

An efficient method to review annotation and create bookmark for case report form (acrf.pdf) using SAS program, FDF files, excel and JavaScript in Acrobat

Chen-Jung Wu, Firma Clinical Research

ABSTRACT

A common method to annotate case report form (acrf.pdf) is to use Acrobat comment tool to draw box and add text; however, this method is time consuming. If the case report form is changed due to protocol amendment, it may need another round to annotate manually. Besides, regular SDTM process involves several people to prepare the package including case report form so it always has some inconsistent issues related to typo, font size and font style. Therefore, converting annotation to excel can help to fix typo issue and update wording quickly; comparing the excel with the metadata in xpt and define.xml. Moreover, making use of excel to remap annotation to migrate page to new version of case report form is another efficient method if there are any changes for case report form due to the protocol amendment.

INTRODUCTION

A case report form is a paper or electronic questionnaire specifically used in clinical trial research.

CDISC Study: CDISC01	Screening
	Assessment Date ____/____/____
DEMOGRAPHY	
Date of Birth: ____/____/____	
Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female	

Figure 1. an example of a blank CRF page.

An annotated case report form (acrf.pdf) is a blank CRF with annotations that document the location of the data with the corresponding names of the datasets and the names of those variables included in the submitted datasets.

DM=Demographics		Screening
CDISC Study: CDISC01		Assessment Date
STUDYID		SCDTC ____/____/____
DEMOGRAPHY		
Date of Birth: ____/____/____ BRTHDTC		
SEX	Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female	
ETHNIC	____	

Figure 2. an example of an annotated CRF page for SDTM

For annotating case report form (acrf.pdf) with related SDTM variables (Figure 3), it is time consuming. There may be other reasons like protocol amendment to have another version of blank CRF and make the process repeatedly involving manual methods and review. Usually, the process needs to involve several people to work on the same file. Individual pdf file does not support multiple users to edit simultaneously. Besides, the submission version of annotate report form (acrf.pdf) needs to provide bookmarks with scheduled events categorized by topics or by visit to link each unique page (Figure 4).

