



**A Simple and User-friendly Solution
for Creating and Maintaining
SDTM/aCRF Annotations**

**Yong Cao
2017 May**

Agenda

- ❑ The two challenges of implementing aCRF
- ❑ JavaScript in Adobe Acrobat and PDF Form
- ❑ aCRF toolkits that meet the challenges
- ❑ Q&A

Challenges of Implementing aCRF

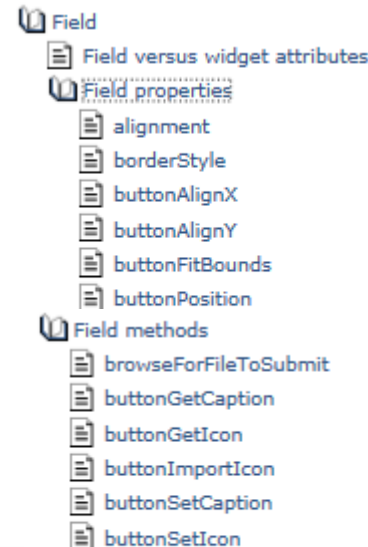
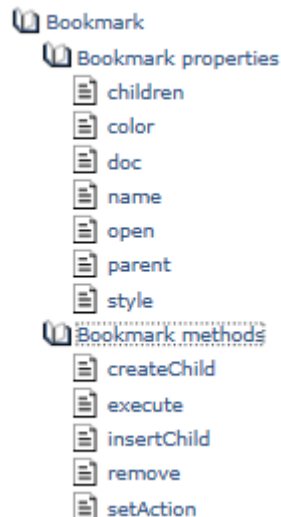
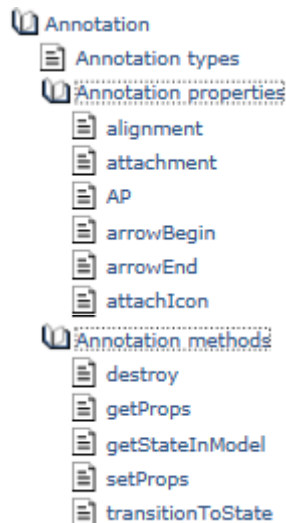
- ❑ Manually Creating Annotations
- ❑ Migrate Annotations after Database Modification

Handy Tools - JavaScript and PDF Form

- JavaScript in Adobe Acrobat/Reader
 - Acrobat provides development environment for JavaScript
 - For advanced document processing and automation
 - JavaScript can be embedded into PDF document (think about VBA in the MS Office)
 - Most scripts can be executed in the Adobe Reader
- PDF Form
 - Editable PDF document with Buttons/Textbox...
 - JavaScript can be embedded into buttons and textbox

How JavaScript Works in PDF Document

- Document Object Model (DOM)
 - Annotation
 - Bookmark
 - Field
 - ...
- JavaScript API in Adobe Acrobat



Challenges of implementing aCRF

- ❑ Manually Creating Annotations
- ❑ Migrate Annotations after Database Modification

