



User manual DEE clinical study documentation

<i>Name:</i>	<i>Function:</i>	<i>Date:</i>	<i>Signature:</i>
<i>Author:</i>			
Maritza Witteveen	Clinical data management consultant, ProCDM		
<i>Reviewed and approved by:</i>			



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ABBREVIATIONS AND DEFINITIONS

<i>CRF</i>	<i>Case Report Form</i>
<i>CSV</i>	<i>Comma Separated Values</i>
<i>CSVIM</i>	<i>Computerized System Validation Installation Maintenance</i>
<i>SOP</i>	<i>Standard Operating Procedure</i>

CRF: a document designed to collect clinical research data with



1 SET-UP DATA MANAGEMENT STUDY BINDER

Setting up a binder for storing and archiving of paper documents for the data management part of a study.

Step	Action	Performed?	
		Yes	No
1.	Create a back for the data management study binder with help of the template to create the 'back' for a data management study binder.	<input type="checkbox"/>	<input type="checkbox"/>
2.	Create the table of contents for the data management study binder with help of the template to create the table of contents for a data management study binder.	<input type="checkbox"/>	<input type="checkbox"/>
3.	For what documents to file at which tab, read chapter 2 Set-up study data management directory.	<input type="checkbox"/>	<input type="checkbox"/>

