

SM07

Every Click Counts: A Smarter Way to Annotate CRFs

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Introduction

Macro Workflow

Step-by-step Process

Key Features

Questions?

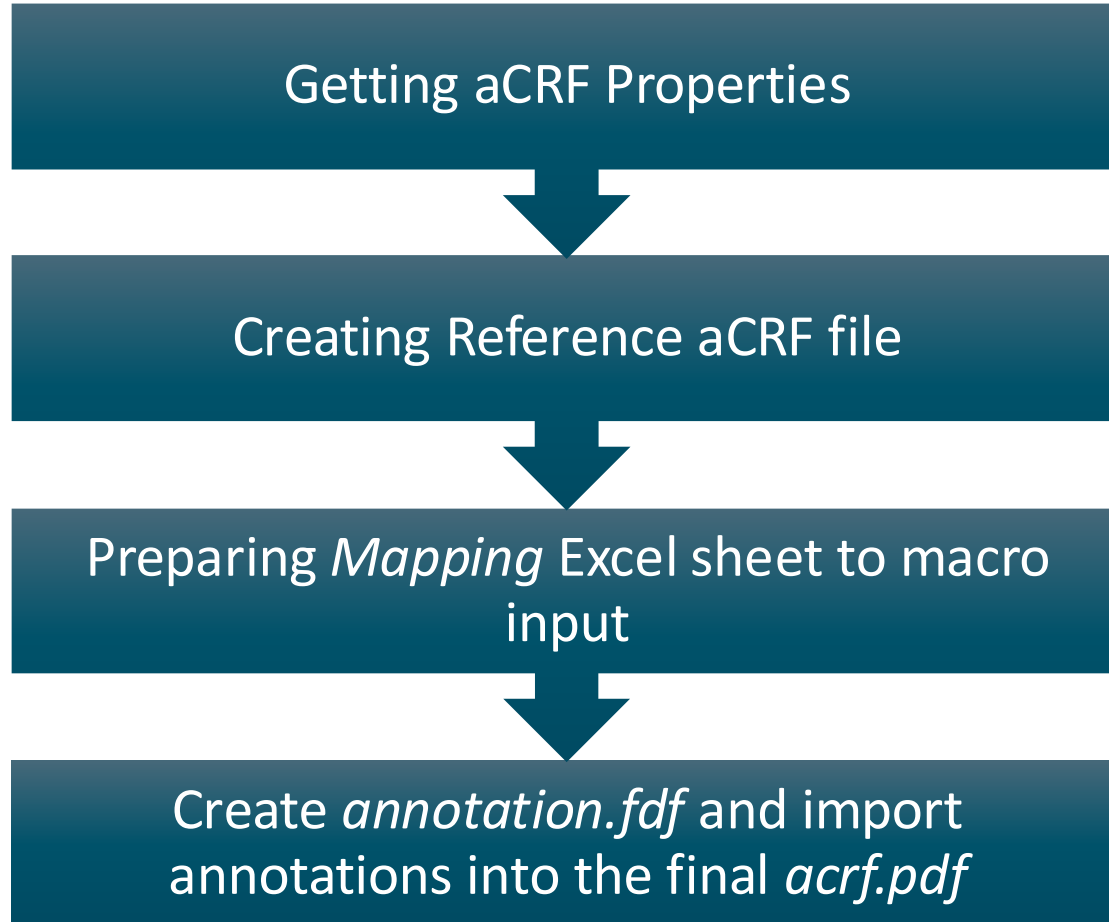




Introduction

- aCRF annotation is essential but traditionally manual, slow, and error prone
- An automated workflow integrates SAS macros, R-based PDF extraction, and Excel templates
- Extracts CRF PDF properties automatically using *pdftools package*
- Generates a line numbered reference aCRF to support accurate positioning
- Users enter annotation details in a structured Mapping Excel sheet
- Final annotations are produced via FDF and imported into the CRF
- Ensures fast, consistent, and precise aCRF creation with minimal manual effort

Workflow





Step 1: Getting aCRF Properties

- Run the R function `acrf_properties(acrf_file = "acrf.pdf")`
- The function will generate a spreadsheet named `annotation_map.xlsx` with a sheet called *Properties*

	A	B	C	D	E
1	page	height	width	lmargin	rmargin
2	52	792	612	90	522

```
library(pdftools)
pdf_data <- pdf_data(acrf_file)
```



Step 2: Creating Reference aCRF File

- Execute the macro: `%autoanno(usage=ref);`
- This macro will generate the file: `ref_acrf.fdf`.
- Additionally, two Excel sheets named "*Position*" and "*Mapping*" will be added to the spreadsheet `annotation_map.xlsx`
- Import `ref_acrf.fdf` file into the aCRF file and create `acrf_ref.pdf` file as a reference for aCRF annotation

	A	B	C
1	y1	position	x2
2	780	1	520
3	765	2	520
4	750	3	520
5	735	4	520
6	720	5	520
7	705	6	520
8	690	7	520