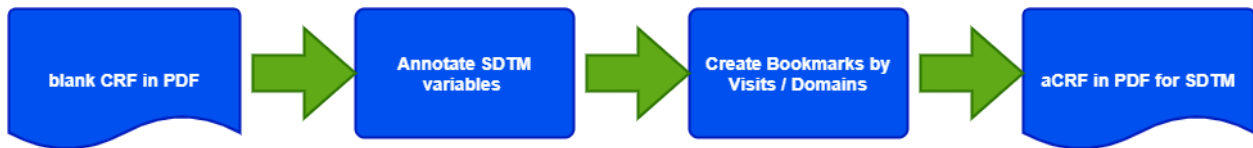


Figure 3. standard workflow for preparing aCRF for SDTM

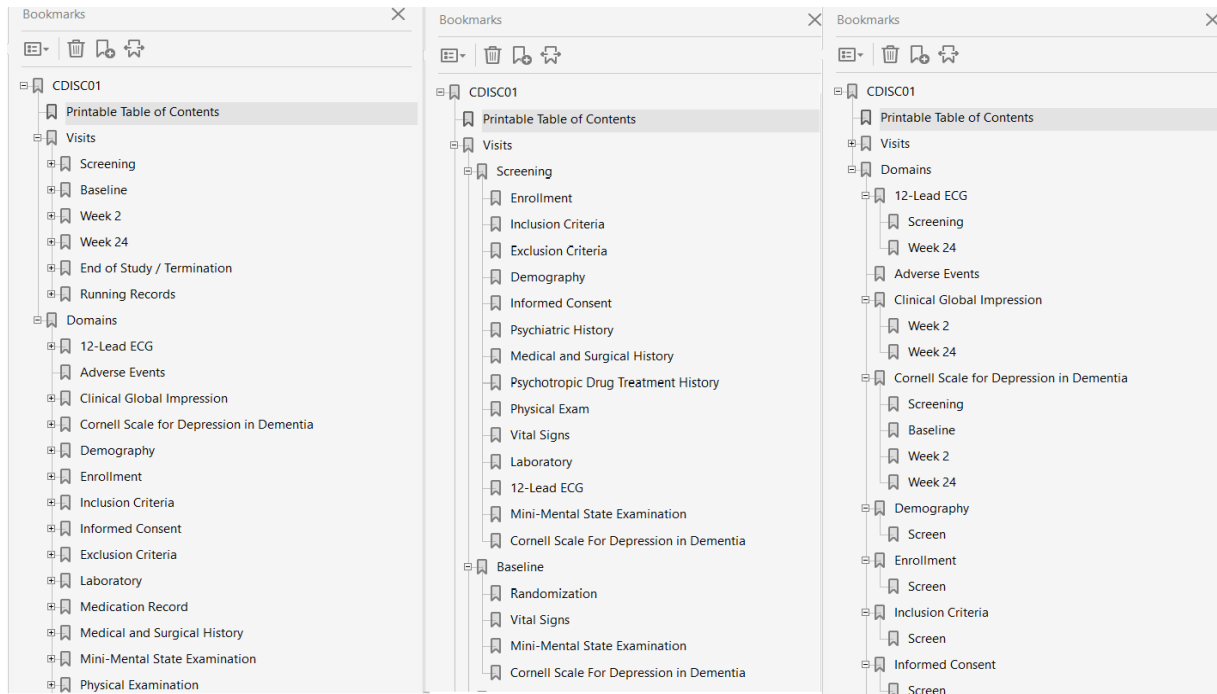


Figure 4. an example of an annotated CRF with bookmark by Visits and by Domains

Thus, the paper proposes the workflow for the annotation process is to minimize manual review, repeating process and reduce any inconsistencies between case report forms and data. Even protocol amendment with new version of case report forms or additional new page(s), we can reuse original annotation to avoid copy and paste. The whole process needs to use SAS programming and Adobe Acrobat Pro to achieve.

MUTIPLE USERS WORK ON ANNOTATING CRF

For complicated study with a lot of unique pages, it is not easy to have one person to finish all annotation task in a short period including programming. In practice, several people were assigned to work on the whole process. Figure 5 show the solution to use import/export comments function in Adobe Acrobat to have several people to annotate the blank CRF.

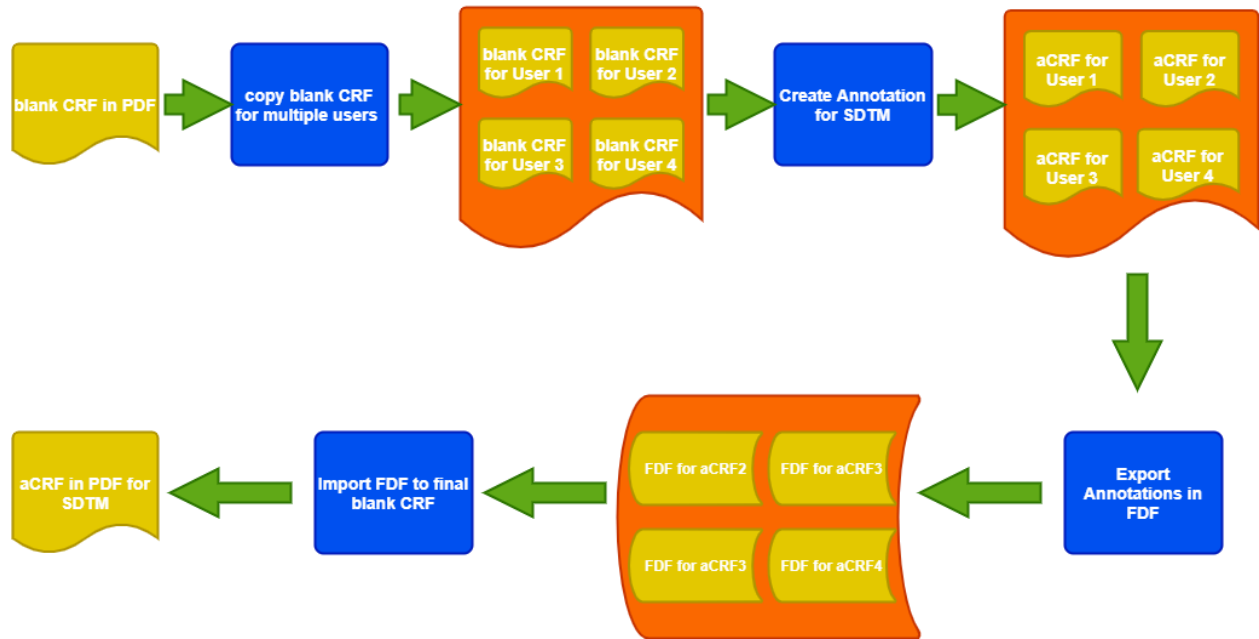


Figure 5. workflow for preparing aCRF with multiple users simultaneously.

SOLUTIONS FOR INCONSISTENT ISSUES OF ACRF

For annotation case report form (acr.pdf), there are some rules for appearance, font style, font color, font style and font color (Figure 6); variables related with the same domain should have same background color for text box; multiple domains at the same pages should use different background color for text box to identify. Review each page and update all individual text box are traditional method and labor intensive. The paper proposes new workflow to export all annotations through Adobe Acrobat to FDF file then using SAS to retrieve related information to be Excel. Reviewers can efficiently identify inconsistent issue or use embedded functions in EXCEL like filter data (Figure 7).

