
Tool for MedDRA coding in DataFax

Name Tessa Tensen,
Senior Data Manager
Company Factory CRO, *Clinical Research for
Medical Devices*
Bilthoven, The Netherlands



Motive coding tool

- Factory CRO:
 - Niche CRO for medical devices
 - Typical of medical device studies:
 - *low number of subjects
 - *low number of adverse events
 - Limited budget coding tools AE's

Objective of company

- **Factory CRO:**

‘Coding tool for in-house coding of Adverse Events preferably integrated in DataFax’

Options

- Demonstrated tool by SCHARP at DFUG
- MedDRA browser
- Create own coding tool...?

Coding Tools

- “SCHARP-tool”:
browser function did not work properly in our environment
 - MedDRA browser:
Not integrated in DataFax
- Conclusion:
- create own in-house coding tool

Basic idea

Basic idea of in-house coding tool:

- Use MedDRA to encode Adverse Events
- Entirely store Lowest Level, Preferred Term & Social Organ Class in DataFax
- No use of external vendor coding applications

Technical background

- Convert ASCII files of MedDRA to DataFax compatible lookup tables
- Create an extra CRF-page in DataFax for coding purposes
- Create some global variables and edit checks

Actual use of coding tool (1)

- Open Adverse Event coding page
- Adverse event term automatically copied from AE page
- Confirm search term for Lowest Level Term
- Determine Lowest Level Term via lookup table

Actual use of coding tool (2)

- Preferred Term & SOC are automatically generated and stored
- If LLT is difficult to determine, use MedDRA browser
- It is possible to deviate from primary SOC

Conditions coding tool

- Correct and clear adverse event terms
- MedDRA browser and ASCII files available
- Program like MSAccess or SAS available to create lookup tables
- Version control of MedDRA

In actual practice

Live demonstration of coding tool in
iDataFax 3.8.3

Conclusion

Benefits coding tool:

- Easy to create, implement and use
- Low costs
- DataFax 3.8.3: global lookup tables & edit checks

Points of interest:

- Multi-axiality
- Performance

?????

Questions?