Clinical Coding

What is Clinical Coding ?

Why do we need it ?

How do we do this ?

Module 10 Topic 7

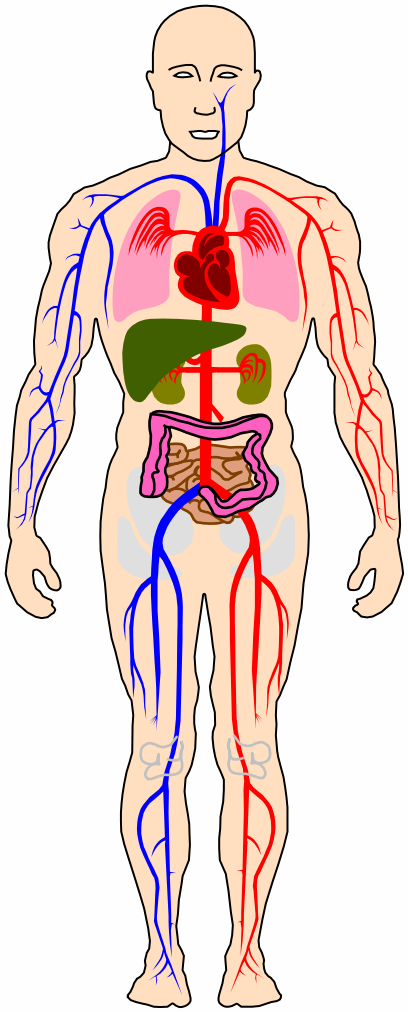
Coding

- Allows consistency of reporting within a trial and across a project
- Alpha-numeric codes are assigned from standard dictionaries in order to maintain consistency and to categorise terms
- Quantifiable numeric results can be used in statistical reports to identify patterns

Ae	Prefterm	Code	Hltcode	Soccode
NEUCLEAR SCLEROSIS	CATARACT NUCLEAR	10007759	10007772	10015919
NUCLEAR SCLEROSIS	CATARACT NUCLEAR	10007759	10007772	10015919
NUCLEAR SCLEROSIS	CATARACT NUCLEAR	10007759	10007772	10015919
NUCLEAR SCLEROSIS.	CATARACT NUCLEAR	10007759	10007772	10015919

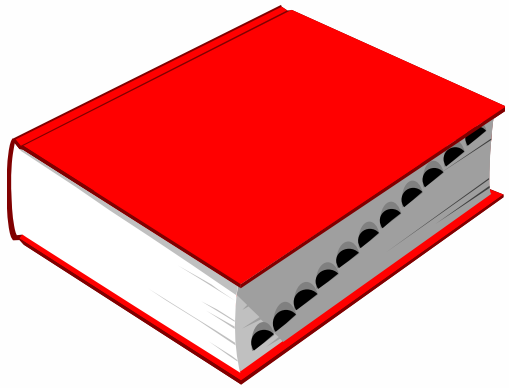
Coding (contd)

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



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)



What is MedDRA?

- Medical Dictionary for Regulatory Activities
- A Dictionary for coding all medical information obtained during all phases of development and marketing:
  - Symptoms & Signs
    Diseases
  - Diagnosis
  - Indications
  - Investigations/Procedures
  - Medical/Social/Family History

Development, ownership and maintenance

- MedDRA was developed by the **International Conference on Harmonisation (ICH)**

- It is owned by the **International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)** acting as trustee for the ICH steering committee

- Maintained by **Maintenance and Support Service Organization (MSSO)** that is responsible for updating and maintaining MedDRA and distributing the terminology, on license, to users in the industry and regulatory agencies.

Development, ownership and maintenance

Before MedDRA:

- **Available Tools -** FDA's COSTART, WHO-ART, J-ART, H-ARTS, ICD-9 and ICD-9CM
- **Challenges - I**nfrequent updates leading to individual users creating their own version and standardization was lost.
- **Need -** Standard Medical Terminology to provided the scope and level of granularity that was needed by regulatory authorities and industry

