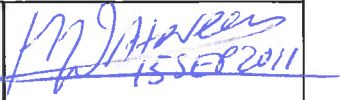




Procedure DEE quality control

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Reviewed & approved by:			



REVISION HISTORY

Version number	Description	Date
10.0	New SOP	23FEB2009
7.1	SOP in English language New numbering One user manual instead of several forms, templates and examples	14SEP2011

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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.

Audit trail: automatically, independent storage of data modifications by whom and when.

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.



data convention: *unambiguous error where the correction is clear. E.g. spelling error. The Clinical Investigator is noted upfront of the data conventions, but doesn't receive a query.*

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

Inspection: *Comparing clinical data as recorded at different points in the data management process. For example comparing CRFs with raw data listings.*



1. INTRODUCTION

Clinical trial data must fulfil an acceptable quality level to allow for acceptance by regulatory authorities. The study data should equal interpretations and conclusions as drawn from error-free data (Institute of Medicine). The required quality level as shown by an error rate acceptance of 0,5 % (1 error per 200 CRF data fields) is agreed upon per this SOP.

Error prevention is assured by clear CRF design, electronic data checks, review and standardization as described in DEE SOPs.

In order to measure data quality, inspections and review of aggregate statistics are performed. If results do not meet the required quality level, this could result in additional work as to meet the required quality level. Or worse, in data not being accepted by a health authority or excluded from the analysis, adversely impacting the results of the study.

2. SCOPE

This SOP describes the DEE steps to conduct inspections to measure the data quality level.

In fact, inconsistencies found by comparison of received CRFs with the corresponding data files, need to have a valid explanation; (1) data update due to applied data convention or (2) data update in line with received query answer form study site.

Outside the scope is computerized system validation, implementation of quality assurance and study specific validation. These are respectively covered in SOP 2.1 DEE computerized system validation, installation and maintenance, by the quality assurance department and the study specific validation by SOP 3.1 DEE CRF creation, SOP 5.1 DEE data export and SOP 6.1 DEE study data verification.

3. AIM

This SOP assures that the quality of the study data is assessed where not already assured or validated, meeting clinical research requirements (GCP, GCDMP). To control the reproducibility and data integrity of the study.

Accepted is a 0,5 % error rate. A 10% sample is taken for inspection. In case the error rate is > 0,5 % corrective action is done by inspecting all clinical study data (100% sample). A maximum of one error per CRF data field (variable) is counted. Even when several errors are made in one CRF data field (e.g. several spelling inconsistencies or days AND years inconsistent in a date field).

At least a 10% sample should be inspected (1) when the study is around 25% of the study conduct phase (25% of all subject CRFs received) and (2) just before database lock (around 100% of the CRFs received).

4. RESPONSIBILITIES

The Inspector; a Data Manager or Clinical Study Team member who did not perform the work being inspected, performs inspection of data samples. If needed, the Inspector randomly picks subject numbers to fulfil the sample being inspected.

The Inspector;

- *compares received CRFs with data files to be delivered for analysis, combined with completed queries from the study site(s) and study data conventions,*



- *conducts a 10% sample of all study subjects received,*
- *randomly picks subject numbers for the required sample,*
- *conducts an inspection when the study is around 25% of the study conduct phase (25% of all subject CRFs received) and study data updates due to queries and data conventions took place,*
- *conducts an inspection just before database lock (around 100% of the CRFs received).*

