

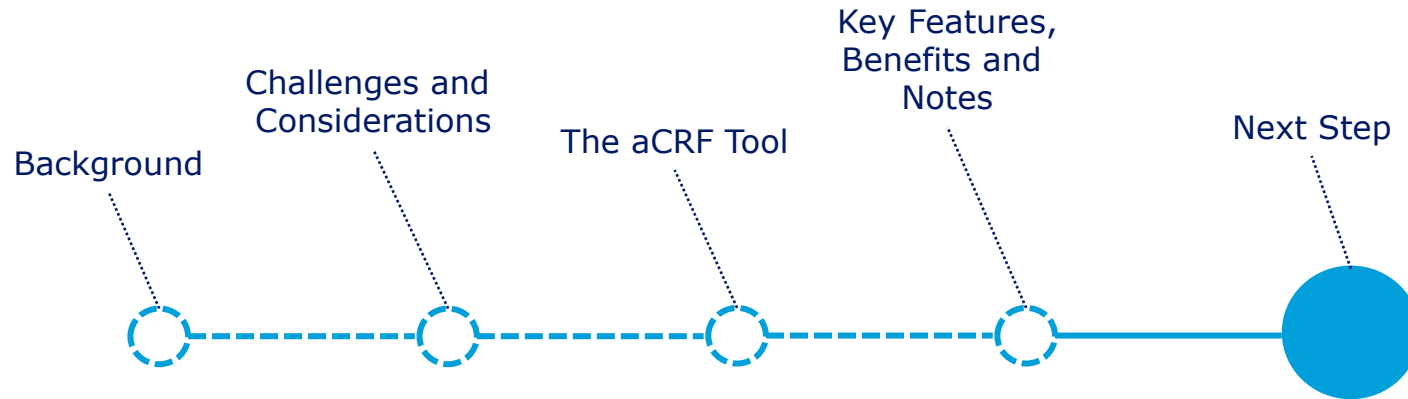


MAURIZIO BARDINI
Italy
Maurizio has type 1 diabetes

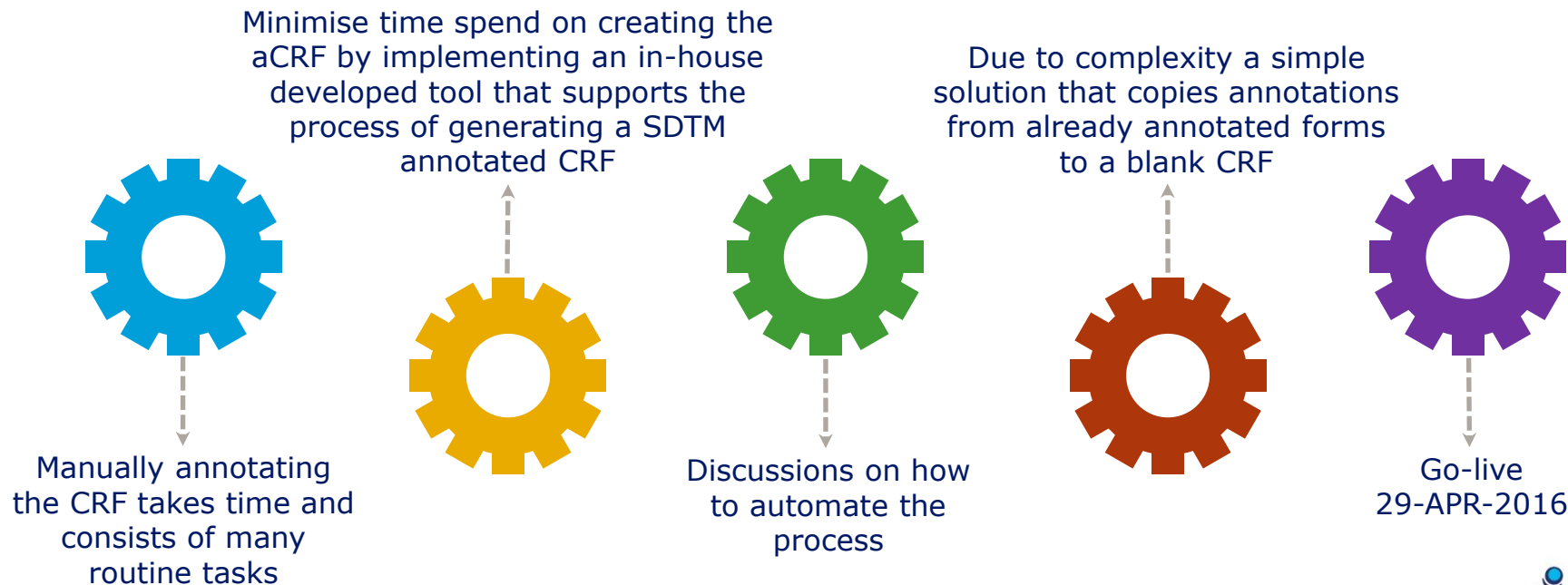
Experience of Implementing an aCRF Tool

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Agenda



Background



Challenges and Considerations

How to ensure optimal Usability and Benefits