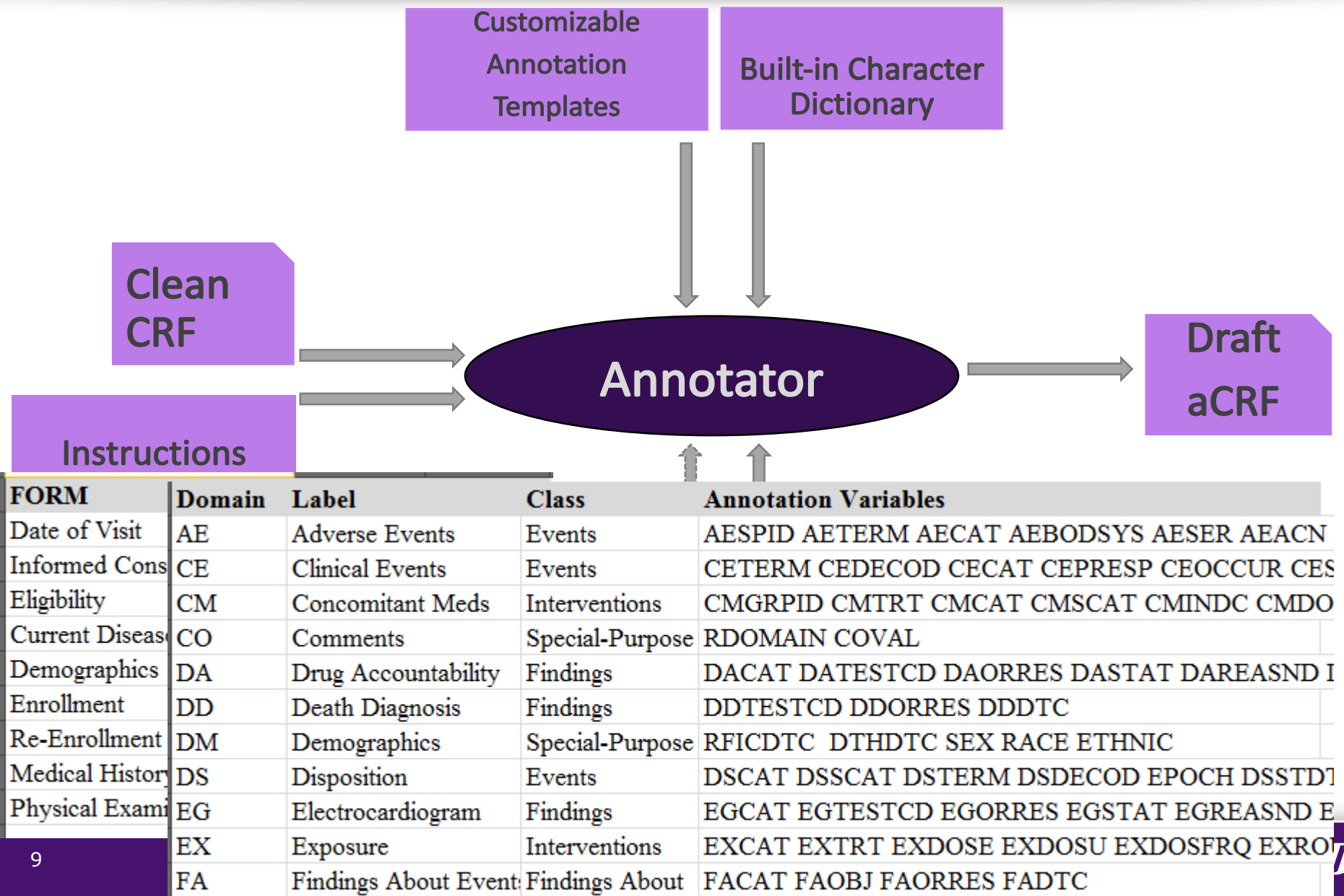
Challenge - Manually Creating Annotations



Solution - Drag and Move

[DS = Disposition]	[DM = Demographics]	Source = IC
DSCAT	RFICDTC	
DSSCAT	[DS = Disposition]	Source = IC
DSTERM	[DM = Demographics]	
DSDECOD	PROD_25MAY2016_3.00: UNIQUE Form: Informed Consent Generated On: 15 Jul 2016 12:00:00	DSCAT = "PROTOCOL MILESTONE"
EPOCH		
DSSTDTC	Was informed consent obtained?	NO ☐ 1
DSDTC		DSDECOD = "INFORMED CONSENT" YES ☐
SUPPDS.QVAL	Date subject or legally authorized representative signed informed consent (dd-mon-yyyy):	DSSTDTC RFICDTC 2
[NOT SUBMITTED]		

