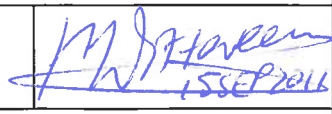




## Procedure DEE data recording

Name:	Function:	Date:	Signature:
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## REVISION HISTORY

Version number	Description	Date
6.0	New SOP	23FEB2009
4.1	SOP in English language New numbering One user manual instead of several forms, templates and examples Digital CRF recording instead of paper CRFs Guidance for digital CRF recording	13SEP2011

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## ABBREVIATIONS AND DEFINITIONS

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

/ or

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

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

*This SOP describes how to provide the necessary guidance for study site personnel to be able to record, sign and save patient data with Adobe Reader (version 9 or higher) in DEE CRFs. Each digital CRF form asks for a digital signature which captures who completed the form when (time-stamped) (21CFR11). The data recording procedure meets clinical research requirements for traceability (GCP).*

*Study site personnel should maintain the privacy of any subject. Taking care the recorded information is not identifiable, outside the study site, to a particular subject (GCDMP).*

*Accompanying CRF instructions for paper CRFs as well as electronic CRFs should be agreed upon as guiding to obtain the protocol required information, before they are distributed to the study sites.*

## 2. SCOPE

*This SOP applies to digital CRFs created with DEE. Out of scope is the initial creation and writing of study content-specific CRF instructions, which is recommended to be written by the CRA or Clinical Study Manager and reviewed, amongst others, by the Data Manager.*

## 3. AIM

*The SOP assures guidance of study site personnel in using blank CRFs, recording CRFs, signing CRFs for complete recording and saving CRFs.*

## 4. RESPONSIBILITIES

*The Data Manager,*

- *prepares the "How to store blank CRF forms and recorded CRF forms at the study site" section of the CRF instructions,*
- *prepares the "How to generate and use a personal digital signature" section of the CRF instructions,*
- *prepares the "How to validate the study site" section of the CRF instructions,*
- *prepares the "How to save a digital CRF form for future updates and for completion" section of the CRF instructions,*
- *prepares the "How to handle data check pop-ups and data alerts during recording and signing for completion" section of the CRF instructions,*
- *reviews the CRF instructions.*

*The Study Data Manager stores a copy of the CRF instructions for the clinical data management center.*

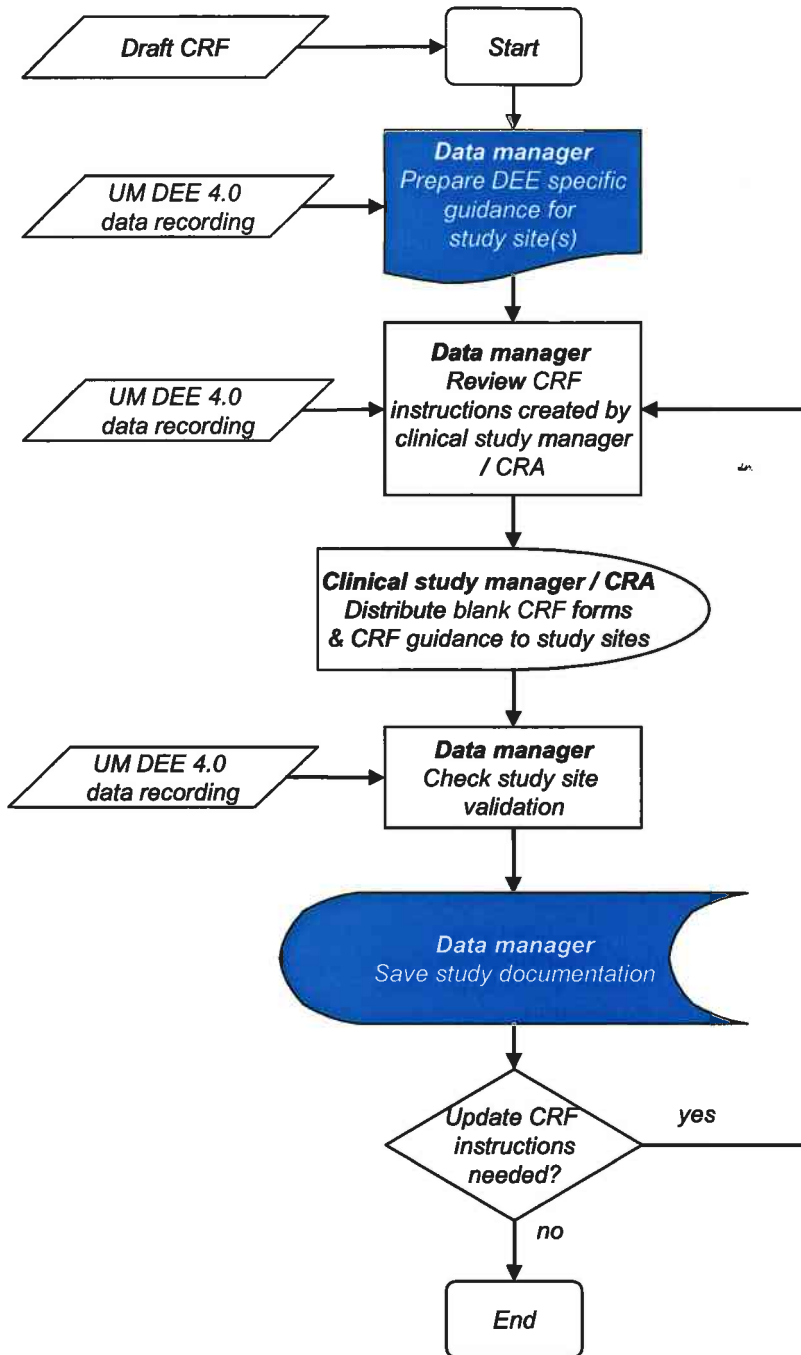


## 5. *TIMELINE*

*From the study preparation phase, during finalization of the CRF, to the study conduct phase of the data management process for a clinical study.*



### 6. ACTUAL PROCEDURE





**7. CHANGES DURING THE STUDY**

*Blank CRF form updates due to a CRF adjustment. Which requires distribution of the new blank CRF forms to the study sites.*

*Updates to CRF instructions.*

**8. REFERENCES**

- FDA – 21CFR11
- ICH-E6 Guideline
- Good Clinical Data Management Practices

**9. APPENDICES**

*UM 4.0 DEE data recording*