TEMPLATE TO CREATE THE 'BACK' FOR A DATA MANAGEMENT STUDY BINDER

<study name>

2011

<organization>
Clinical data
management
study binder



TEMPLATE TO CREATE THE TABLE OF CONTENTS FOR A DATA MANAGEMENT STUDY BINDER

TABLE OF CONTENTS

- 1** **COMPUTERIZED SYSTEM VALIDATION,
INSTALLATION & MAINTENANCE**

- 2** **CRF**

- 3** **DATA CHECKS SPECIFICATION**

- 4** **DATA RECORDING INSTRUCTIONS**

- 5** **STUDY DATA VERIFICATION**

- 6** **DATA EXPORT**

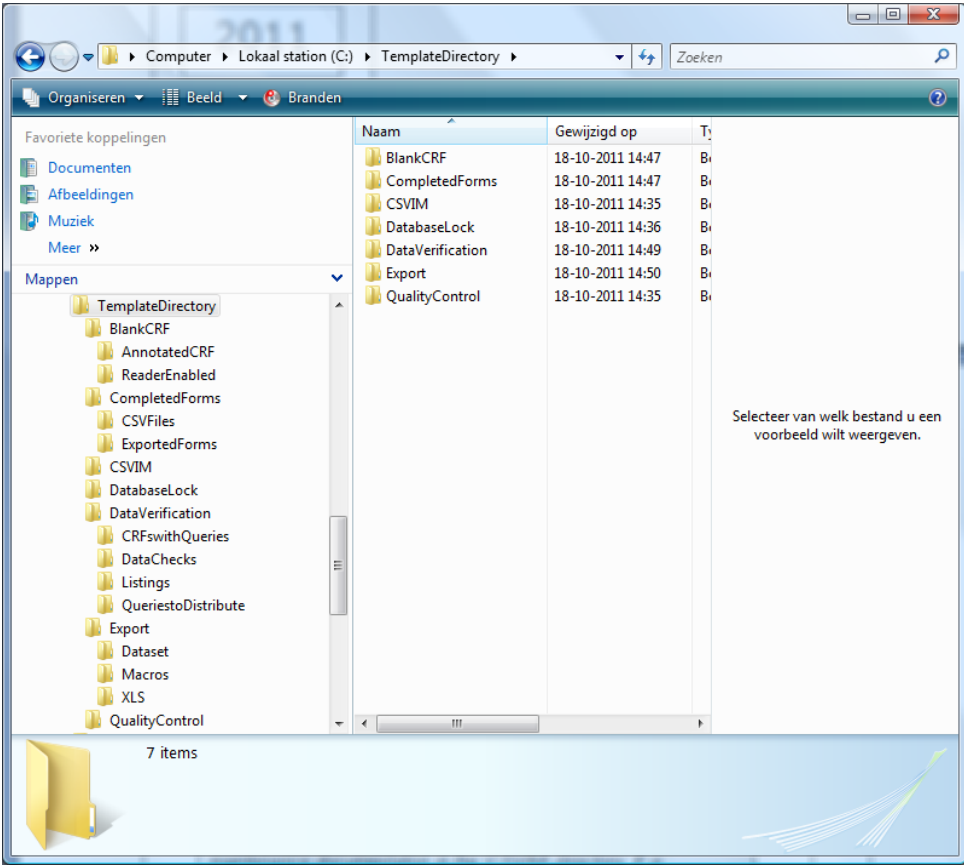
- 7** **QUALITY CONTROL**

- 8** **DATABASE LOCK**

- 9** **MISCELLANEOUS**

2 SET-UP STUDY DATA MANAGEMENT DIRECTORY

Setting up the data management study directory for storage of electronic documents.

Step	Action	Performed?	
		Yes	No
1.	<p>Create a data management directory for the study with help of the list data management study directories.</p> <p>Tip for new DEE users:</p> <ul style="list-style-type: none"> - create the study directory according to the list - immediately create a copy of the directory structure and store this copy in C:\ with 'TemplateDirectory' as short study name. (This way you can simply copy & paste the TemplateDirectory structure for use by future studies.) 	<input type="checkbox"/>	<input type="checkbox"/>
2.	<p>Store computerized system validation, DEE installation and DEE maintenance documentation in the \CSVIM\ directory. E.g.:</p> <ul style="list-style-type: none"> DEE installation checklist, DEE access log, DEE modifications & problems log, validation plan, test scripts, validation report. <p>Also the DEE Risk Analysis for the study should be stored here.</p>	<input type="checkbox"/>	<input type="checkbox"/>
3.	<p>Store any documents with regards to CRF development in the \BlankCRF\ directory. E.g.:</p> <ul style="list-style-type: none"> blank CRF forms, 	<input type="checkbox"/>	<input type="checkbox"/>



	<p>a copy of the Data Checks Specification document, dummy data to test the CRF, documented evidence of data checks within the CRF forms, CRF Approval Form, CRF design related correspondence.</p>		
4.	<p>Store any documents with regards to the annotated CRF in the \BlankCRF\AnnotatedCRF\ directory. E.g.: annotated CRF, code list.</p>	<input type="checkbox"/>	<input type="checkbox"/>
5.	<p>Store any documents with regards to finished CRF forms that are reader enabled in the \BlankCRF\ReaderEnabled\ directory. E.g.: reader enabled CRF forms.</p> <p>The reader enabled CRF forms can be distributed to the site when the CRF Approval Form is signed for review & approval.</p>	<input type="checkbox"/>	<input type="checkbox"/>
6.	<p>Store any received CRFs or Query forms from the study site in the \CompletedForms\ directory. E.g.: received CRF forms from the study site, received Query forms from the study site, received DEE validation form from the study site.</p>	<input type="checkbox"/>	<input type="checkbox"/>
7.	<p>Store all CSV files in the \CompletedForms\CSVFiles\ directory. Per unique CRF form. In other words, create subdirectories for each blank CRF form, within the \CompletedForms\CSVFiles\ directory, to store the corresponding CSV files in.</p> <p>E.g. CSVFiles \AE\ \CONM\ \Screening\ \FUvisits\ \Questionnaires\ \EndofStudy\</p>	<input type="checkbox"/>	<input type="checkbox"/>
8.	<p>Move any received CRFs or Query forms from the study site that you've exported to a csv file from the \CompletedForms\ to the \CompletedForms\ExportedForms\ directory.</p>	<input type="checkbox"/>	<input type="checkbox"/>
9.	<p>Store any documents with regards to data checks in the \DataVerification\DataChecks\ directory. E.g.: the Data Checks Specification documentation.</p>	<input type="checkbox"/>	<input type="checkbox"/>
10.	<p>Store any documents with regards to listings for review in the \DataVerification\Listings\ directory. E.g.: listings for medical review, listings for manual review, overviews for tracking, listings that reveal study data inconsistencies.</p>	<input type="checkbox"/>	<input type="checkbox"/>
11.	<p>Store any documents with regards to query generation in the \DataVerification\QueriestoDistribute\ directory. E.g.: the Query form template, the prepared Query forms, correspondence about queries.</p>	<input type="checkbox"/>	<input type="checkbox"/>