aCRF tool - based on Keywords

- Very automated, but difficult to use
- Likelihood approach – possibility for errors
- Maintenance of Keywords

aCRF tool – based on copying

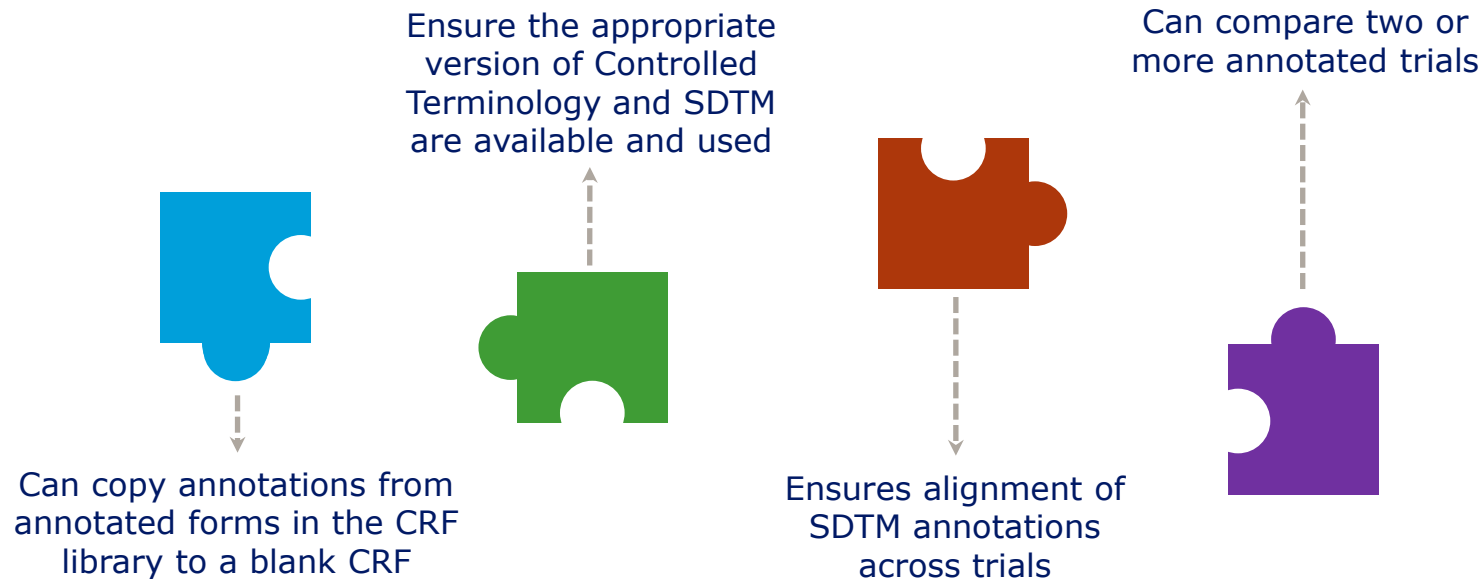
- Less automated, but easy to use
- What you see is what you get
- Maintenance of aCRFs in the CRF Library

