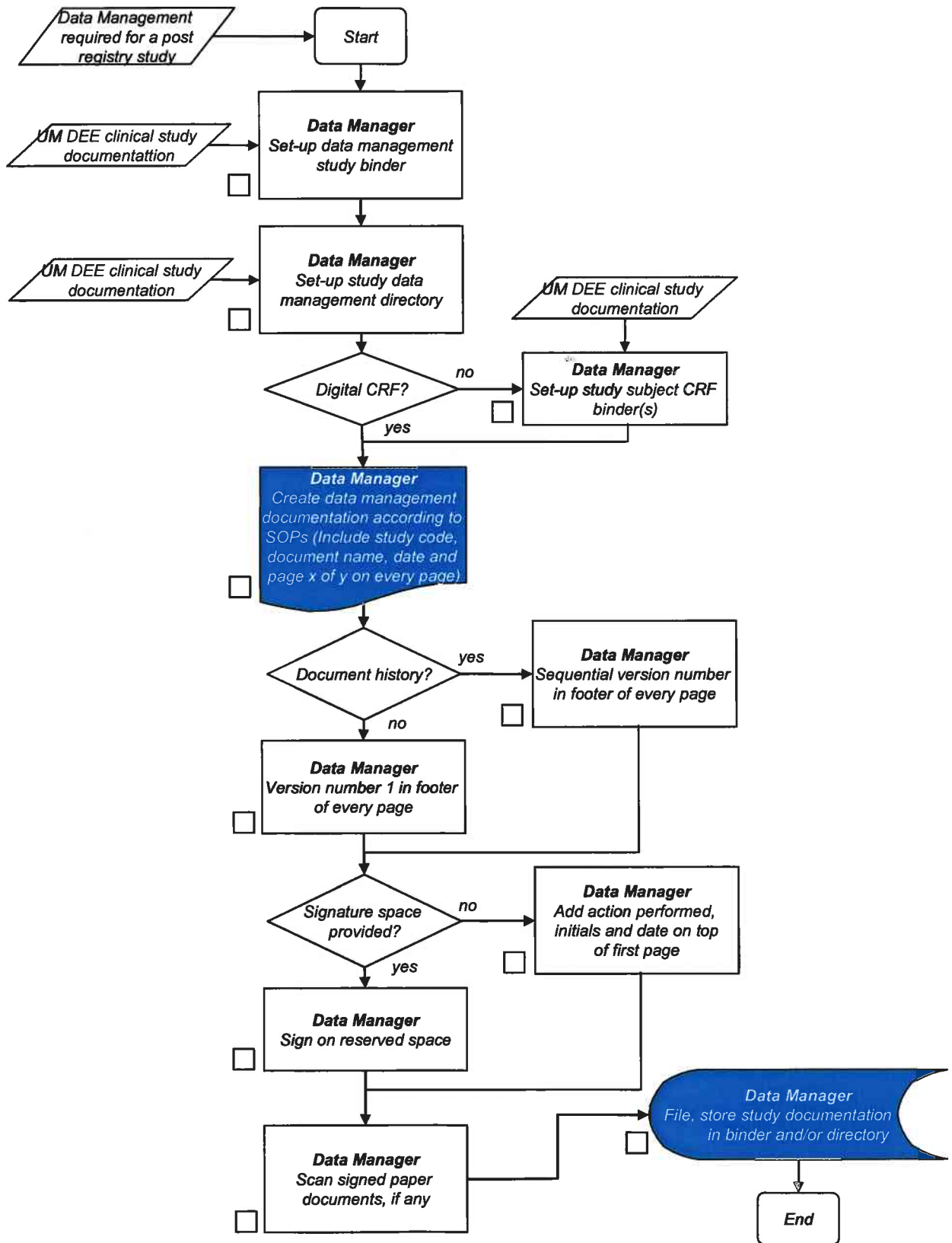
- *creates the study data management binder,*
- *creates the subject CRF binder(s) for the study, if the study collects data on paper CRFs,*
- *sets up the directory structure,*
- *adds document name, study code, version number, last modification date and page x of y on every page,*
- *signs documentation to be stored as documented evidence, either on the reserved space or at the top of the document's first page,*
- *files study documentation, in the appropriate binder and study directory.*

## 5. TIMELINE

*During the installation of a data management service up to decommissioning of this service.*



6. ACTUAL PROCEDURE





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

**8. REFERENCES**  
*ICH-E6 Guideline*

**9. APPENDICES**  
*UM 1.0 DEE clinical study documentation*