

PP02

Guideline for submission ready aCRF

Working Group of CDISC DACH User Network

Background

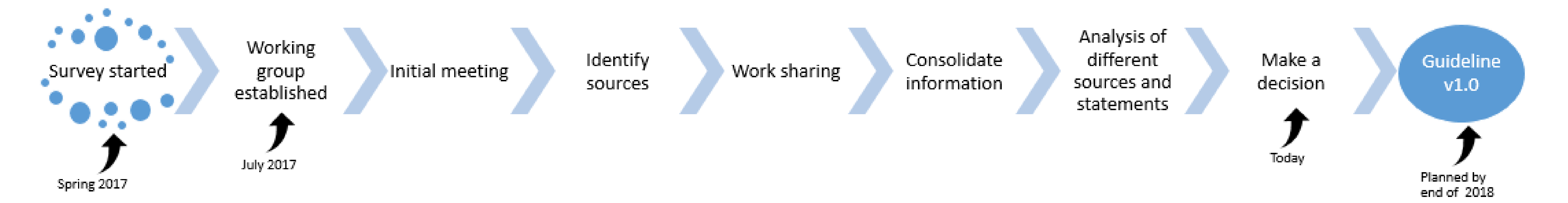
The CDISC DACH User Network is a very active group with german speaking members from pharmaceutical industry, CROs, and other institutions. During monthly conference calls and two face-to-face meetings per year, questions and experiences regarding CDISC implementation are discussed.



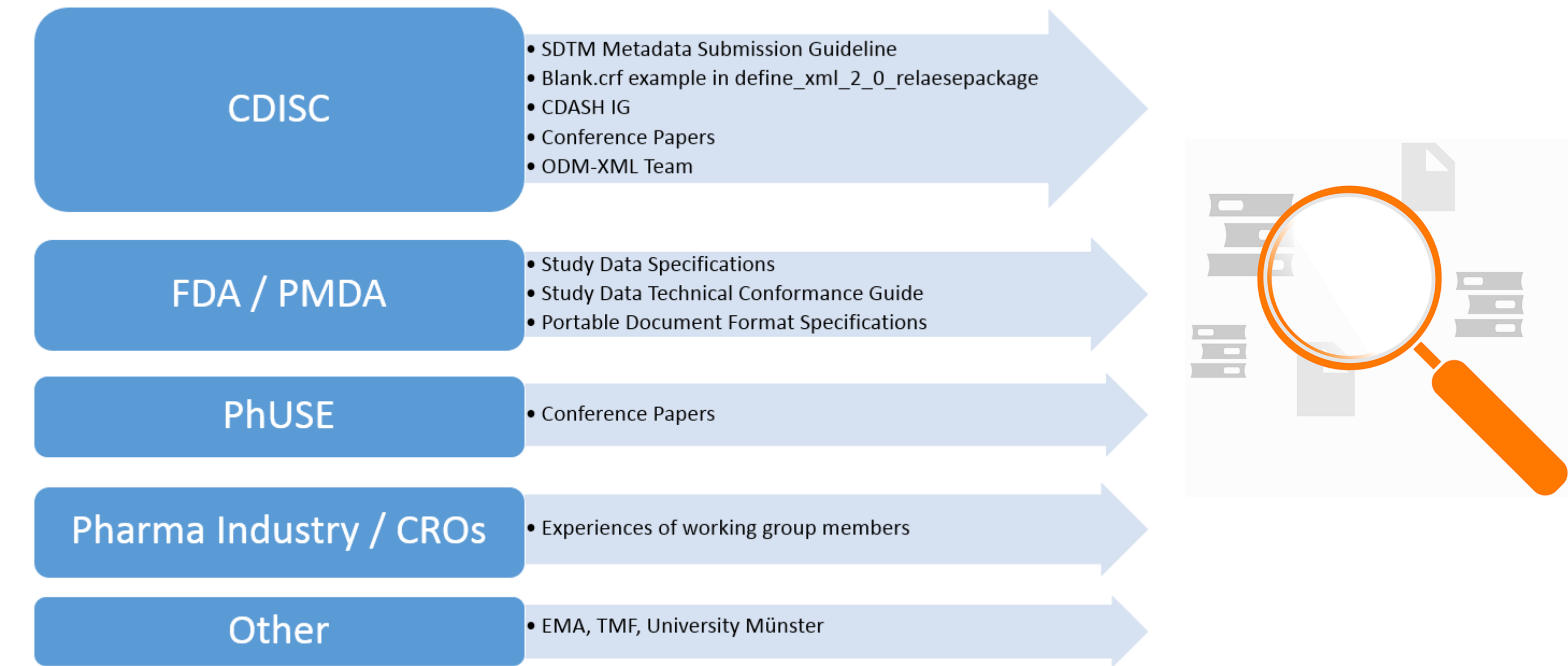
During the face-to-face meeting in spring 2017 the idea of a working group that would focus on topics of high interest in the community came to light. A survey was started within the CDISC DACH User Network to assess the potential topics and to find volunteers for the working group. In July 2017 the working group was established and the first topic „How to create a submission ready annotated CRF“ was chosen.

