Background

The CDISC DACH User Network is a very active group with German-speaking members from the 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

Survey started  | Working group established  | Initial meeting  | Identify sources  | Work sharing  | Consolidate information  | Analysis of different sources and statements  | Make a decision  | Guideline v1.0

Sources

CDISC

FDI / PMDA

PhUSE

Pharma Industry / CROs

Other

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)

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

Planned Content of Guideline v1.0

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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