




# Procedure DEE study data verification

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## REVISION HISTORY

Version number	Description	Date
7.0	New SOP	23FEB2009
6.1	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

/ or  
 - until

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.



**data convention:** *unambiguous error where the correction is clear. E.g. spelling error. The 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.*



## 1. INTRODUCTION

Everything someone notices as questionable clinical data should be acted upon in order to be able to make final interpretations and conclusions equal to those derived from error-free data (Institute of Medicine, GCDMP). The Data Checks Specification lists all electronic data checks, manual data checks and listings to be reviewed. Items that generate questions study data verification results in queries for the study site(s). Query resolutions by the study site(s) could result in corresponding database adjustments. For example missing data without a valid reason and conflicting data is verified.

Data Managers could be exposed to sources revealing information that can lead to the identification of a subject. E.g. accidentally in an answer to a query. In all cases the privacy of any subject should be maintained (GCDMP).

## 2. SCOPE

This SOP describes the steps to generate, manage and resolve study data questions at the data management center with DEE. Most data checks were already implemented and fire for inconsistencies at the CRF data recording level. This SOP is only valid after data receipt from the study sites. Therefore, this SOP focuses on possible inconsistencies across CRF forms (study visits) and text review.

The SOP describes the procedure to capture who modified which data, why and when. To assure traceability and reproducibility (GCP). Digital signatures on completed digital query forms reveal who answered queries, when, at the study site (21CFR11).

Out of scope are, as mentioned above, the creation and testing of CRF data checks. These are described in SOP CRF creation.

## 3. AIM

Performance of structured study data verification. If something is noticed, take action. The main rule in this data cleaning process. The actions eventually resulting in quality data for analysis meeting clinical requirements for accurateness, reliability and completeness (GCP)

## 4. RESPONSIBILITIES

The Study Data Manager,

- collects queries, through structured review and electronic query generation, according to the Data Checks Specification,
- creates corresponding query descriptions in digital query forms, per site, per study subject,
- sends queries to CRA for study site(s),
- collects, reviews query resolutions and alters the corresponding study data, if necessary,
- applies data conventions,



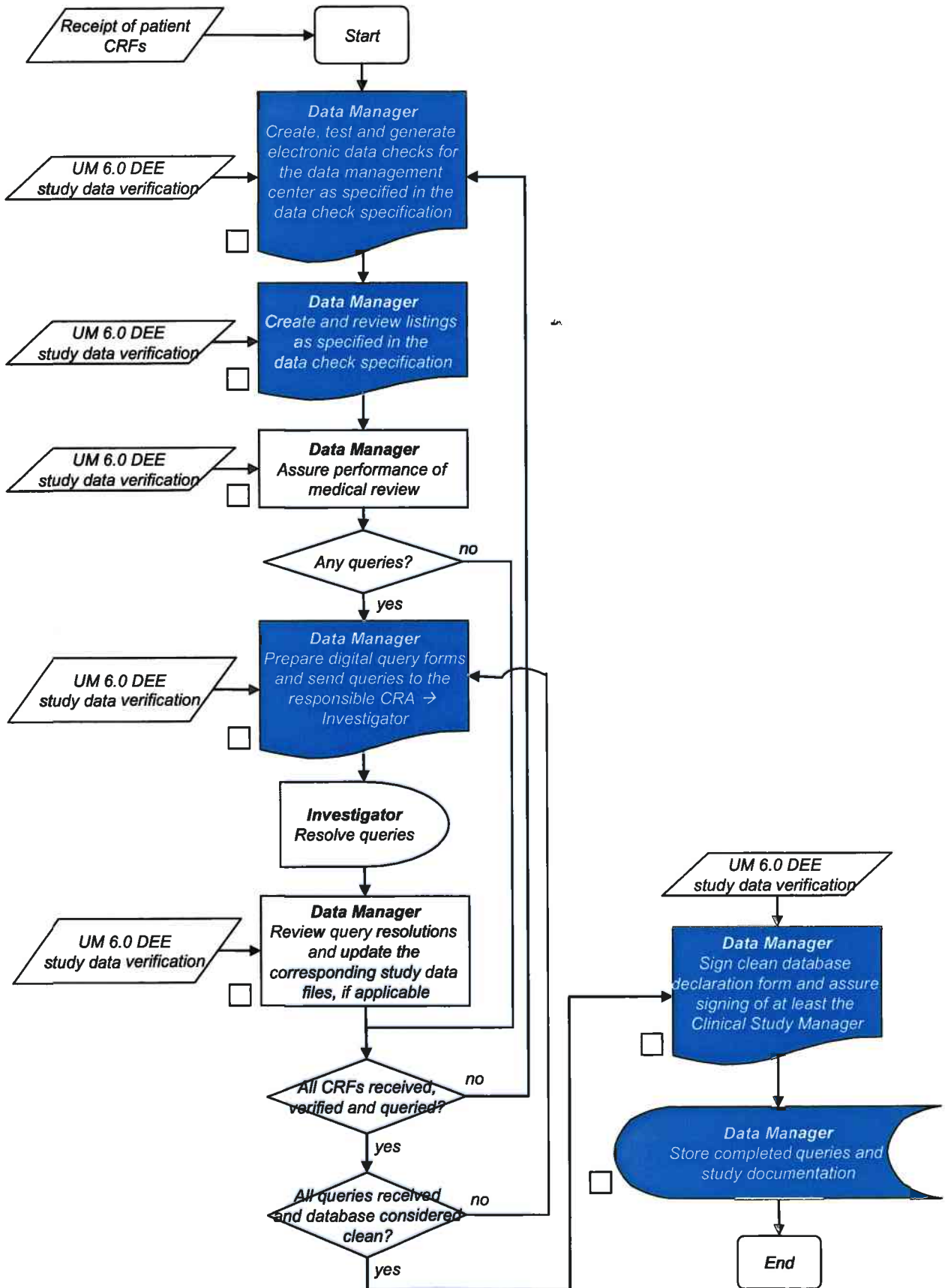
- signs the Clean Database Declaration form, and has the Clinical Study Manager and CRA sign it,
- files completed query forms and study documentation.

5. **TIMELINE**

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



6. ACTUAL PROCEDURE





## **7. CHANGES DURING THE STUDY**

**Updates to the Data Check Specification can require corresponding updates to electronic data checks, manual data checks or listings to be reviewed at the data management center.**

## **8. REFERENCES**

- **FDA – 21CFR11**
- **ICH-E6 Guideline**
- **Good Clinical Data Management Practices**
- **Institute of Medicine**

## **9. APPENDICES**

**UM 6.0 DEE study data verification**