Tool for MedDRA coding in DataFax

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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

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**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

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**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?