

PhUSE 2015: Vienna

CC04:

Automating Production of the blankcrf.pdf in a CRO Environment

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Overview

- **CDISC SDTM METADATA SUBMISSION GUIDELINES (SDTM-MSG)**
 - Annotation Guidance
 - Bookmarking Guidance
- **EXTENDING ADOBE ACROBAT WITH JAVASCRIPT**
 - Creating Annotations
 - Creating Bookmarks

CDISC SDTM METADATA SUBMISSION GUIDELINES

Overview

- Published by CDISC in late 2011
- Guidance on how to compile the eCTD module5 “sdtm” folder, including
 - annotated CRF (blankcrf.pdf)
 - submission datasets
 - define.xml

CDISC SDTM METADATA SUBMISSION GUIDELINES

Annotation Guidance

- Different Domains with different background colours
- Distinguish between Domain and Variable annotations
 - Font colour
 - Font size

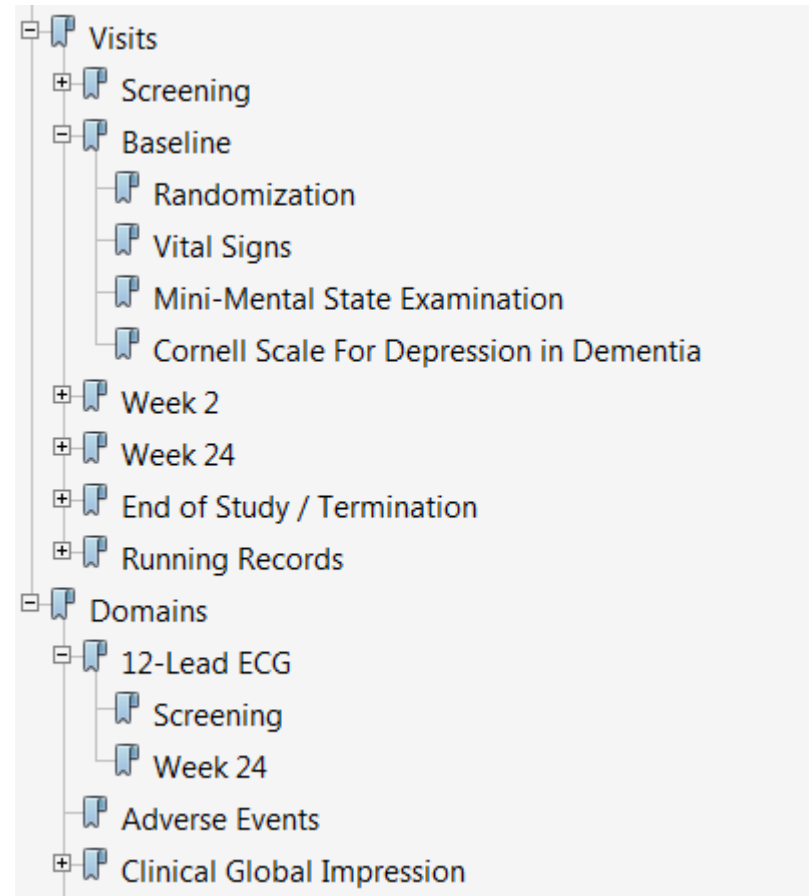
DM=Demographics		Screening
CDISC Study: CDISC01 STUDYID		Assessment Date SCDTC
DEMOGRAPHY		
Date of Birth: ____/____/____ BRTHDTC		
SEX		
Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female		
ETHNIC		
Ethnicity: <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino		
RACE		
Race: Check all that apply		
<input type="checkbox"/> White	RACE, when more than one selected, RACE=MULTIPLE and individual responses are RACE1, RACE2, etc. in SUPPDM	
<input type="checkbox"/> American Indian or Alaska Native		
<input type="checkbox"/> Black or African American		
<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input type="checkbox"/> Asian		
<input type="checkbox"/> Other: __ RACEOTH in SUPPDM		
SC=Subject Characteristics		SCORRES when SCTESTCD = MARISTAT
FamilyStatus: <input type="checkbox"/> Never Married <input type="checkbox"/> Domestic Partner		
<input type="checkbox"/> Married <input type="checkbox"/> Divorced		
<input type="checkbox"/> Legally Separated <input type="checkbox"/> Widowed		

CDISC SDTM METADATA SUBMISSION GUIDELINES

Bookmarking Guidance

- Dual bookmarking

- By time point
- By CRF domain



EXTENDING ADOBE ACROBAT WITH JAVASCRIPT

Overview

- Extending functionality of MS Word or Excel using VBA macros is common place
- Adobe Acrobat allows extending functionality by writing JavaScript
 - JavaScript files are plain text
 - Saved within the Adobe Acrobat installation folder
- We can write JavaScript to automate standard Adobe Acrobat functionality

EXTENDING ADOBE ACROBAT WITH JAVASCRIPT

Creating Annotations (1)

From the SDTM-MSG

- different font size
- different font colour
- different fill colour
- fix size of annotations

Required detail is created in an Excel file

- Page
- Domain / Variable
- Text content
- Fill colour

	A	B	C	D	E	F
1	Page	Type	Label	Colour	Notes	function acrf_annotate_CDISC()
2	4	D	DM = Demographics		1	acrf_annotate(this, 4, "DM = Demographics", "D", 1);
3	4	V	STUDYID		1	acrf_annotate(this, 4, "STUDYID", "V", 1);
4	4	D	SC = Subject Characteristics		2	acrf_annotate(this, 4, "SC = Subject Characteristics", "D", 2);
5	4	V	SCDTC		2	acrf_annotate(this, 4, "SCDTC", "V", 2);
6						}
7						app.addMenuItem({cName:"Annotate - CDISC", cParent:"Annotated CRF", cExec:"acrf_annotate_CDISC()", nPos:1});
8						

