

SDTM: CRF Annotation and Metadata Validation

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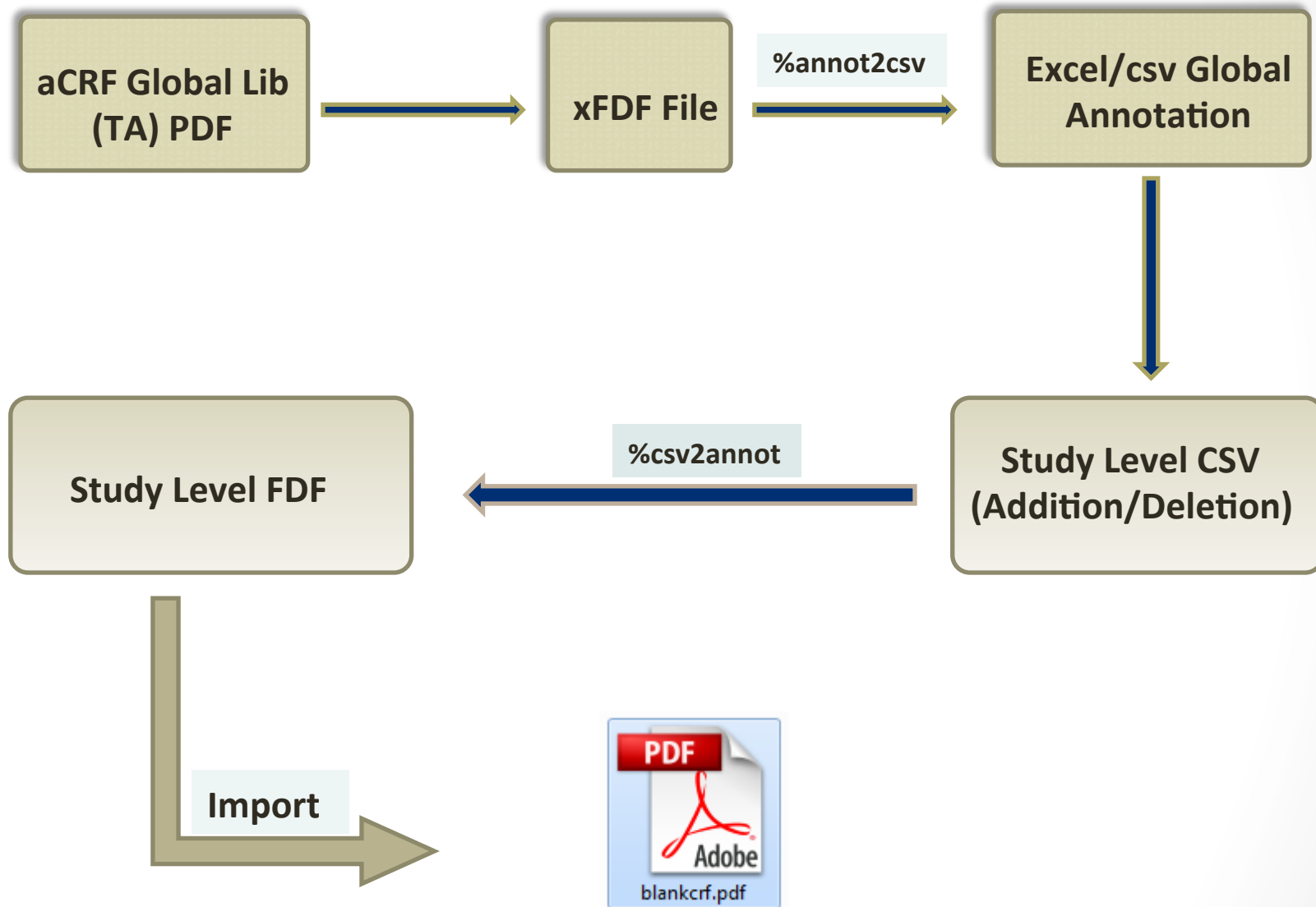
Manoj Mishra (Cytel)