CRF Library

Contains aCRF forms used by the aCRF tool

☐ CRF Title	SDTM	CT	CRF Link	aCRF Link	XFDF Link	Status	Comment	Minimum Content
[-] CRF Type : Electronic (71)								
[-] Assessment : Adverse Event (1)								
Adverse Event	3.1.3	2015-06-26	Adverse Event	Adverse Event	Adverse Event	Active		Yes
[-] Assessment : Alcohol Breath Test (1)								
Alcohol Breath Test	3.1.3	2015-06-26	Alcohol Breath Test	ABT	ABT	Active		No
[-] Assessment : Body Measurements (4)								
Body Measurements 1	3.1.3	2015-06-26	Body Measurements 1	BM1	BM1	Active	Design 1 contains all the standard questions.	Yes
Body Measurements 2	3.1.3	2015-06-26	Body Measurements 2	BM2	BM2	Active	Design 2 is used when height and weight are collected.	No
Body Measurements 3	3.1.3	2015-06-26	Body Measurements 3	BM3	BM3	Active	Design 3 is used when weight is collected.	No
Body Measurements 4	3.1.3	2015-06-26	Body Measurements 4	BM4	BM4	Active	Design 4 is used when repeated hip and waist are collected.	No
[-] Assessment : Chest X-Ray (1)								

The aCRF Tool



The aCRF Tool

Supports the process of generating a SDTM annotated CRF



import



aCRF tool
SAS EG



PDF

Blank CRF

PDF

Blank CRF

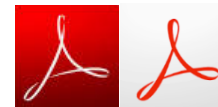
aCRF tool



aCRF Tool Process

1. Setup Copy annotation excel sheet and Map old CRF pages to new pages
 - Setup copy annotation mapping excel sheet (Use standard template)
 - Map old pages from old CRF to new pages in new CRF
2. Export Annotation file (.xdf) from old CRF or take from CRF library
 - Export annotation file (.xdf) from old CRF or take from the CRF library
 - Place the XDF files in the same folder on UNIX SCE
3. Run SAS EG project
 - Open SAS EG project
 - Specify parameters in the form and run the program
4. Import new annotation file
 - Import new annotation file in the target PDF
 - Reposition and QC annotations

Adobe – CRF to be Annotated



Body Measurements - Form Version: 27-Nov-2013 09:25

Site: Subject: Subject No:

Trial ID:

1.	Height		☐ cm ☐ in
2.	Body weight		☐ kg ☐ lb
3.	BMI (calculated)		kg/m ²

MS Excel – Page number mapping sheet (1)



	A	B	C	D	E	F	G
1	disable	new_page	new_domain	new_title	old_page	old_domain	old_title
2	To disable a row put 'x'	New Page Number (Mandatory)	New Domain Name (Not Mandatory)	New Form Name (Not Mandatory)	Old Page Number (Mandatory)	Old Domain Name (Not Mandatory)	Old Form Name (Not Mandatory)
3			1 Front				
4			2 Flowchart				
5			3 Inform Screening				
6			4 Inform Enrollment				
7			5 Date of visit		1		
8			6 Informed Consent and Demography		1		
9	x		7 Informed Consent and Demography				
10			8 Exclusion Criteria		1		
11	x		9 Exclusion Criteria				
12			10 Inclusion Criteria		1		
13	x		11 Inclusion Criteria				
14			12 Medical History		1		
15			13-14 Physical Examination		1-2		
16	x		15 Physical Examination				

MS Excel – Page number mapping sheet (2)



