
Implementing MedDRA Adverse Event Coding into DataFax

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Overview

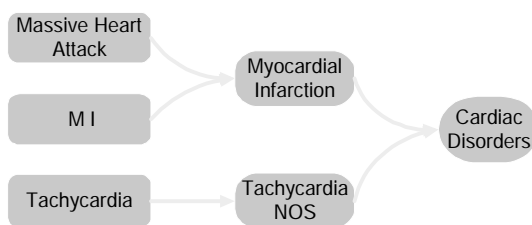
- Part I
 - » Adverse Events
 - » MedDRA Dictionary
 - » System Design
 - » Program Development
- Part II
 - » DataFax Interface
 - » Difficulties Encountered

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Adverse Events (AE's)

- Any complaint reported by participant or diagnosis made by clinician
- Need to be coded
 - Meet regulatory requirements for standardization
 - Simplification of analyses



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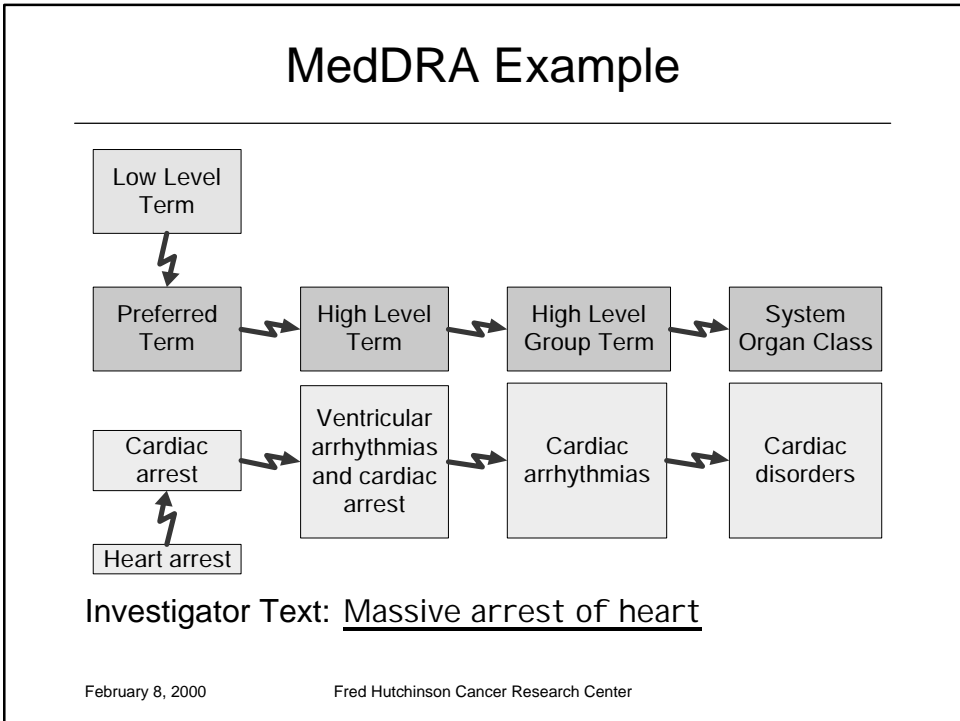
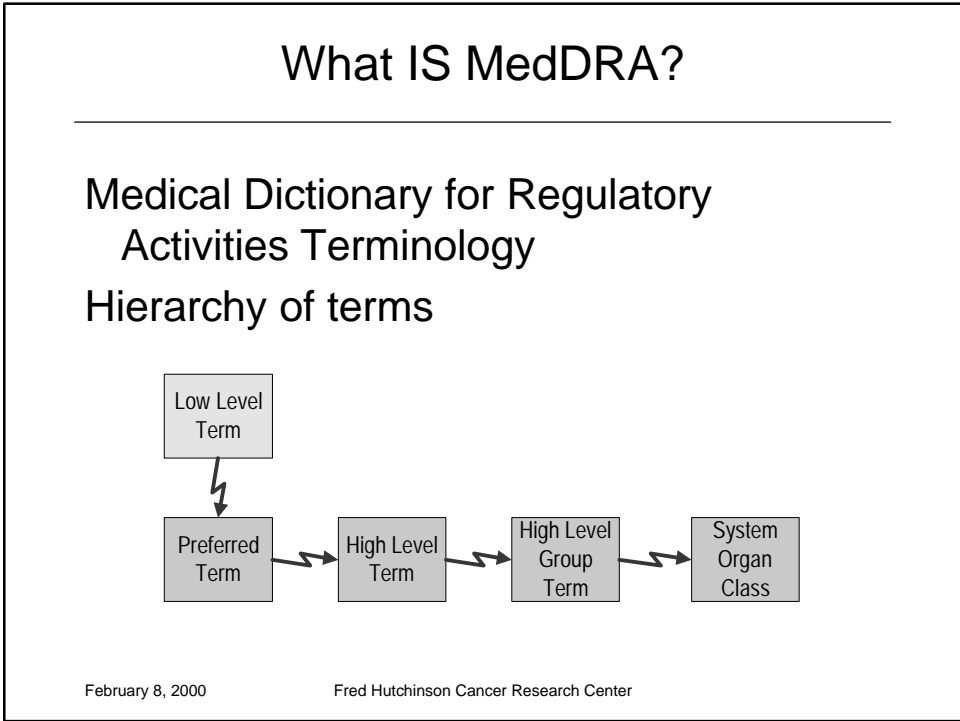
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Adverse Events Coding