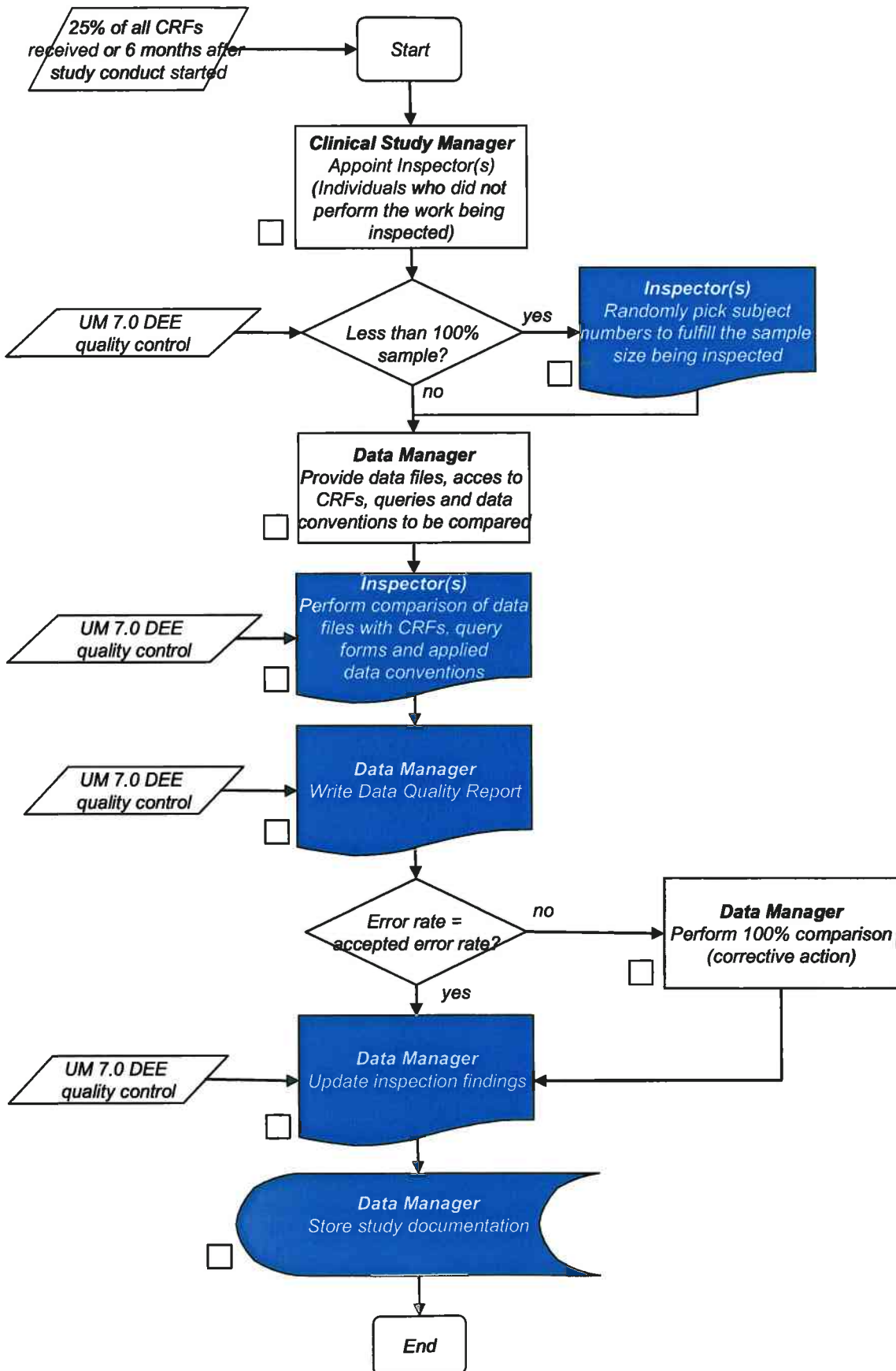
The Data Manager,

- *provides completed CRFs, completed query forms, applied data conventions and data files (ready for analysis) for inspection,*
- *writes the Data Quality Report and calculates the error rate,*
- *updates inspection findings,*
- *carries out corrective action,*
- *files study documentation.*

5. TIMELINE

During the study conduct phase of the data management process for a clinical study. From receiving subject data to database closure.

6. ACTUAL PROCEDURE





7. CHANGES DURING THE STUDY
Not applicable.

8. REFERENCES

- *ICH-E6 Guideline*
- *Good Clinical Data Management Practices*
- *Institute of Medicine*

9. APPENDICES

UM 7.0 DEE quality control