Auto-Annotator : Work Flow



Auto-Annotator : Product

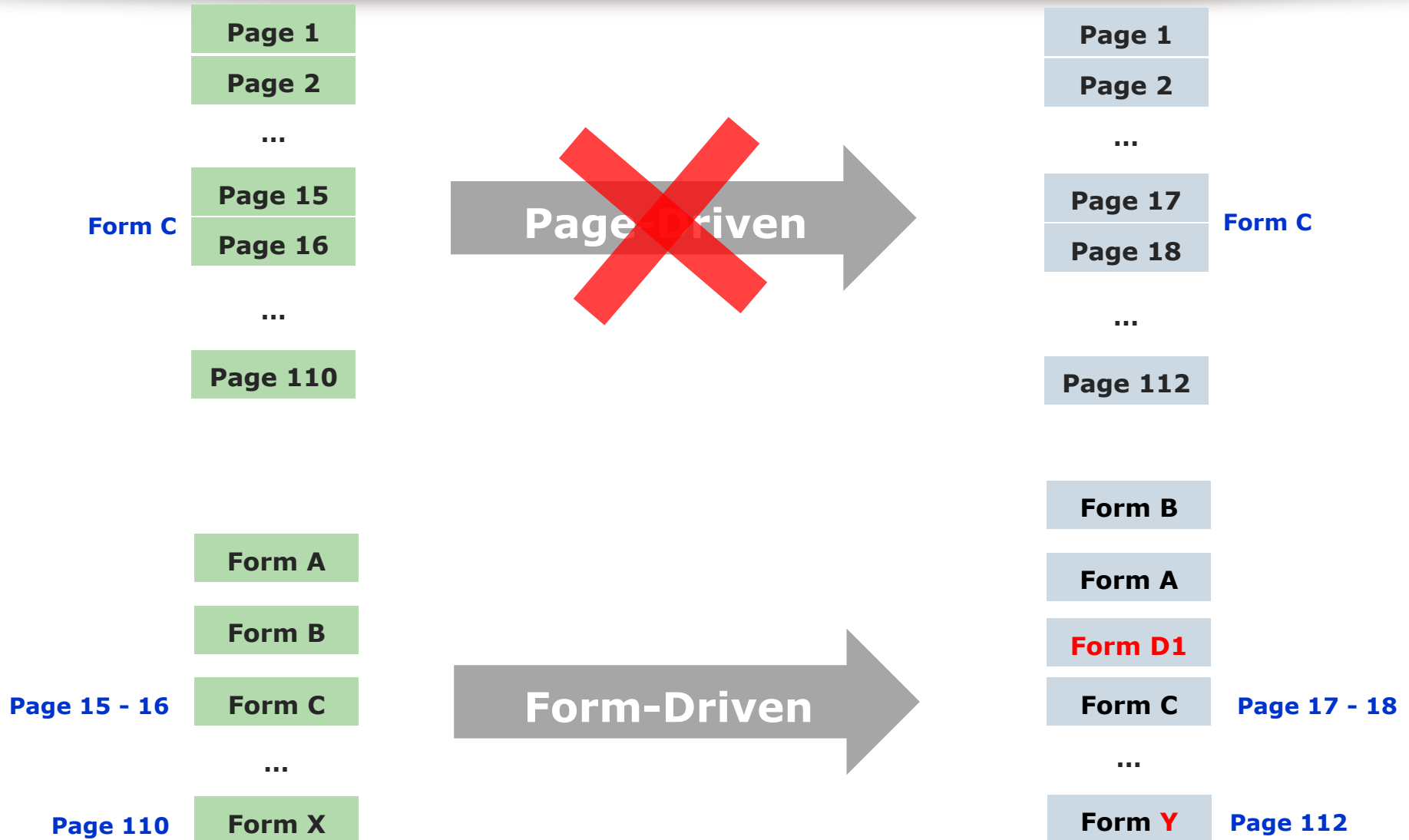
The screenshot shows the Auto-Annotator web application. On the left is an 'Attachments' sidebar with a file list: 'dictionary-charwidth.txt', 'dictionary-sdtmig.txt', and 'example-dataset-level-meta.txt'. The main area has a dark blue header with the title 'Auto Annotate'. Below the header, there is a instruction: 'Please DO read the instructions starting on page 2 first before you using this tool.' The form includes several sections: 'Rave's unique CRF' with a text input and a 'Browse' button; 'Form Level Metadata' with a text input and a 'Browse' button; 'Load user defined SDTM Dictionary (Optional)' with a checkbox; 'Annotate common SDTM variables' with a checkbox; 'Customizable Annotation style' with three rows of colored boxes: 'Domain annotation' with '[DM = Demographics]', '[TU = Tumor Identifier]', and '[RELREC = Related Records]'; 'Variable annotation' with 'SUBJID' and 'SUPPDM.QVAL where QNAM = RACE1'; 'Not Submit' with '[NOT SUBMITTED]'; and 'Source Dataset' with 'Source = DM1'. At the bottom of the form are 'Annotate' and 'Reset' buttons. Below the form is a 'Log' section with a large empty box and a 'Debug' button at the bottom right. The page number 'Page 1' is at the bottom center.