12.	Store any documents with regards to queries popping up from received CRFs in the \DataVerification\CRFswithQueries\ directory. E.g.: the CRF form Queries template, CRF form Queries documents.	<input type="checkbox"/>	<input type="checkbox"/>
13.	Store any documents with regards to datasets in the \Export\Dataset\ directory. E.g.: generated MsExcel datasets.	<input type="checkbox"/>	<input type="checkbox"/>
14.	Use the \Export\XLS\ directory to store xls files generated by the macro to merge csv files to one xls file in.	<input type="checkbox"/>	<input type="checkbox"/>
15.	Store MsExcel macro's in the \Export\Macros\ directory. E.g.: macro's to generate datasets, macro's to generate listings, macro's to centrally check study data for inconsistencies.	<input type="checkbox"/>	<input type="checkbox"/>
16.	Store all quality control documentation in the \QualityControl\ directory. E.g.: listing inspection observations, quality control report, dataset print-outs used for quality control.	<input type="checkbox"/>	<input type="checkbox"/>
17.	Store all database lock documentation in the \DatabaseLock\ directory. E.g.: request for database lock form, database lock form.	<input type="checkbox"/>	<input type="checkbox"/>

LIST DATA MANAGEMENT STUDY DIRECTORIES:

```
C:\<short study name> \CSVIM\
                        \BlankCRF\
                        \BlankCRF\ReaderEnabled\
                        \BlankCRF\AnnotatedCRF\
                        \CompletedForms\
                        \CompletedForms\ExportedForms\
                        \CompletedForms\CSVFiles\
                        \DataVerification\CRFswithQueries\
                        \DataVerification\DataChecks\
                        \DataVerification>Listings\
                        \DataVerification\QueriestoDistribute\
                        \Export\Dataset\
                        \Export\Macros\
                        \Export\XLS
                        \QualityControl\
                        \DatabaseLock\
```



3 SET-UP STUDY SUBJECT CRF BINDER(S)

Setting up subject binder(s) for storage of data recorded on paper CRF forms for the study.

Step	Action	Performed?	
		Yes	No
1.	Create a back for the study subject CRF binder with help of the template to create the 'back' for a subject CRF study binder.	<input type="checkbox"/>	<input type="checkbox"/>

TEMPLATE TO CREATE THE 'BACK' FOR A SUBJECT CRF STUDY BINDER

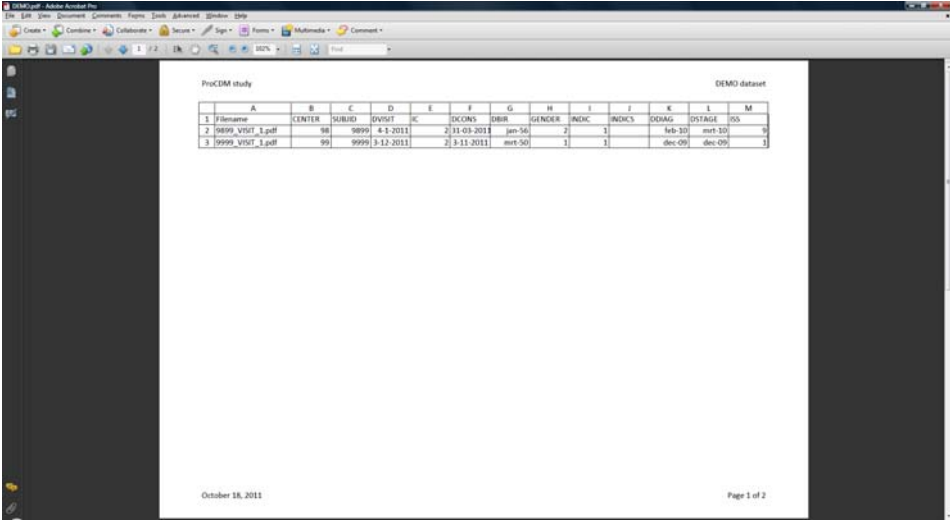
<study name>
 <Subject number
 -subject number>