SDTM: CRF Annotation Library

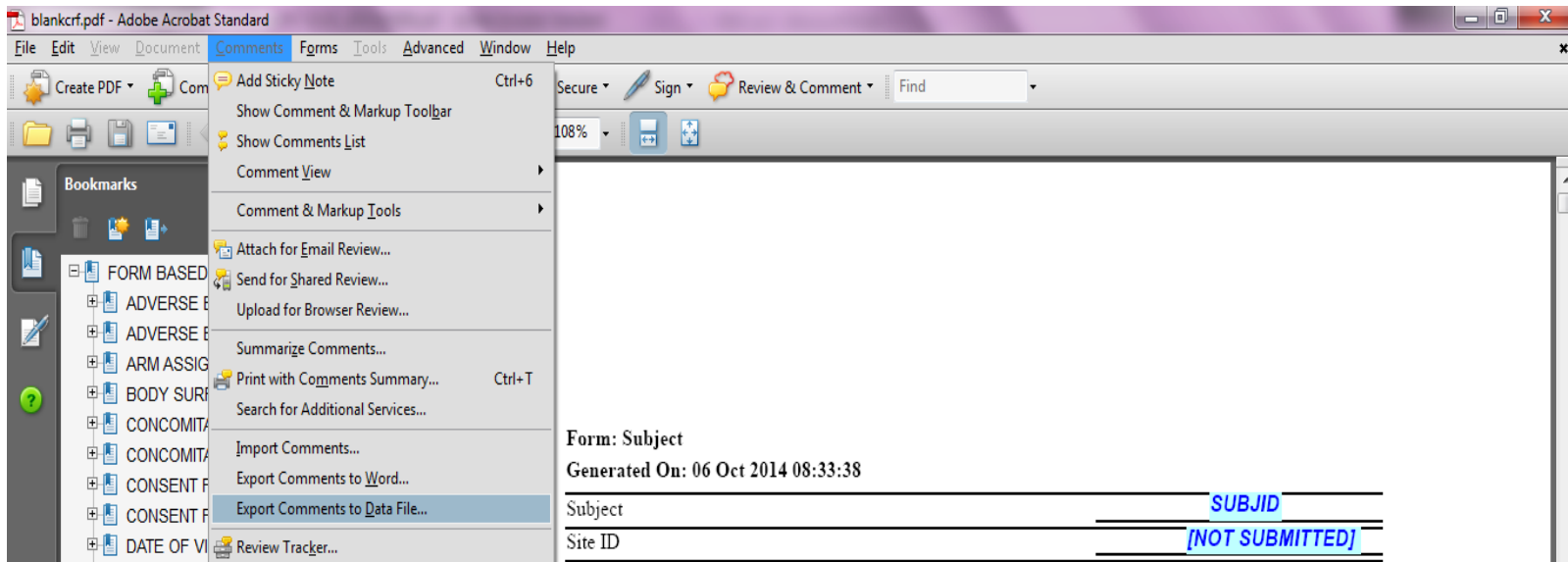
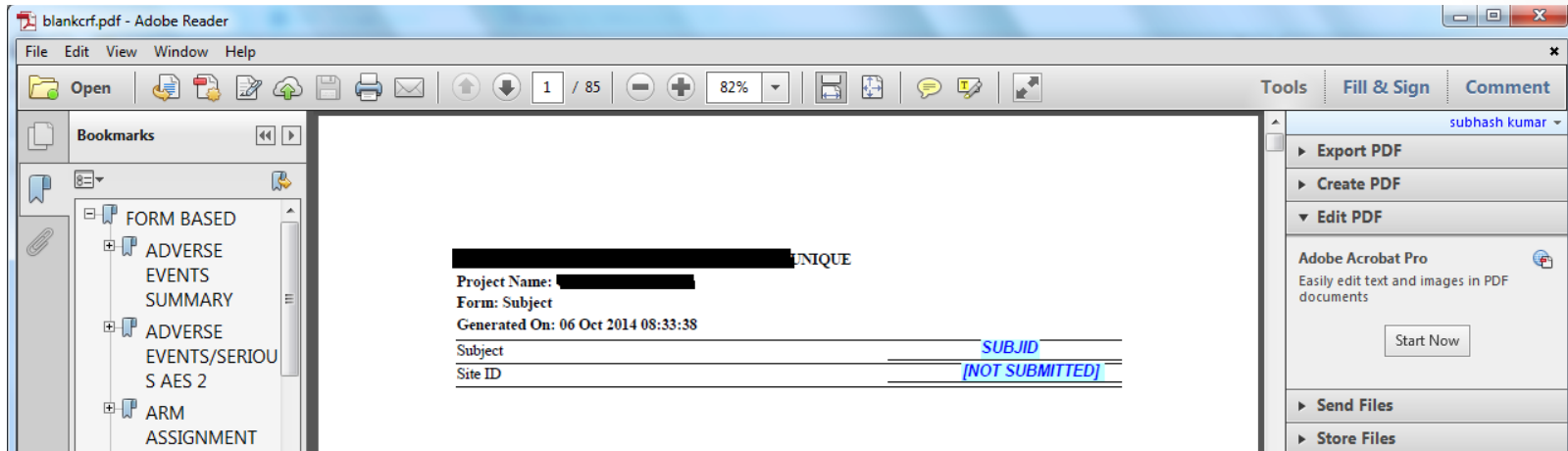
- **Global Library of Annotation**
 - **Global Library are maintained at CRF Form level**
 - **Governance Control**
 - **Study specific change requirement are approved, updated at global level**
 - **Standard library – Standard forms at study level**
- **Client specific library**
 - **Maintain these CRF Annotation library at pdf and excel sheet level.**

SDTM: CRF Annotation at study level

- Use of Library at Study level
 - Review the CRF pages and create excel of Annotation at study level.
 - Use program code to create .fdf file of Annotation
 - Import .fdf on to the study CRF
 - After self review share within the team for peer review



Export Annotation: xFDF (XML version of annotation)