- All major international regulatory agencies have agreed that MedDRA is the future for AE coding
- SCHARP system previously used COSTART which had several limitations
- The move to MedDRA afforded SCHARP the opportunity to improve the system

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Goals of the System

Optimize automation

- Exact matches without human intervention
- Interactive coding
 - Multiple search criteria
 - View complete mapping during coding
 - Ability for coder to review an exact match

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Decision Point: Implement in SAS or DataFax?

DataFax!



- Image can be seen by the coder during coding
- MedDRA code stored in DataFax AE database
- QC's can viewed or added at time of coding
- Image with the code is available to anyone authorized to view it
 - SCHARP statisticians and clinicians use DataFax to view data
- DataFax has built-in audit trail capabilities
- The SAS database matches the DataFax database

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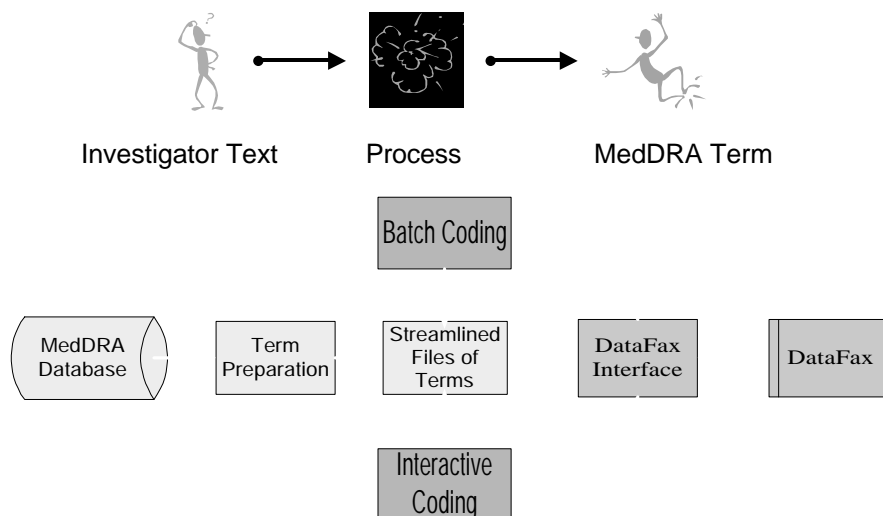
Requirements

- Necessary information to keep in the database
 - Preferred Term
 - System Organ Class
 - Source flag to track the coding process for
 - Potential requests to MedDRA MSSO
 - Site training to improve automated exact matches
 - MedDRA version number (new version issued quarterly)
- Capability to handle re-faxes

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Tools



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Preparing MedDRA Terms

- Removes superfluous terms
 - Those no longer used (from former coding systems)
 - Secondary mappings
- Automatically runs nightly (accommodates version changes)
- Written in Perl