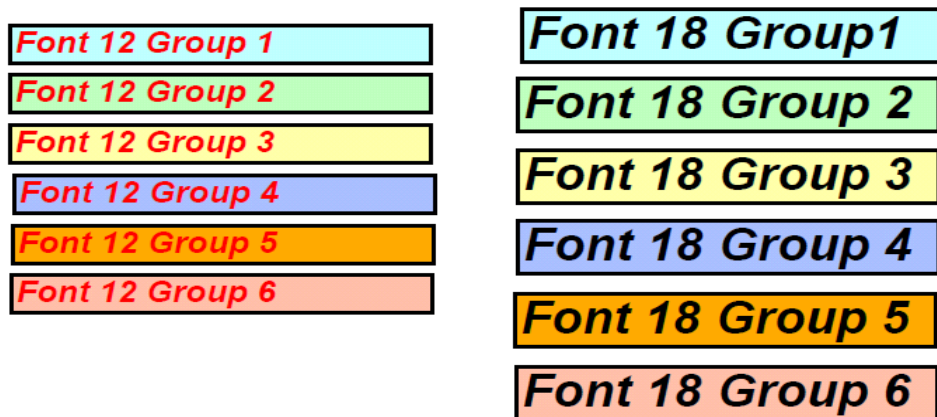


Figure 6. annotation color recommendations for Domains and Variables at the same page

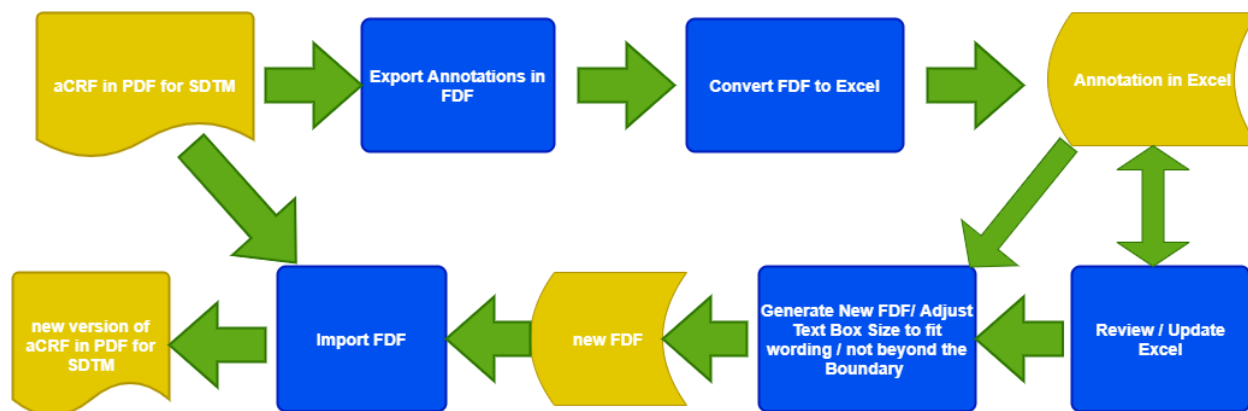


Figure 7. workflow for reorganizing annotation

EXPORT ANNOTATIONS IN FDF FILE

A Forms Data Format (FDF) file is text file format used by Adobe Acrobat which contains (key: value) pairs defining the field names and associated values that are used to populate a form. FDF files are used for text files exported from .PDF files. Output 1 displays an example generated by Adobe Acrobat comment export tool. The example is based on a single annotated PDF pages containing 6 text box same as the Figure 2.

```

%FDF-1.2
%ääïÓ
1 0 obj
<</FDF<</Annots[2 0 R 3 0 R 4 0 R 5 0 R 6 0 R 7 0
R]/F(/C/Users/robin.wu.CLINICAL/OneDrive - Firma Clinical
Research/Desktop/define/define_xml_2_0_releasepackage20140424/sdtm/blankcrf
.pdf)/ID[<C6C81CE3F560FE9B869397FFF64BF8D6><C58325DDD276474D997BDABBA0E7E39
8>]/UF(/C/Users/robin.wu.CLINICAL/OneDrive - Firma Clinical
Research/Desktop/define/define_xml_2_0_releasepackage20140424/sdtm/blankcrf
.pdf)>>/Type/Catalog>>
endobj
2 0 obj
<</C[0.75 1 0.75]/Contents (SCDTC)/CreationDate (D:00000000000000Z)/DA(0 0 0
rg /Arial,BoldItalic 12 Tf)/DS(font: italic bold Arial 12.0pt; text-
align:left; color:#FF0000 )/F 4/M(D:20090518091559-04'00')/NM(d73ef27f-
07f7-4698-87f9-10e1a27cd7bd)/Page 5/RC(<?xml version="1.0"?><body
xmlns="http://www.w3.org/1999/xhtml"
xmlns:xfa="http://www.xfa.org/schema/xfa-data/1.0/"
xfa:APIVersion="Acrobat:7.0.8" xfa:spec="2.0.2" style="font-
size:12.0pt;color:#FF0000;font-weight:bold;font-style:italic;font-
family:Arial\
"><p dir="ltr">SCDTC</p></body>)/RD[0.50015 0.50015 0.50015
0.50015]/Rect[394.157 681.315 465.847
698.325]/Subj (SC)/Subtype/FreeText/Type/Annot>>
endobj
3 0 obj
<</C[0.75 1 1]/Contents (ETHNIC)/CreationDate (D:00000000000000Z)/DA(0 0 0 rg
/Arial,BoldItalic 12 Tf)/DS(font: italic bold Arial 12.0pt; text-
align:left; color:#FF0000 )/F 4/M(D:20090304080711-05'00')/NM(7abefc9d-
174a-4895-b8cf-26c81e7bac7a)/Page 5/RC(<?xml version="1.0"?><body
xmlns="http://www.w3.org/1999/xhtml"
xmlns:xfa="http://www.xfa.org/schema/xfa-data/1.0/"