	B	C	H	I	J
1	new_page	new_domain	type_old_page	type_new_page	name_diff_xfdf_file
2	New Page Number (Mandatory)	New Domain Name (Not Mandatory)	Specify Old Page Type if different from Old PDF Type option on the screen	Specify New Page Type if different from New PDF Type option on the screen	If XFDF File is from any other study, enter the name of XFDF here. Copy the XFDF file in the same location as the original
3	1 Front				
4	2 Flowchart				
5	3 Inform Screening				
6	4 Inform Enrollment				
7	5 Date of visit				
8	6 Informed Consent and Demography		A3 Landscape (Size -16.54in * 11.69in)	A4 Portrait (Size -8.26in * 11.69in)	Informed Consent and Demography.xfdf
9	7 Informed Consent and Demography				
10	8 Exclusion Criteria				Exclusion Criteria.xfdf
11	9 Exclusion Criteria				
12	10 Inclusion Criteria				Inclusion Criteria.xfdf
13	11 Inclusion Criteria				
14	12 Medical History				Medical History.xfdf
15	13-14 Physical Examination				Physical Examination 1.xfdf
16	15 Physical Examination				

Adobe Acrobat Standard – Export XFDF File(s)



File Edit View Window Help

Open Create Save Print Comment Settings Tools Fill & Sign Comment

1 / 2 56,7%

Annotated Study Book - Novo Nordisk CORE Library Page 16 of 278

VS=Vital Signs

Novo Nordisk CORE Library: Body measurements (Body Meas) [BODY_MEASUREMENT_2]

Trial ID: NNO0000-XXXX

1. Date of examination [hidden] [Exam Date]	[BODY_MEAS_DATE_2] Req [✓] / Req [✓] / Req [✓] (2014-2020)
2. Date and time of examination [hidden] [Exam Date & Time]	[BODY_MEAS_DATE_TIME1] Req [✓] / Req [✓] / Req [✓] (2014-2020) Req/Link [✓] : Req/Link [✓] 24-hour clock VSDTC
3.* Height [read-only] [Height]	[p(BODY_HEIGHT1)] [BODY_HEIGHT1] [HEIGHT_UNIT1] [A:340] [A:380] [A:720] [A:720] VSORRES:VSORRESU when VSTESTCD=HEIGHT
4.* Body weight [read-only] [Body weight]	[p(BODY_WEIGHT1)] [BODY_WEIGHT1] [BODY_WEIGHT_UNIT1] [A:220] [A:700] [A:700] VSORRES:VSORRESU when VSTESTCD=WEIGHT
5. Body weight derived (calculated) [hidden] [Body Weight]	[BODY_WEIGHT_DERIVE_2] [A:220] [A:700] [A:700] VSORRES:VSORRESU when VSTESTCD=WEIGHT
6. BMI (Calculated) [read-only] [BMI]	[BMI_DERIVED_V2] [A:220] [A:700] [A:700] VSORRES:VSORRESU when VSTESTCD=BMI

Key: [✓] = Source verification required [B] = Base Unit
Note: Source verification critical settings made in Inform will override any settings made in Central Designer.

Study Object Descriptions: Body measurements

Type	RefName	Description

Annotations
Drawing Markups
Review
Comments List (5)
Find
Expand All
Collapse All
Undock Comment List
Print with Comment Summary
Create Comment Summary
Import Data File...
Export Selected to Data File...
Export All to Data File...

SAS EG (UNIX SCE) – Run Program



Specify Values for Project Prompts

☐ Show only required items (denoted by ★)

General [Reset group defaults](#)

★ Full Name + Path of old XFDF file to be migrated
 [Browse](#)

Specify name of output XFDF File
If left blank then new XFDF filename is equal to new_amp;lt;old xfdf filename>:

xxxxx_xxxx.xfdf

★ Select migration map excel file
 [Browse](#)

Name of worksheet in the migration map excel file

Example : MigrateAnno

★ Old PDF Type
Press Ctrl+D on old pdf page to know the dimensions of the page.