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Batch Coding

- Attempts to match the Investigator AE text with a MedDRA Low Level Term
- If an exact match is found, the return values are
 - Preferred Term associated with the matching Low Level Term
 - System Organ Class
 - Source flag
 - MedDRA version number

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Batch Coding (continued)

- If an exact match is NOT found, the return values are
 - "No exact match" instead of Preferred Term and System Organ Class
 - Source flag
 - MedDRA version number
- Written in Perl

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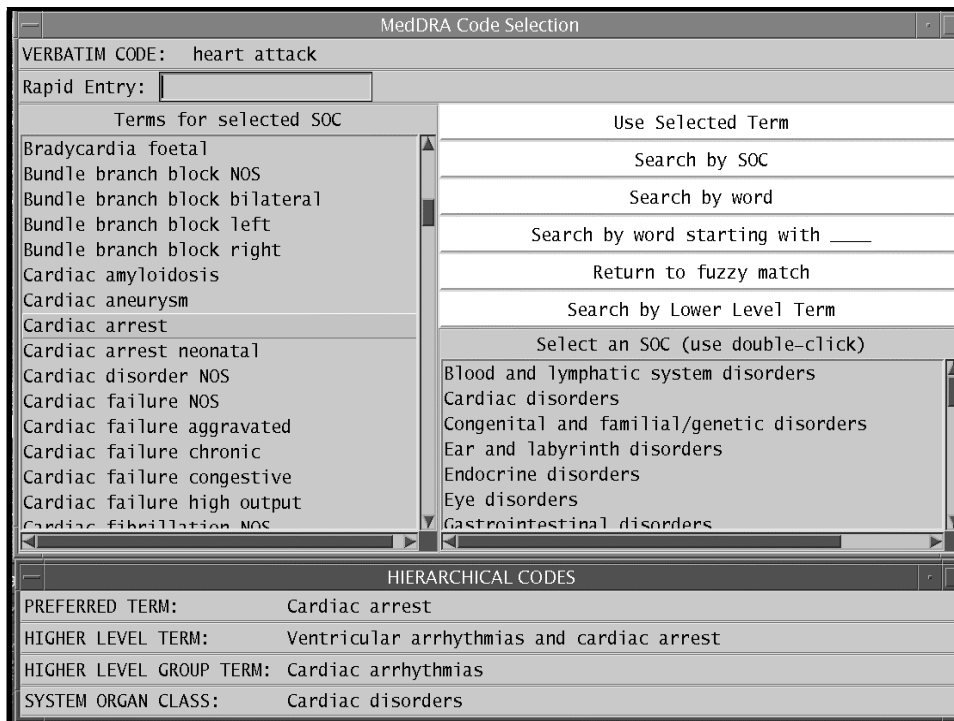
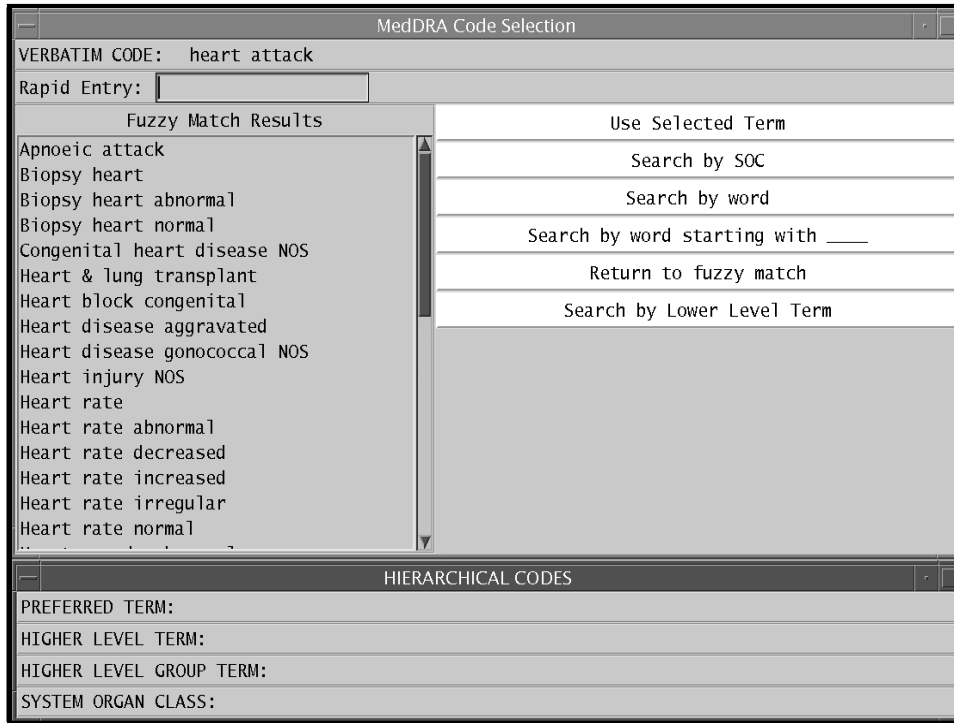
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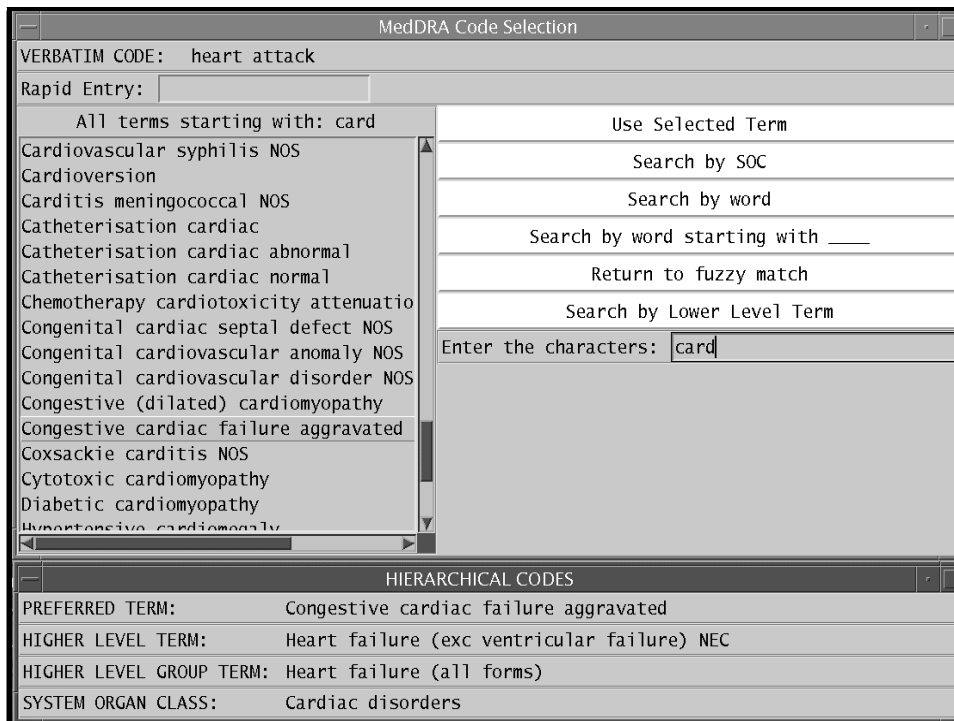
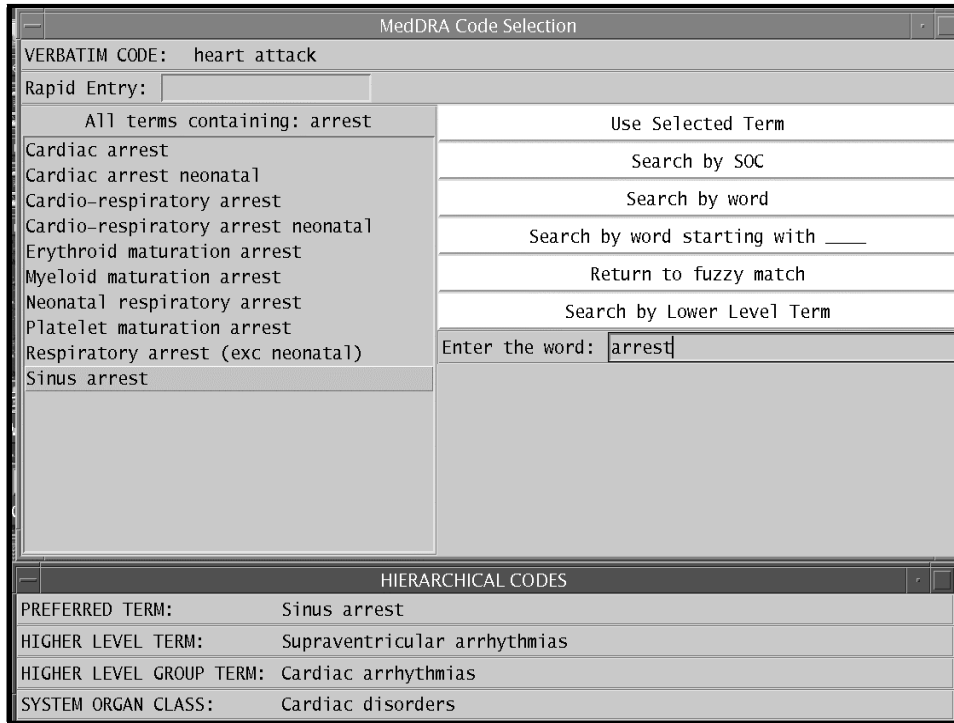
Interactive Coding