- ☐ Annotations are created by tool
- ☐ Mapping is done by user
- ☐ Functionalities: JavaScript
- ☐ Graphic Interface: PDF Form
- ☐ **ONLY Adobe Reader required**

Challenges of Implementing aCRF

- ❑ Manually Creating Annotations
- ❑ Migrate Annotations after Database Modification

Challenge – Database Modification



Solution – Move Annotations by Form

- Situation 1
 - # of pages of the old form = # of pages of the new form
- Situation 2
 - # of pages of the old form < # of pages of the new form
- Situation 3
 - # of pages of the old form > # of pages of the new form

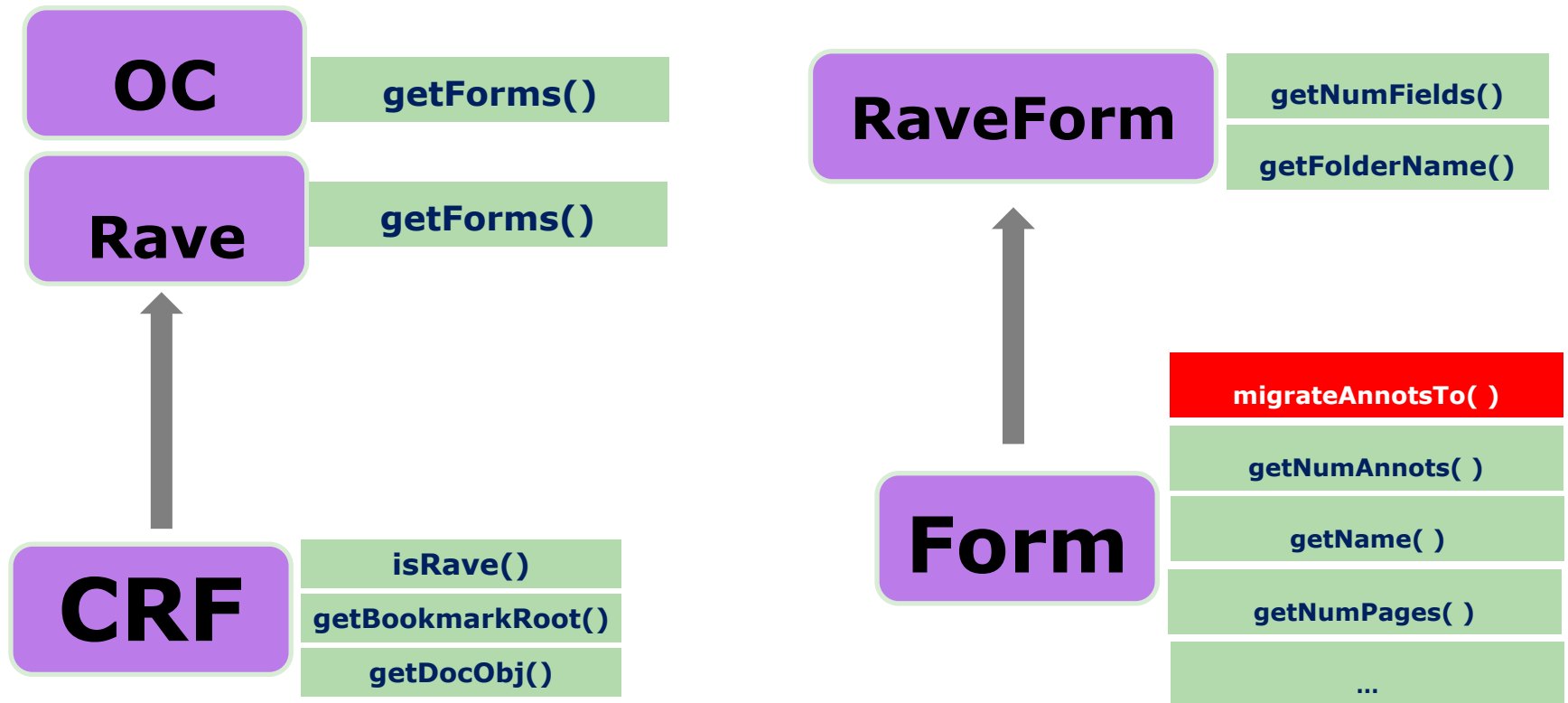
Object-Orientated Design (Auto-Migrator)