CRF Annotation: xFDF

Annotation Box Coordinates

```
4 <freetext rect="431.011993,634.093994,468.468994,646.177002" creationdate="D:20140526145627+05'30'"
5   name="594d4e06-b6e4-40cc-b56f-70796e130261" width="0"
6   color="#BFFFFFF" flags="print" date="D:20140811151212+05'30'"
7   title="D Thakur" subject="Text Box" page="0">
8   <contents-richtext>
9     <body xmlns="http://www.w3.org/1999/xhtml" xmlns:xfa="http://www.xfa.org/schema/xfa-data/1.0/"
10       xfa:APIVersion="Acrobat:8.0.0" xfa:spec="2.0.2"
11       style="font-size:10.0pt;text-align:left;color:#0000FF;
12       font-weight:bold;font-style:italic;font-family:Arial;font-stretch:normal">
13       <p dir="ltr">SUBJID</p>
14     </body>
15   </contents-richtext>
16   <defaultappearance>1 0 0 rg /Arial,BoldItalic 10 Tf</defaultappearance>
17   <defaultstyle>font: italic bold Arial 10.0pt; text-align:left; color:#0000FF</defaultstyle>
18 </freetext>
```

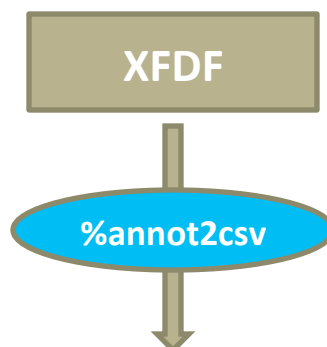
Background Fill Color

Page No on CRF

Annotation Text Properties

Annotation Text

CRF Annotation: xFDF-to-CSV Conversion



	A	B	C	D	E	F
1	ANNOTATION	CRFPGNO	X0	Y0	X1	Y1
2	SUBJID	1	431.012	634.094	468.469	646.177
3	[NOT SUBMITTED]	1	418.867	619.678	510.683	630.875
4	SVSTDTC, SVENDTC, IEDTC, DMDTC, MHDTC, FADTC, VSDTC	2	220.391	633.224	521.947	643.674
5	DSSTDTC when DSDECOD/DSTERM = INFORMED CONSENT OBTAINED	3	392.446	617.809	578.822	643.898
6	BRTHDTC	3	392.26	591.16	447.864	601.611
7	AGE	3	403.539	574.514	430.133	586.818
8	AGEU	3	419.064	533.127	451.407	545.432
9	SEX	3	434.471	467.923	459.272	480.228
10	ETHNIC	3	363.638	416.009	403.855	428.314
11	RACEW in SUPPDM when IDVAR=NULL	3	326.307	359.413	522.269	368.757
12	RACEBA in SUPPDM when IDVAR=NULL	3	319.419	343.84	522.63	355.232
13	RACEA in SUPPDM when IDVAR=NULL	3	328.16	329.046	522.884	339.466
14	RACEAIAN in SUPPDM when IDVAR=NULL	3	314.345	313.125	522.884	323.758
15	RACENHOP in SUPPDM when IDVAR=NULL	3	309.381	299.458	522.956	309.684

CRF Annotation: CSV-to-FDF

%CSV2annot (Snippet)

```
*** Annotate ***;
data _null_;
  set _dsin_anno end=fin;
  file annocrf mod flowover;

  * Annotations for variables;
  if not missing(annotation) then do;

    put objn ' 0 obj'
      / '<<'
      / '/Rect[' x0 y0 x1 y1 ']'
      / '/BS << /W 0 >>'
      / '/Subtype/FreeText'
      / '/C[' bckcolor ']'
      / '/F 4'
      / '/Contents(' anno ') '
      / '/DA(1 1 1 rg /Arial,Bold 10 Tf)'
      / '/DS(font: italic bold Arial 10.0pt; text-align:left; color::#0000FF)'
      / '/Subj(Text Box)'
      / '/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:8.0.0" xfa:spec="2.0.2" \
      / 'style="font-size:10.0pt;color:#0000FF;font-weight:bold;font-family:Arial;font-stretch:normal">\
      / '<p dir="ltr"><span style="color:' txtcolor ';'font-family:Arial">' anno '</span></p></body>)'
      / '/RD[0.500153 0.500153 0.500153 0.500153]'
      / '/Subj (VOID) /Subtype/FreeText/Type/Annot/Page ' pdfpg
      / '>>'
      / 'endobj'

  ;
end;
run;
```

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%csv2annot

FDF Annotation
File

Import to blankcrf

SDTM: Annotation Checker

- Validation of Annotation against Metadata
 - Variable Level Validation
 - TESTCD Level Validation
 - SUPPQUAL Level Validation
- Missing annotated Variables/TESTCDs/QNAMs in Metadata
- Presence of Variables/TESTCDs/QNAMs on CRF with origin in Metadata other than “CRF”
- Origin in Metadata as “CRF” without mention of page number(s)
- Mismatch in page numbers Variables/TESTCDs/QNAMs between Annotated CRF and Metadata

Thank You!

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