

Clinical Coding

What is Clinical Coding ?

Why do we need it ?

How do we do this ?



Module 10 Topic 7

Coding

- Allows consistency of reporting within a trial and across a project



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- Alpha-numeric codes are assigned from standard dictionaries in order to maintain consistency and to categorise terms



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Coding

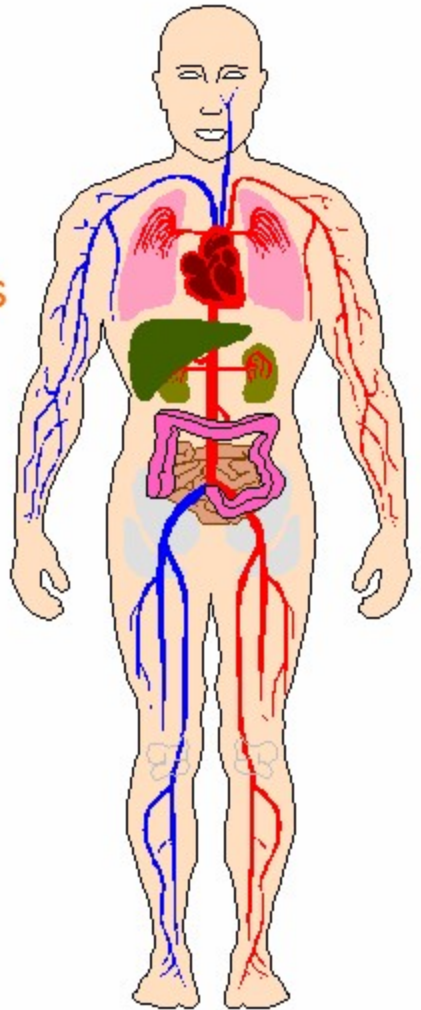
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- Alpha-numeric codes are assigned from standard dictionaries in order to maintain consistency and to categorise terms
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Ae	Preterm	Code	Hltcode	Soccode
NEUCLEAR SCLEROSIS	CATARACT NUCLEAR	10007759	10007772	10015919
NUCLEAR SCLEROSIS	CATARACT NUCLEAR	10007759	10007772	10015919
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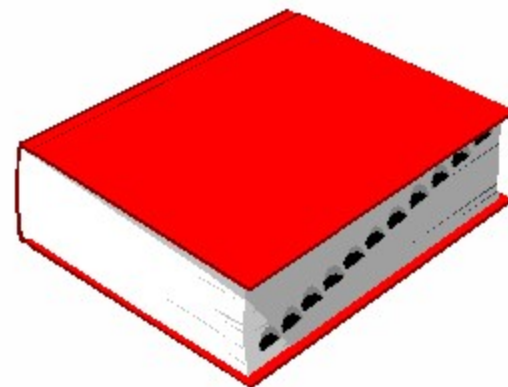


Coding (contd)

- Assigning codes to classify data
 - Adverse Events
 - Concomitant Medication
 - Indications for Concomitant Medications
 - Medical History
 - Physical Examination

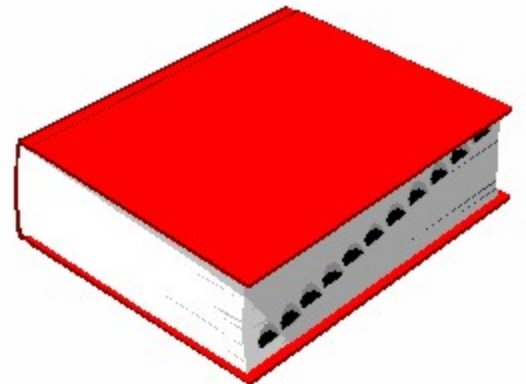


Coding Dictionaries



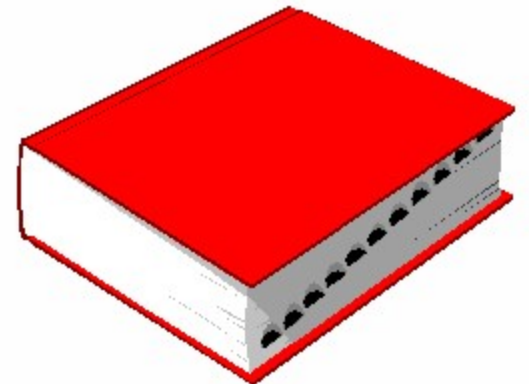
Coding Dictionaries

- ICD9CM and ICD series - Diseases



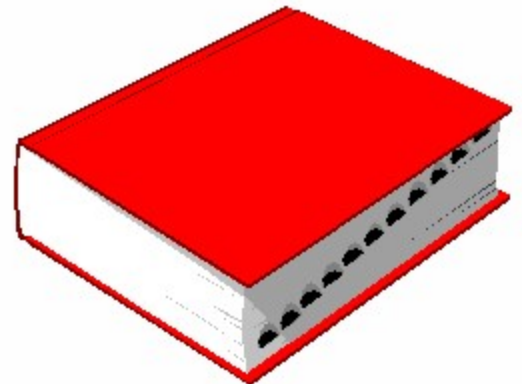
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- ICD9CM and ICD series - Diseases
- COSTART - Adverse events