Rationale for MedDRA

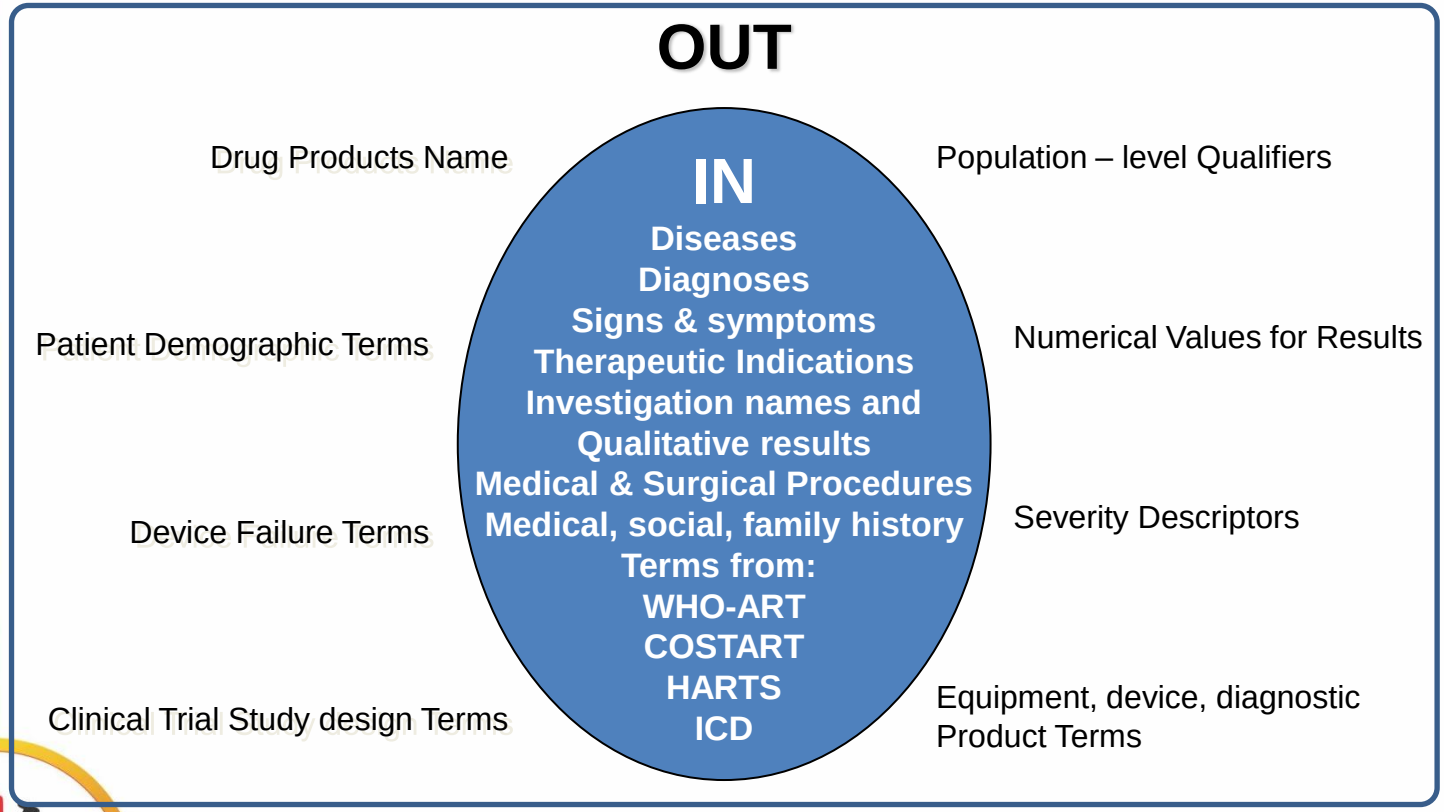
Challenges with Established terminologies (WHO-ART, COSTART, etc.)

- Lack specificity
- Have limited data retrieval options
- Unable to handle complex combinations of signs and symptoms (syndromes)

Need for global standardization

- Across regulatory agencies
- Across multinational pharmaceutical companies
- Necessary through-out product lifecycle
- Necessary for electronic data transfer
- Avoids translation distortions/errors across countries

Scope of MedDRA



Purpose of using MedDRA

- To aggregate reported terms in medically meaningful groupings for the purpose of reviewing and /or analyzing safety data.
- To facilitate consistent retrieval of specific cases or medical conditions from a database .
- To improve consistency in comparing and understanding “safety signals” and aggregated clinical data.
- To facilitate electronic data interchange of clinical safety information.

