
The DataFax - MedDRA Connection

Betty Carr
Clinical Coding Software

Betty Carr
Clinical Coding Software



MedDRA Overview

- “Medical Dictionary for Regulatory Activities Terminology”
- The standard for reporting Adverse Event (AE) data
- Delivered as a set of ASCII (text) files

Betty Carr
Clinical Coding Software



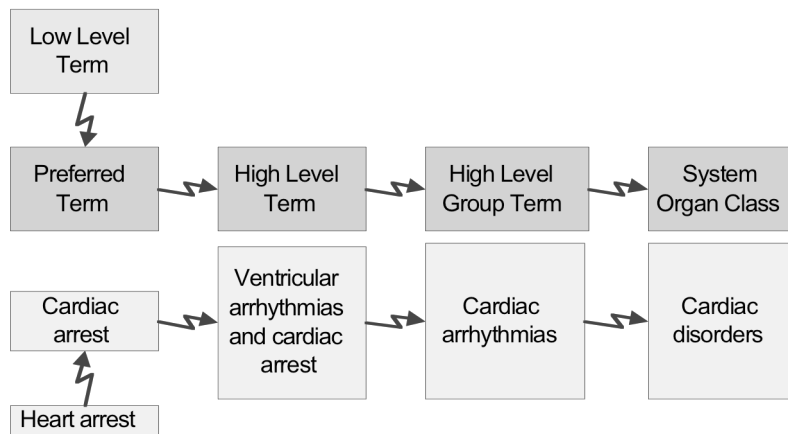
MedDRA Hierarchy

- Low Level Term (LLT)
- Preferred Term (PT)
- High Level Term (HLT)
- High Level Group Term (HLGT)
- System Organ Class (SOC)

Betty Carr
Clinical Coding Software



MedDRA Example



Investigator Text: Massive arrest of heart

Betty Carr
Clinical Coding Software



Clinical Coding Software (CCS)

- Unix based
- Written in Perl and Perl/TK
- Loads two of the MedDRA files
LLT.asc: LLT and corresponding PT
MDHier.asc: PT and mapping to the SOC
- Two types of coding
Auto-encoder
Browser

Betty Carr
Clinical Coding Software



The Auto-encoder

- Receives the AE verbatim
- Automatically attempts to match an existing LLT
- Returns information
Match type
 - "M" indicates a match
 - "N" indicates no matchMedDRA version number

Betty Carr
Clinical Coding Software



The Auto-encoder

- Returns information (continued)

MedDRA mapping

- LLT code (8-digit number)
- LLT name (text)
- PT code (8-digit number)
- PT name (text)
- SOC code (8-digit number)
- SOC name (text)

Note: If there isn't a match, these fields are left blank

Betty Carr
Clinical Coding Software



The Browser

- Receives the AE verbatim
- Displays windows and buttons
- Contains a variety of search modalities
- Lists LLT's only
- Option to display the entire mapping
 - First pass coding should *not* display the mapping
 - Higher level review should display the mapping
- Returns the same information as the auto-encoder

Betty Carr
Clinical Coding Software



Integrated Coding

- Auto-encoder and browser can be called from within DataFax
- Trigger CCS from the AE plate
 - Use DF Edit Check DFRun function
 - Pass the necessary parameters, e.g.
 - AE verbatim
 - Switch to turn mapping on/off
- Capture the return values using DF Edit Check Language

Betty Carr
Clinical Coding Software



Batch Coding

- Auto-encoder and browser can be called from the Unix command line
- Pass the necessary parameters (same as for integrated coding)
- Process a *list* of AE's
- Return values are written to the AE record in the list
- Useful for coding legacy data with MedDRA

Betty Carr
Clinical Coding Software



Coding Levels

- **CCS tracks three coding levels**
 - Automated (auto-encoder)
 - Manual coding
 - Code review
- **Levels are labeled simply 1, 2, and 3**
 - Allows user to describe the coding levels specifically
 - For example
 - Institution A coding level 3 is: Clinical Review
 - Institution B coding level 3 is: Medical Officer Review

Betty Carr
Clinical Coding Software



Types of CCS Parameters

- Auto-encoder/Browser
- Interactive/Batch
- MedDRA version number to use
- Verbatim text to match
- Coding level being used
- Display MedDRA mapping On/Off
- Synonym list On/Off

Betty Carr
Clinical Coding Software



Additional Tools

- Sample INPUT statements to load the MedDRA dictionary into SAS:
For AE analysis and Reporting
Useable on Unix or Windows
- Sample DataFax edit checks to integrate CCS into DataFax
Useable only on Unix
- These are *only* samples: they must be customized for your system

Betty Carr
Clinical Coding Software



Planned Future Enhancements

- Synonym list processing
- Additional match algorithms to increase auto-encoder hit rate
- Recoding AE's from older MedDRA versions into the most recent version
- Compiling into an .EXE file (won't need Perl, Perl/TK on your system)

Betty Carr
Clinical Coding Software



Planned Future Enhancements (Cont)

- Reports on CCS settings to accompany data submissions
 - Whether a synonym list was used
 - Matching algorithms employed
- Report of AE's to be recoded for a MedDRA version update
- Basic Safety Reports
- Drug coding dictionaries

Betty Carr
Clinical Coding Software



CCS Development

- Projected release date: June 20, 2005
- Cost
- License
- I really want to know...
 - Send your suggestions/comments to CCSAED@comcast.net
- Questions before we discuss the Browser screen?

Betty Carr
Clinical Coding Software



The CCS Browser

The screenshot shows a software window titled "MedDRA_Coding : Form". At the top, there is a "Verbatim Text:" field containing "Abnormal heart Biopsy" and a "Rapid Entry:" field. Below this is a "Search Results: Verbatim words match" list with the following items: Apnoeic attack, Biopsy heart, Biopsy heart abnormal (highlighted), Biopsy heart normal, Congenital heart disease, Heart and lung transplant, Heart block congenital, Heart disease aggravated, Heart disease gonococcal, Heart injury, Heart rate abnormal, Heart rate decreased, Heart rate increased, Heart rate irregular, and Heart rate normal. To the right of the list is a "Search Modalities:" section with several input fields: "Word", "Word starting with...", "System Organ Class", "Other??", "Other??", and "Verbatim words match". Below the search modalities are two buttons: "Do not select a term" and "Select highlighted term". At the bottom of the window are fields for "Preferred Term:", "Higher Level Term:", "Higher Level Group Term:", and "System Organ Class:".

Betty Carr
Clinical Coding Software