This guideline is currently under development and will provide recommendations, best practice approaches and examples.

Process Flow



Sources



Planned Content of Guideline v1.0

1. Introduction and Purpose
2. Prerequisites / Recommendations
3. Format
4. Bookmarks
5. Table of Content (TOC)
5. Annotations
6. Glossary

Examples

Recommendation → Annotations: Analysis of different statements

*“The annotated CRF should provide the variable names and coding for each CRF item included in the data tabulation datasets.”
(FDA – Study Data Technical Conformance Guide)*

Approach 1

BMI	VSORRES / VSORRESU when VSTESTCD = 'BMI'	Fixed Unit: kg/m2
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Approach 2

BMI	VSTESTCD=BMI	VSORRESU=kg/m2	Fixed Unit: kg/m2
		VSORRES	

Approach 3 – including codelist references

BMI	VSTESTCD (CL.VSTESTCD=BMI)	VSORRESU (CL.VSUNIT=kg/m2)	Fixed Unit: kg/m2
		VSORRES	

Approach 4 – including codelist references

BMI	VSTESTCD (CL.VSTESTCD)	VSORRESU (CL.VSUNIT)	Fixed Unit: kg/m2
		VSORRES	

Recommendation → Bookmarks

4. Bookmarks

The annotated CRF is required to contain bookmarks. Bookmarks should be created in two ways (dual bookmarking):

- Chronologically - by time points according to study event schedule with study-level bookmarks (e.g. AE) available last
- Alphabetically - by CRF topics or DCT (sequence used in EDC tool). Available bookmarks within a topic have to be ordered chronologically according to study event schedule, too.

Bookmarks have to reflect forms as many times as needed to give evidence how the data were collected; e.g. "Subject Status" is bookmarked in visits 1, 3, and 5, all three bookmarks would link to the unique subject status page. Magnification has to be set to "Inherit Zoom". Bookmarks have to be created at least in chronologically order - this has to be confirmed by reviewer.