```

```
xfa:APIVersion="Acrobat:7.0.8" xfa:spec="2.0.2" style="font-size:12.0pt;color:#FF0000;font-weight:bold;font-style:italic;font-family:Arial\  
><p dir="ltr">ETHNIC</p></body>)/RD[0.50015 0.50015 0.50015 0.50015]/Rect[29.5967 559.475 85.6492 578.735]/Subj (DM) /Subtype/FreeText/Type/Annot>>  
endobj  
4 0 obj  
<</C[0.75 1 1]/Contents (BRTHDTC) /CreationDate (D:00000000000000Z) /DA(0 0 0 rg /Arial,BoldItalic 12 Tf)/DS(font: italic bold Arial 12.0pt; text-align:left; color:#FF0000 )/F 4/M(D:20090304080616-05'00') /NM(29000ea) /Page 5/RC(<?xml version="1.0"?><body xmlns="http://www.w3.org/1999/xhtml" xmlns:xfa="http://www.xfa.org/schema/xfa-data/1.0/" xfa:APIVersion="Acrobat:7.0.8" xfa:spec="2.0.2" style="font-size:12.0pt;color:#FF0000;font-weight:bold;font-style:italic;font-family:Arial\  
><p dir="ltr">BRTHDTC</p></body>)/RD[0.50015 0.50015 0.50015 0.50015]/Rect[176.001 625.187 248.212 643.096]/Subj (DM) /Subtype/FreeText/Type/Annot>>  
endobj  
5 0 obj  
<</C[0.75 1 1]/Contents (DM=Demographics) /CreationDate (D:00000000000000Z) /DA(0 G 0 0 0 rg 0 Tc 0 Tw 100 Tz 0 TL 0 Ts 0 Tr /Arial,BoldItalic 18 Tf)/DS(font: italic bold Arial,sans-serif 18.0pt; text-align:left; color:#000000 )/F 4/M(D:20090610133839-04'00') /NM(33c65005-9c45-4e19-b8f2-edf22c98b158) /Page 5/RC(<?xml version="1.0"?><body xmlns="http://www.w3.org/1999/xhtml" xmlns:xfa="http://www.xfa.org/schema/xfa-data/1.0/" xfa:APIVersion="Acrobat:7.0.8" xfa:spec="2.0.2" style="font-size:18.0pt;font-weight:bold;font-style:italic;font-family:Arial,sans-serif"><p dir="ltr"><span style="text-align:center;font-family:Arial">DM=Demographics</span></p></body>)/RD[0.50015 0.50015 0.50015 0.50015]/Rect[17.9189 724.011 220.069 752.121]/Subj (IE) /Subtype/FreeText/Type/Annot>>  
endobj  
6 0 obj  
<</C[0.75 1 1]/Contents (SEX) /CreationDate (D:00000000000000Z) /DA(0 0 0 rg /Arial,BoldItalic 12 Tf)/DS(font: italic bold Arial 12.0pt; text-align:left; color:#FF0000 )/F 4/M(D:20090304080901-05'00') /NM(a2608cbc-f2c6-40ba-8e17-a0124214f0c9) /Page 5/RC(<?xml version="1.0"?><body xmlns="http://www.w3.org/1999/xhtml" xmlns:xfa="http://www.xfa.org/schema/xfa-data/1.0/" xfa:APIVersion="Acrobat:7.0.8" xfa:spec="2.0.2" style="font-size:12.0pt;color:#FF0000;font-weight:bold;font-style:italic;font-family:Arial\  
><p dir="ltr">SEX</p></body>)/RD[0.50015 0.50015 0.50015 0.50015]/Rect[33.2325 599.943 83.8357 616.953]/Subj (DM) /Subtype/FreeText/Type/Annot>>  
endobj  
7 0 obj  
<</C[0.75 1 1]/Contents (STUDYID) /CreationDate (D:00000000000000Z) /DA(0 0 0 rg /Arial,BoldItalic 12 Tf)/DS(font: italic bold Arial 12.0pt; text-align:left; color:#FF0000 )/F 4/M(D:20090518091546-04'00') /NM(2900137) /Page 5/RC(<?xml version="1.0"?><body xmlns="http://www.w3.org/1999/xhtml" xmlns:xfa="http://www.xfa.org/schema/xfa-data/1.0/" xfa:APIVersion="Acrobat:7.0.8" xfa:spec="2.0.2" style="font-
```

```

size:12.0pt;color:#FF0000;font-weight:bold;font-style:italic;font-
family:Arial\
"><p dir="ltr">STUDYID</p></body>)/RD[0.50015 0.50015 0.50015
0.50015]/Rect[34.477 682.83 105.157
702.339]/Subj(KEY)/Subtype/FreeText/Type/Annot>>
endobj
trailer
<</Root 1 0 R>>
%%EOF

