MedDRA coding dictionary implementation workflow methodology within DataFax

Michael Duvenhage, Operations Manager
National Institute of Allergy and Infectious Diseases, NIH
Overview

- Countries: 15
- Active DataFax Studies: 81
- DataFax Studies in Setup: 5
- Archived Studies: 11 (previous server)
- Studies Terminated without Stating: 2
- Total CRF pages: 1,856,625
- Active Users: 204
MedDRA coding overview

- **Malaria Vaccine Trials**
  - 6 Studies
  - ~4000 Adverse Events
  - Partial MedDRA dictionaries loaded

- **Dengue Fever Vaccine**
  - 2 Studies
  - ~500 Adverse Events
  - Full MedDRA dictionaries loaded
MedDRA coding workflow (eDC)

- Source Documents
- Site Data Entry (Level 1)
- QC Review (Level 2)
- QA Review (Level 3)
- Level 4...6 Cleaning
- MedDRA Coding (Level 1, Level 2, Level 3 or Level 4)
- *Do not adjust level
- Database Lock (Level 7)
MedDRA coding workflow (Paper)

Source Documents

Data Entry (Level 1)

Data Entry (Level 2)

Level 3...6 Cleaning

Database Lock (Level 7)

Query Process

MedDRA Coding (Level 1, Level 2, Level 3 or Level 4)

*Do not adjust level
MedDRA Dictionaries

DataFax Study (CDS Master)

- Currently holds our “master” validated MedDRA dictionaries, copied into required studies when needed

- Full dictionaries – i.e. contain all records from MedDRA dictionary except “non-current” terms (removed using SAS)

- Does not contain all fields, restricted to fields important for reporting requirements

- Remember to add version number in the Lookup table file name
MedDRA fields

<table>
<thead>
<tr>
<th>MedDRA fields</th>
</tr>
</thead>
<tbody>
<tr>
<td>Search Term</td>
</tr>
<tr>
<td>Lower Level Term code (Level at which coding happens)</td>
</tr>
<tr>
<td>Lower Level Term name</td>
</tr>
<tr>
<td>Preferred Term code (Level at which reporting happens)</td>
</tr>
<tr>
<td>Preferred Term name</td>
</tr>
<tr>
<td>System Organ Class code</td>
</tr>
<tr>
<td>System Organ Class name</td>
</tr>
</tbody>
</table>

Restricted to fields required for DSMB / Safety reports as well as FDA reporting (FDA reporting requires Preferred Term and System Organ Classes)

Also restricted to reduce the initial time for the lookup table to load (in iDataFax) when coding
MedDRA Coding Setup - DFSetup

Adverse Event Verbatim Term

Coding fields: LLT name, LLT code, PT name, PT code, SOC name, SOC code

Corresponds to the data that is loaded into the MedDRA lookup table.
MedDRA Coding Edit Checks - DFSetup

Plate Enter
Masking / Hiding of the MedDRA coding fields for non-coding users.

Field Exit
Triggers the MedDRA lookup table – only for Coding user.

Plate Enter
Sets a global variable = AETERM

Plate Exit
If the current AETERM value is not the same as the global AETERM set at Plate Enter, then it means the AE Terms was changed – thus remove any MedDRA coding.
MedDRA Coding process - iDataFax

Field Exit
Triggers the MedDRA lookup table – only for Coding user.

Lookup Table
Using Lookup Table Filter for the AE term

Lookup Table
Upon selecting the correct AE term the MedDRA items will be populate
MedDRA Coding process - iDataFax

Lookup Table
Populated MedDRA items from Lookup table.
MedDRA Coding process - iDataFax
MedDRA Coding – Task Usage

Task forces Level 1 (or any other level). Wish list – would be great if a task can allow to save at whatever the level currently is.

Where the AELLT = AELLTCD (can only happen when both are BLANK)

Current Edit checks are used to override the level, and we “save” the record at the same level – regardless of what the Task indicates.
MedDRA Coding Demonstration

Demo
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