EXTENDING ADOBE ACROBAT WITH JAVASCRIPT

Creating Annotations (2)

```
acrf_annotate(this, 4, "DM = Demographics", "D", 1);  
annot = obj.addAnnot({  
  page: _page-1,  
  type: "FreeText",  
  rect: [x1, y1, x2, y2],  
  width: 1,  
  strokeColor: color.black,  
  fillColor: bgc,  
  alignment: 1  
});  
annot.richContents = rt;
```


EXTENDING ADOBE ACROBAT WITH JAVASCRIPT

Creating Bookmarks (1)

- From the SDTM-MSG we want to create dual bookmarks
- From a user perspective this is doing the same thing twice
- Instead, specify “By time point” bookmark, then in JavaScript code reverse to create “By domain” bookmark

EXTENDING ADOBE ACROBAT WITH JAVASCRIPT

Creating Bookmarks (2)

Required detail is created in an Excel file

- Visit
- Module
- Page

	A	B	C	D	E
1	Visit	Module	Page	Visit	function acrf_bookmark_CDISC()
2	Screening	Enrollment	1	Screening	acrf_bookmark(this,"Screening","Enrollment", 1);
3		Inclusion Criteria	2	Screening	acrf_bookmark(this,"Screening","Inclusion Criteria", 2);
4		Exclusion Criteria	3	Screening	acrf_bookmark(this,"Screening","Exclusion Criteria", 3);
5	Baseline	Randomization	14	Baseline	acrf_bookmark(this,"Baseline","Randomization", 14);
6		Vital Signs	9	Baseline	acrf_bookmark(this,"Baseline","Vital Signs", 9);
7		Mini-Mental State Examination	11	Baseline	acrf_bookmark(this,"Baseline","Mini-Mental State Examination", 11);
8		Cornell Scale for Depression in Dementia	12	Baseline	acrf_bookmark(this,"Baseline","Cornell Scale for Depression in Dementia", 12);
9	Week 2	Vital Signs	9	Week 2	acrf_bookmark(this,"Week 2","Vital Signs", 9);
10		Laboratory	9	Week 2	acrf_bookmark(this,"Week 2","Laboratory", 9);
11		Cornell Scale for Depression in Dementia	12	Week 2	acrf_bookmark(this,"Week 2","Cornell Scale for Depression in Dementia", 12);
12		Clinical Global Impression	15	Week 2	acrf_bookmark(this,"Week 2","Clinical Global Impression", 15);
13	Week 24	Physical Examination	8	Week 24	acrf_bookmark(this,"Week 24","Physical Examination", 8);
14		Vital Signs	9	Week 24	acrf_bookmark(this,"Week 24","Vital Signs", 9);
15		Laboratory	9	Week 24	acrf_bookmark(this,"Week 24","Laboratory", 9);
16	End of Study / Termination	Termination	16	End of Study / Termination	acrf_bookmark(this,"End of Study / Termination","Termination", 16);
17	Running Records	Study Medication Inventory	17	Running Records	acrf_bookmark(this,"Running Records","Study Medication Inventory", 17);
18		Medication Record	18	Running Records	acrf_bookmark(this,"Running Records","Medication Record", 18);
19		Adverse Events	19	Running Records	acrf_bookmark(this,"Running Records","Adverse Events", 19);
20		Prior/Concomitant Medications	20	Running Records	acrf_bookmark(this,"Running Records","Prior/Concomitant Medications", 20);
21					}
22					app.addMenuItem({cName:"Bookmark CDISC", cParent:"Annotated CRF", cExec:"acrf_bookmark_CDISC()", nPos:1});
23					

EXTENDING ADOBE ACROBAT WITH JAVASCRIPT

Creating Bookmarks (3)

```
acrf_bookmark(this, "Screening", "Enrollment", 1);
_idx = acrf_find_bookmark(_visits, _visit);
if (_idx == null) {
    if (_visits.children == null) {
        acrf_create_bookmark(_visits, _visit, _page, 0);
    } else {
        acrf_create_bookmark(_visits, _visit, _page, _visits.children.length);
    }
    _idx = acrf_find_bookmark(_visits, _visit);
}
_bmk = _visits.children[_idx];
if (_bmk.children == null) {
    acrf_create_bookmark(_bmk, _module, _page, 0);
} else {
    acrf_create_bookmark(_bmk, _module, _page, _bmk.children.length);
}
```

Conclusion

- Creating blankcrf.pdf manually is a laborious process that can be prone to errors
- By extending Adobe Acrobat with JavaScript much of the repetitive work can be automated
- Result is a blankcrf.pdf that is more useful to the reviewer

Stop the press...

- TS06: Unleash the Power of Adobe Acrobat using Javascript
- FDA won't accept PDF's with embedded JavaScript code
 - Can manually convert each bookmark by removing the “Run a JavaScript” action, replacing it with a “Go to a page view” action
 - Googling found a utility online that ‘may’ help – “Convert JavaScript Links To Real Links “
<http://try67.blogspot.de/2011/09/convert-javascript-links-to-real-web.html>

Comments / Questions / Suggestions?