```

Output 1. FDF file example from CDSIC SDTM blankcrf.pdf generated by Adobe Acrobat Comment Tool

USE SAS TO RETRIEVE KEY ELEMENT FROM FDF

The Forms Data Format (FDF) file is generated by Adobe Acrobat Comment Tool with a lot of additional information. For review purpose, we can use SAS code to retrieve key element information like wording, page number and position of the text box. Output 2 displays the SAS code to retrieve key elements.

```

*** wording for text ***;
prxparse("#/Contents\((.*?)\)\#io");

*** page ***;
prxparse("#/Page (.*)\#io");

*** for text box - coordinate ***;
prxparse("#/Rect\[ (.*)\]\#io");

*** for oval - coordinate ***;
prxparse("#/RD\[ (.*)\]\#io");

*** for line - coordinate ***;
prxparse("#/L\[ (.*)\]\#io");

*** check text box, oval, or line ***;
prxparse("#/Subj\((.*?)\)\#io");

```

Output 2. SAS Code using regular expression to retrieve key element.

We can integrate FDF with metadata (spec) then convert to Excel for review. Most of SDTM variables start with two characters same as its domain name (ex: EXSTDTC starts with 'EX'); however, other variables RFSTDTC, AGE and SEX in the DM do not follow the rule. Using SAS to import metadata (spec) to identify variables and assign variables to appropriate domain automatically, it can decrease additional manual review for the Excel file. Figure 8 displays the FDF information in the Excel.

	domain	element	hdrflg	page	orientation	type	coord
2	DM	STUDYID		5		Text Box	34.477 682.83 105.157 702.339
3	DM	SEX		5		Text Box	33.2325 599.943 83.8357 616.953
4	DM	DM=Demographics	Y	5		Text Box	17.9189 724.011 220.069 752.121
5	DM	BRTHDTC		5		Text Box	176.001 625.187 248.212 643.096
6	DM	ETHNIC		5		Text Box	29.5967 559.475 85.6492 578.735
7	SC	SCDTC		5		Text Box	394.157 681.315 465.847 698.325
8							
9							
10							

Figure 8. FDF information integrated with metadata in the Excel.

GENERATE NEW VERSION OF FDF TO REPLACE ORIGINAL

Since we can retrieve the information the FDF, we can rebuild the new version of FDF after review and update wording. Before generating the new FDF, we can do further quality control between FDF and metadata; or adjust text box to have final annotation better.

1. Compare the page number from the FDF against the page number in the metadata (spec) to find any inconsistencies.
2. Use the column “domain” and “page” information to determine the appropriate color. Use column “hdrflg” to enlarge font size for the name of the domain. The example of annotation lists in the Figure 6.
3. Based on length of wording and the coordinate of the text box, adjust text box to have appropriate length to put all wording. The FDF file does not have information regarding orientation (portrait or landscape).
4. “Arial” is standard font used for annotation, but “Arial” is proportional rather than fixed-width for different characters.

```
proc format;
  value $chlen      'A' = 66.5      'B' = 66.5      'C' = 72.2 ...
                   'a' = 55.5      'b' = 55.5      'c' = 50 ...
                   '0' = 55.5      '1' = 48.8      '2' = 55.5 ...
;
run;
```

Output 3. Using SAS format to calculate the length of proportional character.