- Allows user to select an appropriate MedDRA Preferred Term
 - Multiple search criteria
 - Written in Perl, Perl/TK
 - Consists of a GUI interface
- The following is a series of screens from the interactive coding program demonstrating how a code is searched for and selected

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Interactive Coding (continued)

“Use Selected Term” button returns the values

- Preferred Term
- System Organ Class
- Source flag
- MedDRA version number

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DataFax Interface: Batch Coding

- DataFax Edit Check
- dfrun function (result of DFUG 1999 Wish List)
 - Calls Perl batch coding program
 - Passes arguments
 - Investigator text
 - Preferred Term*
 - System Organ Class*
 - Source flag*
- Executed at “plate exit” of second pass entry

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DataFax Interface: Batch Coding (continued)

Receives back

- Preferred Term
- System Organ Class
- Source Flag
- MedDRA version number

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DataFax Interface: Batch Coding (continued)

Exact match found

- No code exists in current DataFax record: returns search result
- Prior code exists: returns search results and additional flag, indicating a re-fax

Exact match NOT found

- No code exists in current DataFax record: returns "No exact match"
- Prior code exists: returns original code and additional flag, indicating a re-fax

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DataFax Interface: Interactive Coding

- DataFax Edit Check
- Auto-launch Perl interactive coding program if DataFax MedDRA code field = "No exact match"
- Review/recode of prior coding: user initiates recode by response to dfask query
- dfrun to launch Perl interactive coding program
 - Pass Investigator text
 - Receive back search results
- Executed at "field enter" with validation level greater than second pass

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DataFax Interface: Hidden Fields

Store MedDRA information in the DataFax AE database

- Source flag~version number
example: E~02.3
- Preferred Term~System Organ Class
example: Nausea~Gastrointestinal Disorders

DataFax edit check skips hidden fields during first and second pass entry

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SCHARP vs. Site Forms

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SCHARP vs. Site Forms

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Uh-Oh! Hidden Driveway, Motorized Vehicles Only

- DataFax record length limitation (related to RPC)
 - Dependent on the DataFax and operating system versions (1024, 2048, etc)
 - Remedy: Don't store High Level Term and High Level Group Term (MedDRA database allows easy merging outside of DataFax)
- Minimum DataFax version requirements
v3.4-002 for dfrun and dfask edit check functions

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Uh-Oh! Slower Traffic Keep Right

- Speed
 - Programs are slowed by the large number of terms in MedDRA
 - Remedies
 - Remove superfluous terms
 - Utilize local storage
 - Customized data structures

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Summary

- Automatic exact matches
- User-friendly GUI interface for interactive coding
- DataFax strengths utilized
- Regulatory requirements met

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