2011

<organization>
 Subject CRF
 study binder

4 CREATE STUDY DATA MANAGEMENT DOCUMENTATION

Creating study data management documentation as documented evidence of the work performed. Documents that reveal what is actually done, when, by whom and how.

Step	Action	Performed?	
		Yes	No
1.	<p>Add the following information on every page to each data management document for your study:</p> <ul style="list-style-type: none"> Study code (e.g. top left in header) Document name (e.g. in header) Page x of y (e.g. right bottom in footer) Date finished (e.g. in footer) 	☐	☐
2.	<p>In case there is a document history, e.g. there is an earlier version of the document available, add the sequential version number to the footer of the document on every page.</p> <p>In case this is the first version of the document, e.g. there is no document history for this study, add version 1 to the footer of the document on every page.</p>	☐	☐
3.	<p>In case there is space provided for signatures, sign in the reserved space as author, or reviewer or for review & approval, With name, function, date and signature.</p> <p>In general, you can find this reserved space for signatures on the first or second page of the document.</p> <p>In case there is no reserved space for signatures in the document, add the action performed, your initials and the date you've finished this action on the top right of the first page of the document. E.g. Reviewed by MW 04OCT2011</p>	☐	☐

	<p>Compared with 9899_VISIT_1.pdf by MW on 18OCT2011. No inconsistencies found.</p> <p style="text-align: right;">DEMO dataset</p> <table border="1" data-bbox="316 293 1129 423"> <thead> <tr> <th></th> <th>G</th> <th>H</th> <th>I</th> <th>J</th> <th>K</th> <th>L</th> <th>M</th> </tr> <tr> <th></th> <th>DBIR</th> <th>GENDER</th> <th>INDIC</th> <th>INDICS</th> <th>DDIAG</th> <th>DSTAGE</th> <th>ISS</th> </tr> </thead> <tbody> <tr> <td>11</td> <td>jan-56</td> <td>2</td> <td>1</td> <td></td> <td>feb-10</td> <td>mrt-10</td> <td>9</td> </tr> <tr> <td>1</td> <td>mrt-50</td> <td>1</td> <td>1</td> <td></td> <td>dec-09</td> <td>dec-09</td> <td>1</td> </tr> </tbody> </table> <p><i>TIP: adding the action performed, initials and date can also be done without printing the document; using Adobe Acrobat Professional. Adding your text to the document that is printed as an .pdf file via menu Tools → Comment & Markup → Text Box Tool. And print the document again as an .pdf file to preserve your added text.</i></p> <p><i>TIP: review recording with Adobe Acrobat Professional can be done via menu Tools → Comment & Markup → Pencil Tool.</i></p>		G	H	I	J	K	L	M		DBIR	GENDER	INDIC	INDICS	DDIAG	DSTAGE	ISS	11	jan-56	2	1		feb-10	mrt-10	9	1	mrt-50	1	1		dec-09	dec-09	1		
	G	H	I	J	K	L	M																												
	DBIR	GENDER	INDIC	INDICS	DDIAG	DSTAGE	ISS																												
11	jan-56	2	1		feb-10	mrt-10	9																												
1	mrt-50	1	1		dec-09	dec-09	1																												
4.	<p><i>Preferably scan paper documents with signatures or initials for electronic storage in the study directory.</i></p> <p><i>File paper documents at the appropriate tab in the study binder (chapter 2).</i></p> <p><i>File electronic documents at the appropriate subdirectory in the study directory (chapter 2).</i></p> <p><i>TIP: Store e-mail about the study in an e-mail study folder.</i></p> 