If the column “orientation” can be provided and apply appropriate width for different characters (Output 3), it can help the adjust the text box precisely not beyond the border. Output 4 displays the new version of FDF after manual review and updating text box by programming automatically. Comparing with Output 1, the new version of FDF (Output 4) has deleted redundant elements. Once the new version has been generated, we can use the Adobe Acrobat comment tool import and replace all annotations.

```
%FDF-1.2
1 0 obj
<</FDF<</Annots [2 0 R 3 0 R 4 0 R 5 0 R 6 0 R 7 0 R]>>/Type/Catalog>>
endobj
2 0 obj
<</Contents (SCDTC)/Page 5/Rect [394.157 681.315 447.157 697.315]/C [0.75 1
1]/BS 21 0 R/DS(font: italic bold Arial 12.0pt; text-align:left;
color:#FF0000 )/Subj(Text Box)/Subtype/FreeText/Type/Annot>>
endobj
3 0 obj
<</Contents (STUDYID)/Page 5/Rect [34.477 682.83 100.477 698.83]/C [0.75 1
0.75]/BS 21 0 R/DS(font: italic bold Arial 12.0pt; text-align:left;
color:#FF0000 )/Subj(Text Box)/Subtype/FreeText/Type/Annot>>
endobj
4 0 obj
<</Contents (SEX)/Page 5/Rect [33.2325 599.943 67.2325 615.943]/C [0.75 1
0.75]/BS 21 0 R/DS(font: italic bold Arial 12.0pt; text-align:left;
color:#FF0000 )/Subj(Text Box)/Subtype/FreeText/Type/Annot>>
endobj
5 0 obj
<</Contents (DM=Demographics)/Page 5/Rect [17.9189 724.011 196.9189
746.011]/C [0.75 1 0.75]/BS 21 0 R/DS(font: italic bold Arial 18.0pt; text-
align:left; color:#000000 )/Subj(Text Box)/Subtype/FreeText/Type/Annot>>
endobj
6 0 obj
```

```

<</Contents (BRTHDTC)/Page 5/Rect [176.001 625.187 247.001 641.187]/C [0.75
1 0.75]/BS 21 0 R/DS(font: italic bold Arial 12.0pt; text-align:left;
color:#FF0000 )/Subj(Text Box)/Subtype/FreeText/Type/Annot>>
endobj
7 0 obj
<</Contents (ETHNIC)/Page 5/Rect [29.5967 559.475 86.5967 575.475]/C [0.75
1 0.75]/BS 21 0 R/DS(font: italic bold Arial 12.0pt; text-align:left;
color:#FF0000 )/Subj(Text Box)/Subtype/FreeText/Type/Annot>>
endobj
trailer
<</Root 1 0 R>>
%%

```

Output 4. New version of FDF file after updating and apply adjustment for the text box

SOLUTIONS FOR NEW VERSION OF ACRF

New version of case report forms or additional new page(s) always happen because of protocol amendment. Migrating previous annotation to new version of case report forms might involve a lot of labor-intensive manual methods like copy and paste. Since protocol amendment, it might be easier to have information for the changes of the specific pages or the specific pages added. Figure 9 proposes workflow to reuse previous FDF and with page mapping between old version and new version of case report forms.