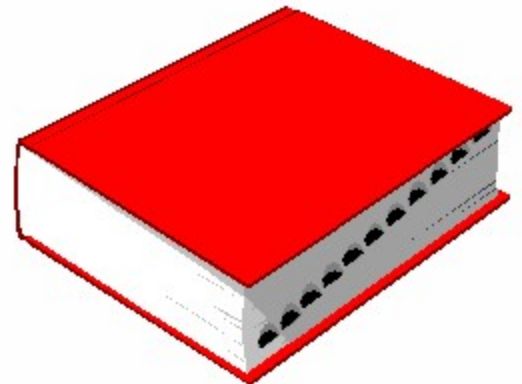
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- ICD9CM and ICD series - Diseases
- COSTART - Adverse events
- WHODRUG and WHOART - WHO's drugs and adverse events



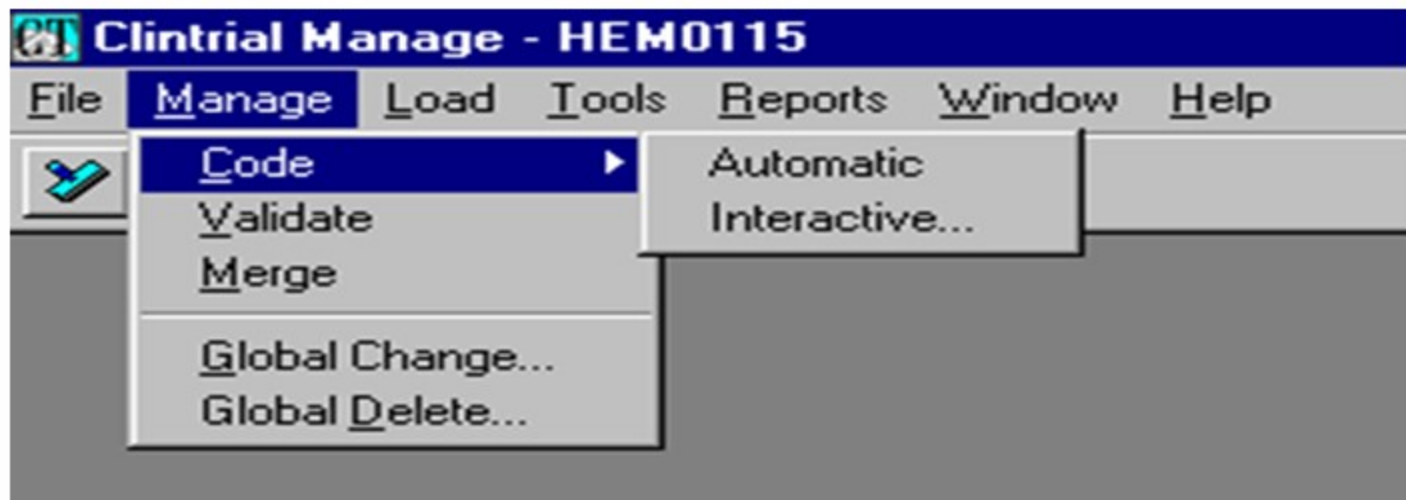
Coding Dictionaries

- ICD9CM and ICD series - Diseases
- COSTART - Adverse events
- WHODRUG and WHOART - WHO's drugs and adverse events
- MedDRA - Adverse events and Medical Terminology (Medical History & Concomitant Indications)



How Do We Code

- Manual
- Electronic
 - The database is able to code data that is a direct match or has been matched to a code previously
 - Automatic
 - Interactive



Multiple Code Text

- 'Dizziness and raised blood pressure'
- Two codes should be allocated
- AE must be entered twice with the same details

Dizziness and raised blood pressure

Dizziness



Raised blood pressure



Coding Considerations



Coding Considerations

- Dealing with spelling mistakes



Coding Considerations

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- Abbreviations



Coding Considerations

- Dealing with spelling mistakes
- Abbreviations
- Splitting Terms



Coding Considerations

- **Dealing with spelling mistakes** Generic/Trade Name
- **Abbreviations** Ask for relevant reference material if trade names apply
- **Splitting Terms** Handling coding problems (e.g. cannot find a suitable code)



Adverse Events

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- An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).



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- Results in persistent or significant disability/incapacity



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- Congenital anomaly/birth defect



Serious Adverse Event Reconciliation