Object

Method



Inheritance



Auto-Migrator : Product

Migrate Annotations

Please DO read the instructions on page 2 first before you using this tool.

Import Annotations From

Full path of annotated CRF

Browse

Migrate Annotations To

Full path of destination CRF

Browse

Migrate

Reset

Migration Log

Debug

Page 1

- Annotations are moved between forms
- Forms are identified using bookmark
- Functionalities: **JavaScript**
- Graphic Interface: **PDF Form**
- ONLY Adobe Reader required.**
- Comprehensive Log

Auto-Migrator : An example

Migrator

Migrating form <!
...10 annotation
...Destination f
.....ALERT: # of

[XG]

PROD_25NOV2016_5.00: UNIQUE

Form: Subsequent Surgery

Generated On: 01 Dec 2016 13:09:33

source = SUBS1

SUBS1

XGCAT = "SUBSEQUENT SURGERY"

Has the subject had any disease related surgery other than biopsy, not previously related? [Not submitted] NO ☐ ①
YES ☐

If Yes, complete below

Tumor code XGLNKID ③

Date of Surgery (dd-mon-yyyy): XGSTDTC ④

Type of surgery XGTRT ⑤

Specify one surgery per row

Primary reason for Subsequent Surgery

XGINDC

Tumor Resection Curative ☐ ⑥

Tumor Resection Palliative ☐

Fluid Aspiration ☐

Fine Needle Aspiration ☐

Other ☐

If other, specify ⑦

Current Date/Time (Hidden field for CF use) [Not submitted] ⑧

Current Date/Time (Hidden field for CF use) ⑧

①

③

④

⑤

⑥

⑦

⑧

Summary

- The vision of this toolkit is to reduce the cost of annotated CRF.
- The goal is achieved by destructing the business logic of aCRF.
- JavaScript and PDF form based solution extends accessibilities of this toolkit.
- Object-orientated design makes it convenient to extend this toolkit to other type of CRFs.

Future Improvements

- ❑ For auto-annotator, how to reduce user's editing work even more?
- ❑ For auto-migrator, can we standardize annotations in the meantime of moving them?
- ❑ Can we even combine the two tools into one?

Q&A