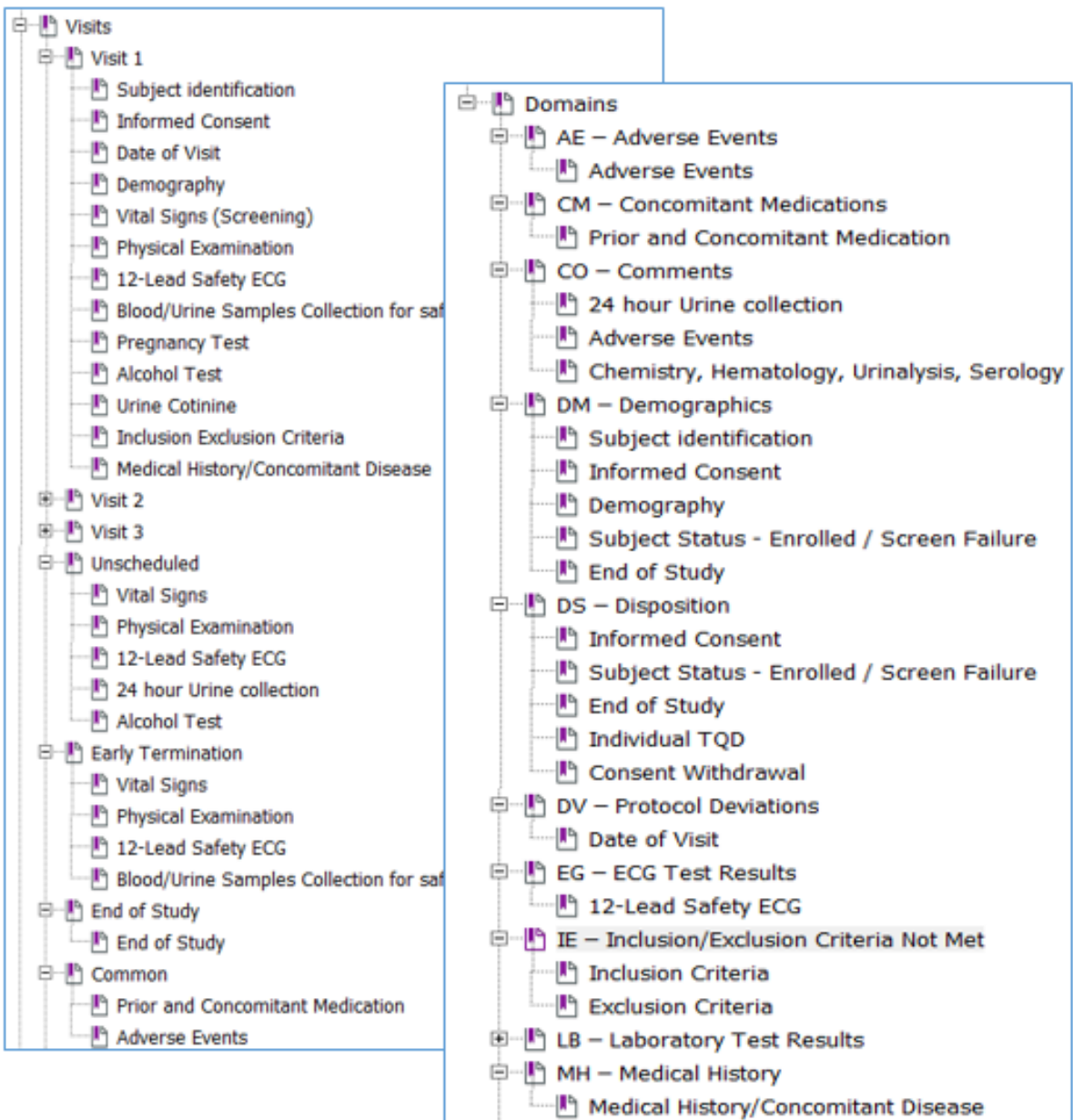


Figure 4-1 Chronologically bookmarks by visits and alphabetically bookmarks by domains

Recommendation → Table of Content

5. Table of Content (TOC)

Bookmarks act as Table of Contents (TOC) for the reviewers. The aCRF has to have a separate TOC when more than 5 pages are available. TOC should be printable as well as hyperlinked to contents. Several commercially available PDF tools create a TOC based on the bookmarks. However it is possible to create a TOC using word processing software when using "SAVE AS" PDF with Options "Include non-printing information" -> "Headings" and "Document structure tags for accessibility".

