



Procedure DEE CRF creation

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REVISION HISTORY

Version number	Description	Date
4.0	New SOP	23FEB2009
3.1	SOP in English language New numbering One user manual instead of several forms, templates and examples CRF created with Adobe Professional	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

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

The CRF is the first step in the data flow impacting data quality.

First thing is to create a study CRF that captures protocol required information with which the efficacy and safety objectives of the study can be analyzed.

The CRF creation process should also take care to:

- *the sequence of CRF items following regular patient care,*
- *the use of unambiguous CRF questions,*
- *avoidance of redundant data,*
- *a user friendly design (GCDMP),*
- *subject privacy protection*
- *and attribution of data to the person completing the CRF.*

In fact a good study CRF serves the study objectives and the people using the CRF; the Investigator(s) and other people of the study site(s), the database designer(s) and the data entry people, if applicable.

The CRF and incorporated data checks to support the recording of subject data, needs to be tested and approved up on before distribution of the CRFs to the study sites.

2. SCOPE

This SOP describes the steps to create a user friendly CRF, including CRF data checks to support clean data capture, with Adobe Professional, able to answer the study objectives (efficacy and safety) of a clinical trial. Fulfilling GCP requirements of solely capturing protocol required information, traceability and subject privacy.

The creation of CRF instructions are outside the scope of this SOP. CRF instructions fall within the scope of SOP DEE data recording.

3. AIM

Creating a user friendly study CRF that collects anonymous study data for each subject, attributable to the person completing the patient CRF, and able to answer the study's efficacy and safety objectives. Focussing on the study specific content; what should we exactly collect for this study?

4. RESPONSIBILITIES

The data manager,

- *creates and tests the CRF, including CRF data checks, following the study protocol and the CRF creation user manual (UM 4.0),*
- *creates an annotated CRF listing the variable names and data file names to document the database specification,*
- *arranges a data check meeting and consecutively writes the data check specifications. Implements and tests CRF data checks,*
- *takes care of signing off the CRF Approval form for the study CRF as author together with at least the clinical study manager and strongly recommended; the principal Investigator as reviewers (CRF Approval form is included in the CRF creation user manual),*



- files study documentation.

The CRF reviewer (a.o. clinical study manager),

- reviews the CRF;
 - o (1) by comparing it with the final study protocol; does it collect all protocol-required data?
 - o and (2) by experiencing the CRF; recording dummy data in the CRF,
- signs the CRF Approval form for the study CRF for review and approval.

5. **TIMELINE**

During the study set-up phase of the data management process for a clinical study. From receiving the draft protocol to distributing the CRF. The CRF should be finalized after finalization of the study protocol and before distribution to the study site(s).

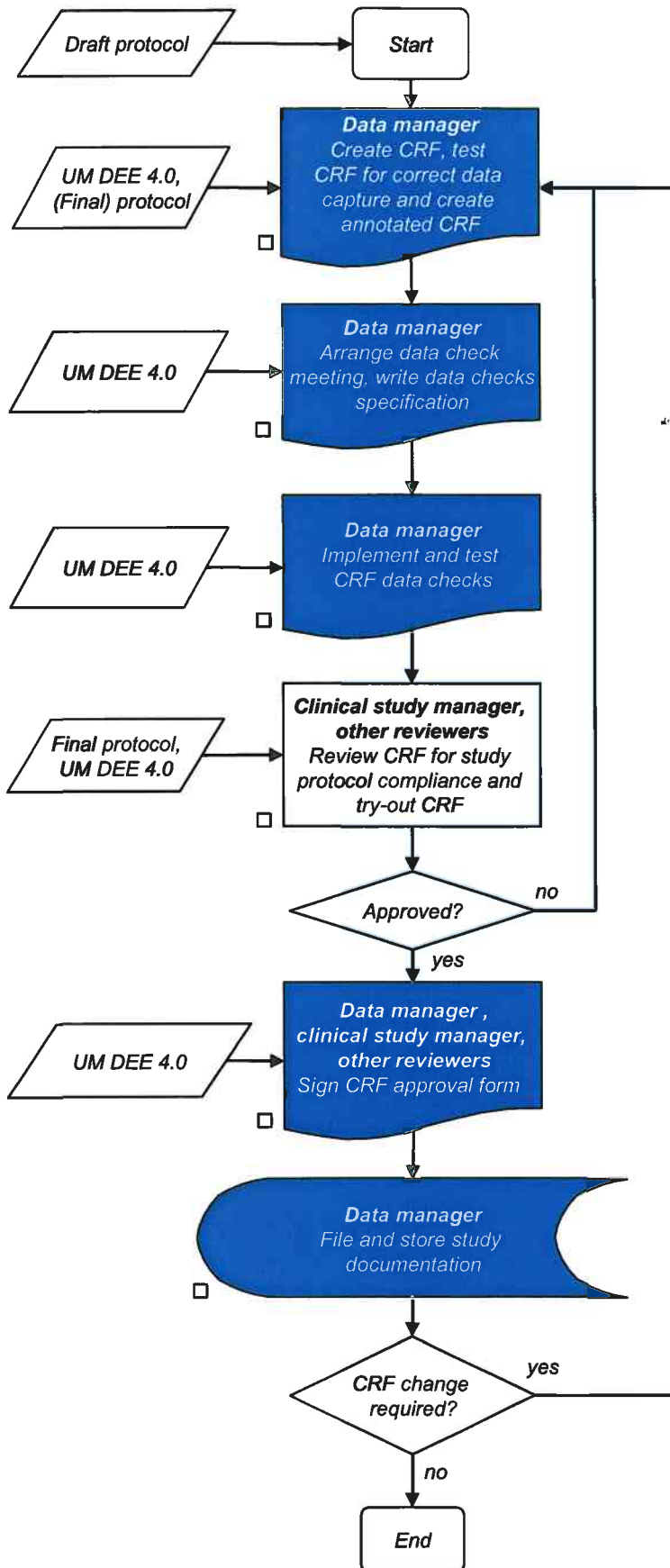
The hourly investment for the creation of a study CRF is estimated to be at least 40 hours. While creating the CRF with all its data collection fields, you simultaneously are building the study data capture tool of DEE; the way collected study data is stored.

The exact hourly investment is dependent on:

- (1) the number of unique CRF pages,
- (2) the number of data collected per unique CRF page
- (3) the number of blank CRF pages in total
- (4) the type and amount of CRF data checks desired



6. ACTUAL PROCEDURE





7. CHANGES DURING THE STUDY

Required CRF changes during the study will be recorded and signed for on a new CRF Approval Form for any changes made. To actually change the CRF this CRF creation procedure should be followed. Institutional Review Board approval could be necessary before the updated CRF is allowed to be used for patient data recording.

8. REFERENCES

- *ICH-E6 Guideline; Good Clinical Practice 1997*
- *Good Clinical Data Management Practices (www.scdm.org)*

9. APPENDICES

User manual DEE CRF creation