★ New PDF Type
Press Ctrl+D on new pdf page to know the dimensions of the page.

[Run](#) [Cancel](#)

A3 Landscape (Size -16.54in * 11.69in)
A3 Portrait (Size -11.69in * 16.54in)
A4 Landscape (Size -11.69in * 8.26in)
A4 Portrait (Size -8.26in * 11.69in)
Letter Landscape (Size -11.0in * 8.5in)
Letter Portrait (Size -8.5in * 11.0in)

Adobe Acrobat Standard – Import XFDF File



File Edit View Window Help

Open Create Save Print Mail Settings Comments PDF Tools Fill & Sign Comment

1 / 1 100%

VS=Vital Signs

Body Measurements - Form Version: 27-Nov-2013 09:25
 Site: Subject: Subject No:

Trial ID:

1. Height		☐ cm ☐ in	VSDTC
2. Body weight		☐ kg ☐ lb	
3. BMI (calculated)		kg/m ²	VSORRES/VSORRESU when VSTESTCD=HEIGHT

VSORRES/VSORRESU when VSTESTCD=WEIGHT

VSORRES/VSORRESU when VSTESTCD=BMI

Annotations
 Drawing Markups
 Review
 Comments List (5)
 Find
 Expand All
 Collapse All
 Undock Comment List
 Print with Comment Summary
 Create Comment Summary
 Import Data File...
 Export Selected to Data File...
 Export All to Data File...
 Export to Word...
 Commenting Preferences...
 Novo Nordisk
 Page 1 Indeterminate
 VSORRES/VSORRESU when VSTESTCD=WEIGHT



Comparison Reports

Feature can be used when comparing internal aCRF with final aCRF to ensure all annotations are the same.

	A	B	C
1	Annotation Count Report		
2			
3	Annotation Value	3625_SDTM_Annotation_20150406_v30_Migrated.xfdf - Count_xfdf	3627_SDTM_Annotation_20150406_v20.xfdf - Count_xfdf
70	DSTERM="OTHER VIOLATION: " + specification	1	1
71	DSTERM=CONSENT TO CONTACT FAMILY DOCTOR	1	1
72	DSTERM=INFORMED CONSENT OBTAINED	1	1
73	DSTERM=OTHER	1	1
74	EC=Exposure As Collected	3	6
75	ECADJ	1	3
76	ECADJ1 in SUPPEC	1	3
77	ECDOSE/ECDOSU	2	3
78	ECDOSFRM=INJECTION	2	2
79	ECDOSTOT/ECDOSU	2	6
80	ECELTM=-P1D	1	1
81	ECLOC	1	1
82	ECSCAT=ACTUAL DOSE	1	4
83	ECSCAT=FIRST DOSE	1	1
84	ECSCAT=LAST DOSE	1	1
85	ECSCAT=PRESCRIBED DOSE		1
86	ECSCAT=RECOMMENDED DOSE	1	2
87	ECSTDTC	3	4
88	ECTPT=BEFORE VISIT		2
89	ECTRT		1
90	ECTRT=BASAL_INSULIN		2
91	ECTRT=STUDY DRUG	2	2
92	EG=ECG Test Results	1	1
93	EGDTC	1	1
94	EGEVAL=INVESTIGATOR	1	1
95	EGORRES	1	1
96	EGTESTCD=INTP	1	1
97	EJEFRAC/EJEFRACU in SUPPMH	1	1

Key Features, Benefits and Notes

Key Features	Benefits	Notes
• Copy Annotations from already annotated forms • Annotations adjusted automatically • Combine multiple source files • Compare annotations	• Speed • Consistency • Comparison Reports • Intuitive & easy to understand	• Repositioning of annotations needed • Single annotations cannot be copied, whole page copied • Manual QC needed

Next steps

More users

Optimise tool

Report on incidents

Knowledge sharing

Knowledge sharing

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