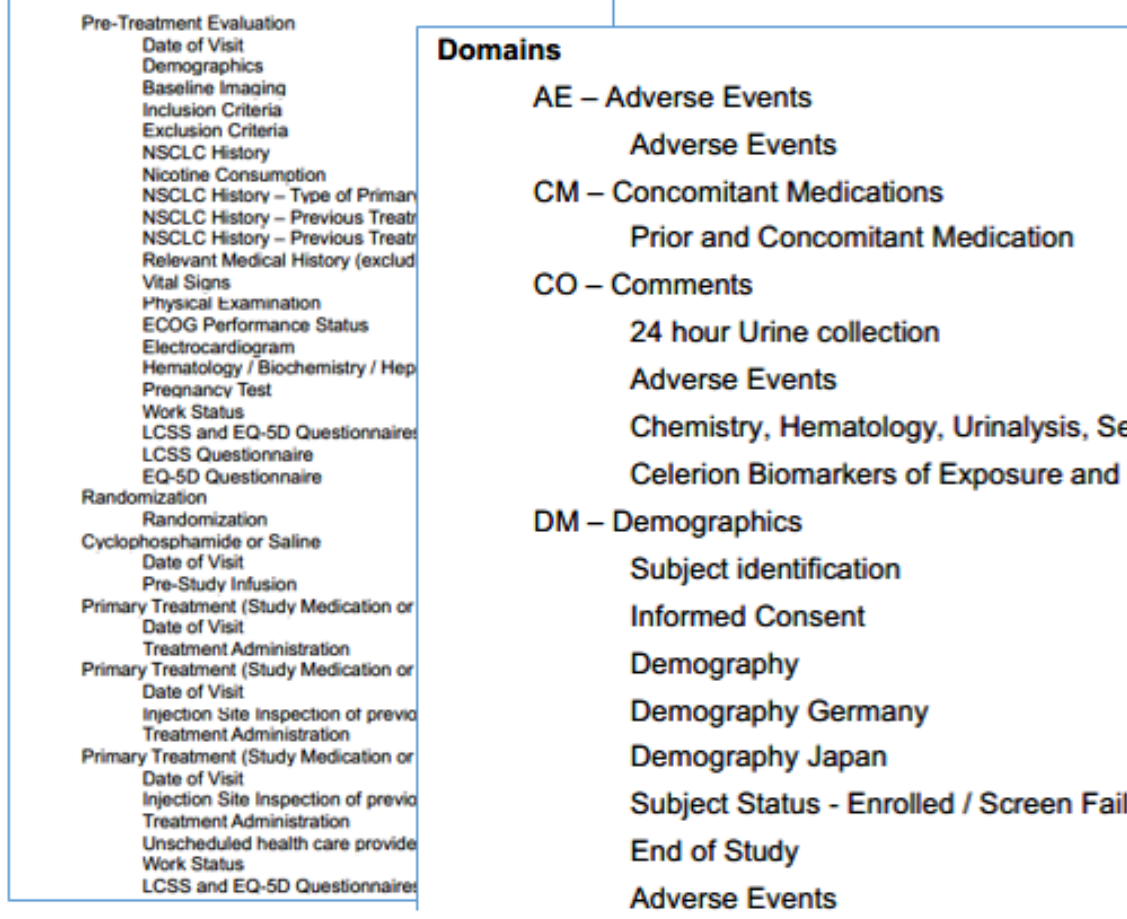


Figure 5-1 Table of Content by Visits and Domains

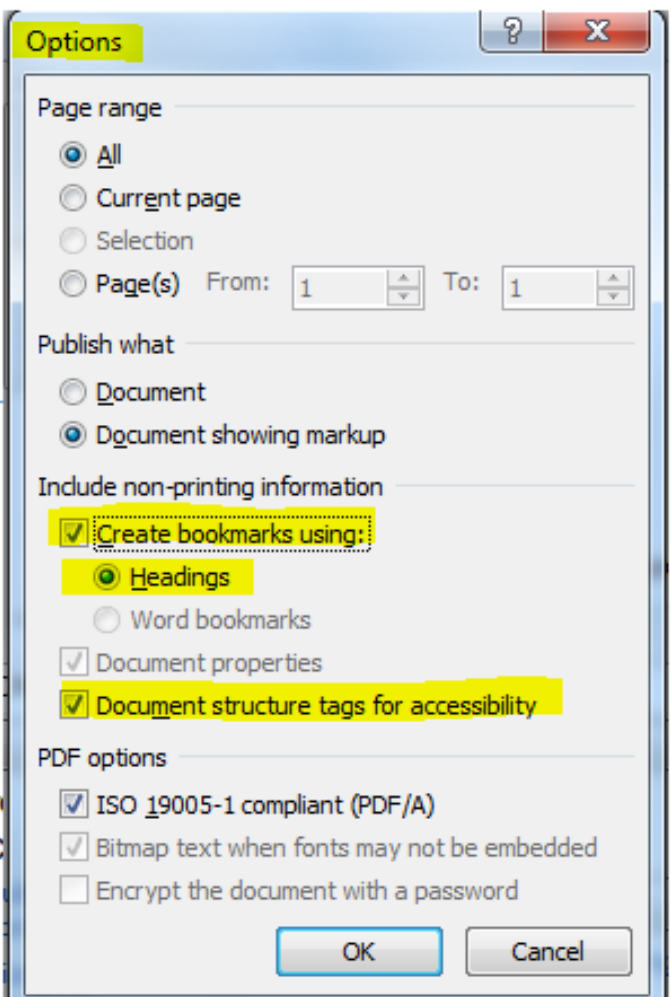


Figure 5-2 How to integrate TOC from word documents

Conclusions

- Only a few official documents regarding CRF annotations with recommendations are available, there is a lack of detailed advice regarding the practical implementation
- All recommendations will be included in our guideline, complemented with best practices and examples
- The guideline should help in setting up a submission ready annotated CRF in an acceptable way for several authorities
- When finalized, the first version of the annotation guideline will be available on the wiki pages of the CDISC DACH User Network:

<https://wiki.cdisc.org/display/DEUUG/German+User+Network+Home>

- Outlook: first version of the annotation guideline available by end of 2018, additional updates are possible

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