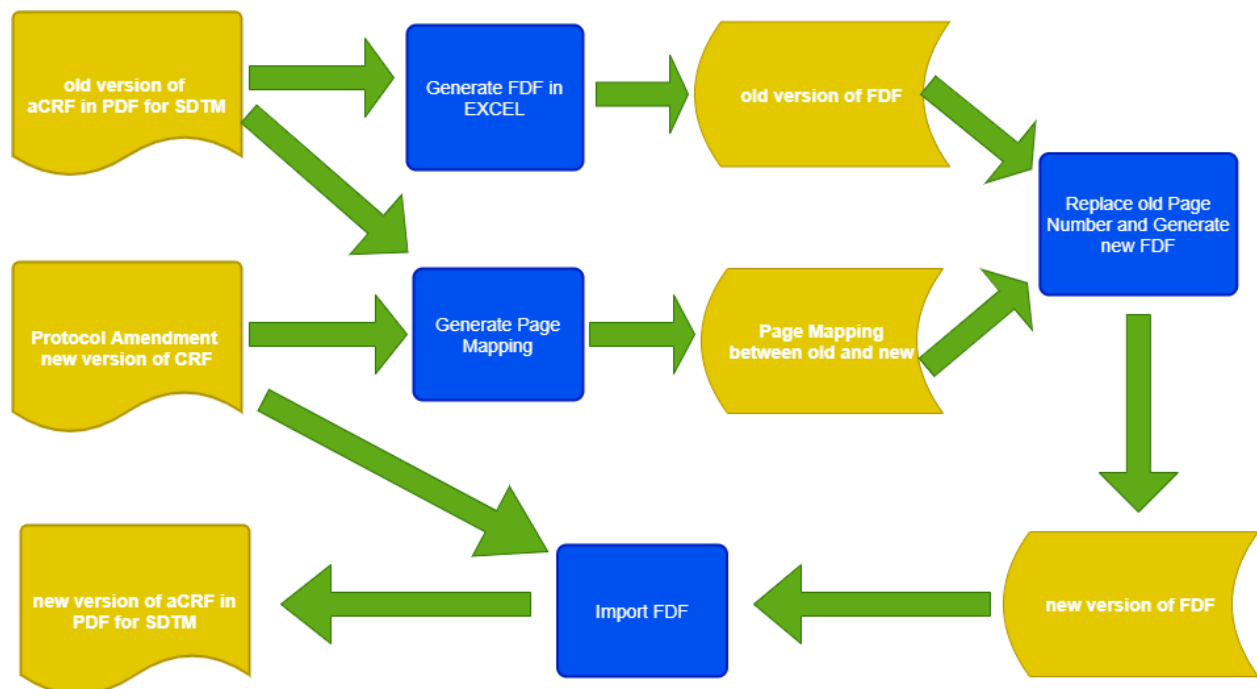


Figure 9. workflow for migrating annotations to new version of aCRF

Integrating the SAS code (Output 5) with previous section regarding generating FDF, this method can efficiently migrate original annotations with minimum review.

```

proc sql noprint;
  create table inannot01 as
  select a.*, b.new_page
  from inannot a
  left join pagemap b
  on a.page=b.old_page;

```



```
quit;
```

Output 5. SAS code for migration old version of aCRF to new version of CRF

SOLUTIONS FOR CREATING BOOKMARKS

the submission version of annotate report form (acrf.pdf) needs to provide bookmarks with scheduled events categorized by topics or by visit to link each unique page (Figure 4). Figure 10 proposes workflow to enter mapping information (domains, visit, and page); use SAS to generate text file for Adobe Acrobat Pro, use Adobe Acrobat Pro action wizard to run JavaScript then generate all bookmarks.

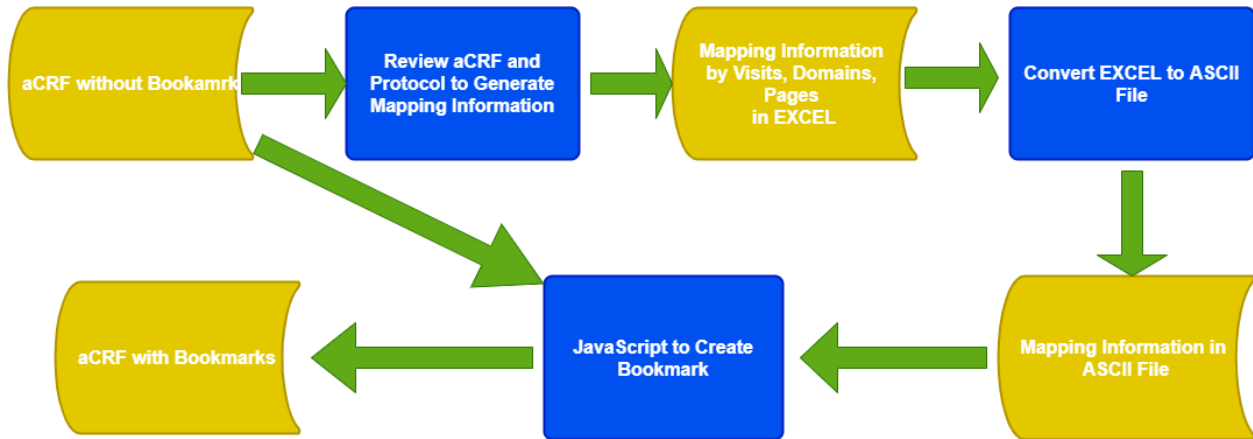


Figure 10. workflow for generating bookmarks for aCRF

GENERATE MAPPING INFORMATION IN EXCEL AND CONVERT TO ASCII FILE

Based on protocol and aCRF, provide related information between visits, domains and pages in EXCEL. Once the information categorized by visit (Output 5), we can use SAS program to recreate the reverse relationship categorized by domain (Output 6).