Position

	A	B	C	D	E	F	G
1	page	text	type	position	domain_order	align	width
2							

Mapping

Step-2 Creating Reference aCRF File

1		1
2		2
3		3
4		4
5		5
6		6
7	Form Demographics	7
8	Generated On:	8
9		9
10		10
11	Birth Date	11
12		12
13	Age at Time of Consent	13
14		14
15	Fixed Unit: Years	15
16		16
17	Sex	17
18		18
19	Is the subject of childbearing potential?	19
20		20
21	Reason not childbearing	21
22		22
23		23
24	Ethnicity	24
25		25
26	Race (select all that apply)	26
27		27
28	White	28
29		29
30	Asian	30
31		31
32		32
33	Black or African American	33
34		34
35	American Indian or Alaska Native	35
36		36
37	Native Hawaiian or Other Pacific Islander	37
38		38
39	Not Reported	39
40		40
41		41
42	Other	42
43		43
44		44
45		45
46		46

acrf_ref.pdf

1		1
2		2
3		3
4		4
5		5
6		6
7	Form Demographics	7
8	Generated On:	8
9		9
10		10
11	Birth Date	11
12		12
13	Age at Time of Consent	13
14		14
15	Fixed Unit: Years	15
16		16

Step 3: Preparing the Excel Sheet “Mapping”

Add the annotation text inputs for the macro in the “Mapping” sheet of the *annotation_map.xlsx* spreadsheet.

A	B	C	D	E	F	G
page	text	type	position	domain_order	align	width
5	DM (Demographics)	1	5	1	LEFT	
5	DS (Disposition)	1	5	2	Center	
5	DSDTC / DSSTDTC	2	14	2	RIGHT	
5	DSREFID	2	16	2	RIGHT	
5	DSTERM = INFORMED CONSENT OBTAINED	3	8	2	RIGHT	
5	RESCRN in SUPPDS	2	19	2	RIGHT	
5	RFICDTC	2	13	1	RIGHT	
5	[NOT SUBMITTED]	3	11	1	RIGHT	
6	DM (Demographics)	1	5	1	LEFT	
6	RP (Reproductive System Findings)	1	5	2	Center	
6	AGE	2	15	1	RIGHT	
6	AGEU = YEARS	3	14	1	Center	
6	BRTHDTC	2	11	1	RIGHT	
6	ETHNIC	2	24	1	RIGHT	
6	RACE	2	27	1	RIGHT	
6	RPORRES when RPTESTCD = CHILDPOT	2	19	2	RIGHT	
6	RPREASND when RPSTAT=NOT DONE	2	22	2	RIGHT	
6	SEX	2	17	1	RIGHT	
6	When multiple values are selected then RACE	3	38	1	RIGHT	

< > Properties Position Mapping +

Step 4: Creating *annotation.fdf* and Adding Annotations in aCRF

- Execute the macro: *%autoanno;*
- The macro will generate an FDF file named *annotation.fdf*.
- Import *annotation.fdf* file into the aCRF file and create acrf.pdf file
- All the annotation will be imported based on the Excel sheet “*Mapping*”

Handling Width of Annotation Box

- The macro automatically determines the width of each annotation box using a reference file named *width.xlsx*
- The file is created using the *pdftools* R package and contains a lookup table of characters letters, numbers, and symbols along with their corresponding widths.
- During macro execution, the annotation text is evaluated by character, and the total width is calculated based on the width values stored in *width.xlsx*.
- Ensures each annotation box is sized appropriately to fit the text.

A	B
letter	len
#	7
[	4
]	4
0	6
1	6
2	6
3	6



Preview of Final Output

DM (Demographics)	DS (Disposition)
Form Informed Consent Generated On:	DSTERM = INFORMED CONSENT OBTAINED
Was Informed Consent provided?	[NOT SUBMITTED]
Date Informed Consent Form Signed	RFICDTC DSDTC / DSSTDTC
Version Number of protocol consented to	DSREFID
Is the subject being re-screened?	RESCRN in SUPPDS



Preview of Final Output

DM (Demographics)

RP (Reproductive System Findings)

Form: Demographics
Generated On:

Birth Date		BRTHTDC
Age at Time of Consent	AGEU = YEARS	Fixed Unit: Years AGE
Sex		SEX
Is the subject of childbearing potential?		RPORRES when RPTESTCD = CHILDPOT
Reason not childbearing		RPREASND when RPSTAT=NOT DONE
Ethnicity		ETHNIC
Race (select all that apply)		RACE
White		When multiple values are selected then RACE = MULTIPLE and individual responses are RACE1,RACE2, RACE3, etc. in SUPPDM
Asian		
Black or African American		



Key Features

- Accurate positioning of the annotations in appropriate locations
- Automatic adjustment of annotation box sizes
- Significantly minimizes manual effort
- User-friendly solution
- Enables us to transfer the annotations in batch rather than having to cut and paste them manually between different pages in PDF files
- Simplifies annotation transfer from one aCRF to another when the aCRF is updated

THANK YOU

QUESTIONS?