	A	B	C	D	E
1	VISIT	VISITN	PAGE	DOMAIN	DORD
2	Screening		0	3 Enrollment	1
3	Screening		0	4 Inclusion Criteria	2
4	Screening		0	5 Exclusion Criteria	3
5	Screening		0	6 Demography	4
6	Screening		0	6 Informed Consent	5
7	Screening		0	7 Psychiatric History	6
8	Screening		0	8 Medical and Surgical History	7
9	Screening		0	9 Psychotropic Drug Treatment History	8
10	Screening		0	10 Physical Exam	9
11	Screening		0	11 Vital Signs	10
12	Screening		0	11 Laboratory	11
13	Screening		0	12 12-Lead ECG	12
14	Screening		0	13 Mini-Mental State Examination	13
15	Screening		0	14 Cornell Scale For Depression in Dementia	14
16	Baseline		1	16 Randomization	1
17	Baseline		1	11 Vital Signs	10
18	Baseline		1	13 Mini-Mental State Examination	13
19	Baseline		1	14 Cornell Scale For Depression in Dementia	14
20	Week 2		2	11 Vital Signs	10
21	Week 2		2	11 Laboratory	11
22	Week 2		2	14 Cornell Scale for Depression in Dementia	14

Figure 11. review and provide mapping information in EXCEL

```
3, Screening,  
3, Screening, Enrollement
```

4, Screening, Inclusion Criteria
 5, Screening, Exclusion Criteria
 6, Screening, Demography
 6, Screening, Informed Consent
 7, Screening, Psychiatric History
 8, Screening, Medical and Surgical History
 9, Screening, Psychotropic Drug Treatment History
 10, Screening, Physical Exam
 11, Screening, Vital Signs
 11, Screening, Laboratory
 12, Screening, 12-Lead ECG
 13, Screening, Mini-Mental State Examination
 14, Screening, Cornell Scale For Depression in Dementia
 16, Baseline,
 16, Baseline, Randomization
 11, Baseline, Vital Signs
 13, Baseline, Mini-Mental State Examination
 14, Baseline, Cornell Scale For Depression in Dementia
 11, Week 2,
 11, Week 2, Vital Signs
 11, Week 2, Laboratory
 14, Week 2, Cornell Scale for Depression in Dementia

Output 5. ASCII file categorized by visit and domain with related page.

3, Enrollement,
 3, Enrollement, Screening
 16, Randomization, Baseline
 4, Inclusion Criteria,
 4, Inclusion Criteria, Screening
 5, Exclusion Criteria,
 5, Exclusion Criteria, Screening
 6, Demography,
 6, Demography, Screening
 6, Informed Consent,
 6, Informed Consent, Screening
 7, Psychiatric History,
 7, Psychiatric History, Screening
 8, Medical and Surgical History,
 8, Medical and Surgical History, Screening
 9, Psychotropic Drug Treatment History,
 9, Psychotropic Drug Treatment History, Screening
 10, Physical Exam,
 10, Physical Exam, Screening
 11, Vital Signs,
 11, Vital Signs, Screening
 11, Vital Signs, Baseline
 11, Vital Signs, Week 2
 11, Laboratory,
 11, Laboratory, Screening
 11, Laboratory, Week 2
 12, 12-Lead ECG,
 12, 12-Lead ECG, Screening
 13, Mini-Mental State Examination,
 13, Mini-Mental State Examination, Screening
 13, Mini-Mental State Examination, Baseline

```
14, Cornell Scale For Depression in Dementia,  
14, Cornell Scale For Depression in Dementia, Screening  
14, Cornell Scale For Depression in Dementia, Baseline  
14, Cornell Scale for Depression in Dementia, Week 2
```

Output 6. ASCII file categorized by domain and visit with related page.

ADOBE ACROBAT PRO – ACTION WIZARD (JAVASCRIPT)

Output 7 displays the JavaScript code using Adobe Acrobat Pro action wizard to have custom function. Once the bookmark created, we can use the similar code to rename bookmark and move bookmark into sub layer like Figure 4.

```
*** ASCII File path ***;  
var tocPath=;  
  
*** import ASCII File ***;  
this.importDataObject("test", tocPath);  
var ofile=this.getDataObjectContents("test");  
var cfile=util.stringFromStream(ofile, "utf-8");  
var tbararray = cfile.split("\n");  
  
*** create bookmarks ***;  
for (var i = 0; i < tbararray.length; i++) {  
    var subarray=tbararray[i].split(",");  
    app.execMenuItem ("FirstPage");  
    while ((this.pageNum+1) < this.numPages) {  
  
        if (this.pageNum+1 == subarray[0].trim()) {  
            app.execMenuItem ("NewBookmark");  
        }  
  
        app.execMenuItem ("NextPage");  
    }  
}
```

Output 7. JavaScript to import and create bookmarks.

CONCLUSION

For creating a perfect submission version of aCRF, it needs to involve several different processes to make sure quality and consistent with metadata. As there might be protocol amendment and new page added, it causes the process more complicated. Thus, the best way is to make use tool to help us review efficiently and programming migrate and reuse any information done before to minimize any labor-intensive process. The paper proposes the comprehensive solutions using SAS, EXCEL, and JavaScript for annotating from blank CRF in the beginning; migrating annotation to new version of CRF; and generating bookmarks for the submission version of aCRF.

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Chen-Jung(Robin) Wu
Firma Clinical Research
robin.wu@firmaclinical.com
www.firmaclinical.com

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