Purpose of using MedDRA contd

- To report adverse reaction/adverse event (ADR/AE) terms via individual case safety reports.
- To include ADR/AE's in tables, analyses, and line listings for report .
- To identify frequency of medically similar ADR/AEs.
- To capture and present product indications, investigations, medical history and social history data.

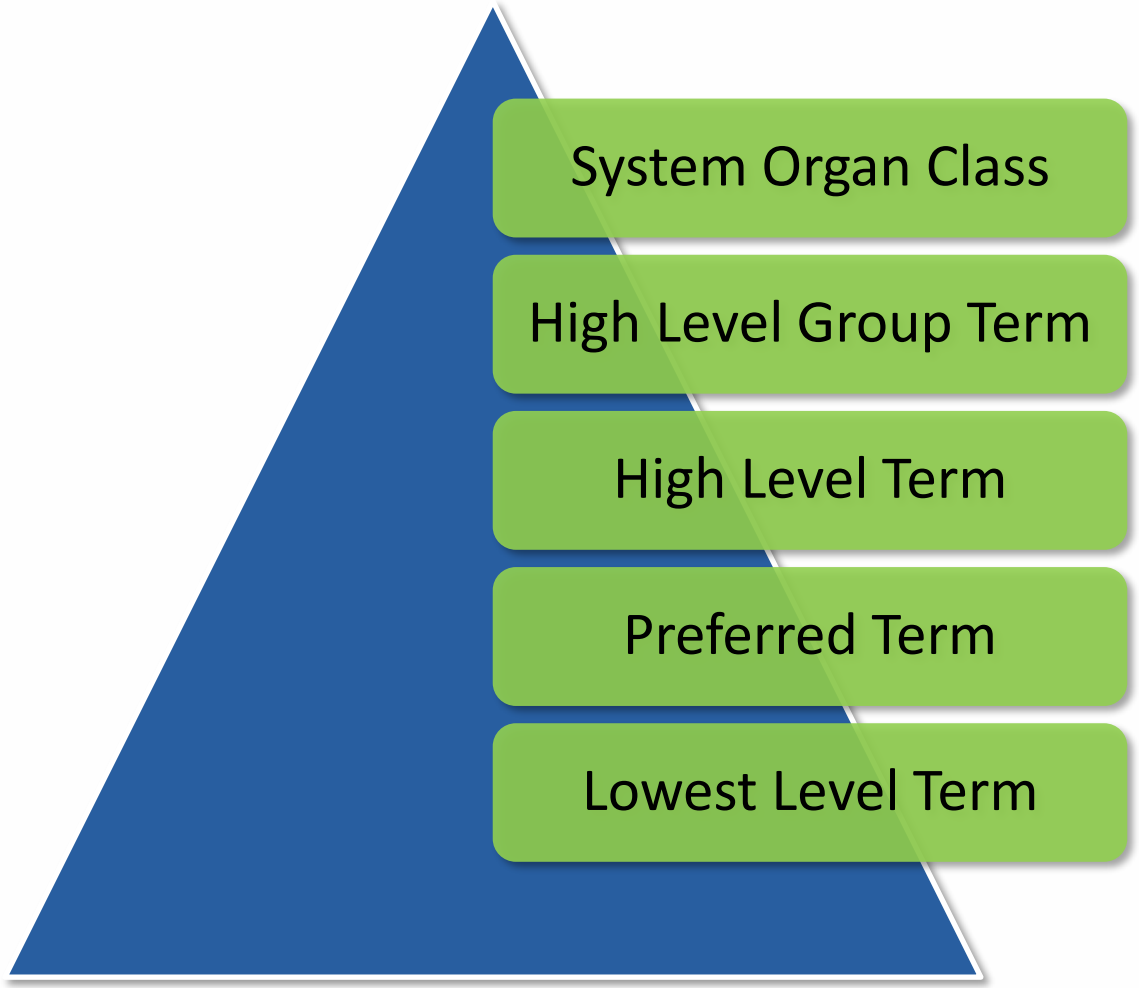
Objectives of Medical Coding

- Record data accurately
- Preserve specificity and meaning
- In uniform and consistent manner

WHY?

- Data Retrievability
- Presentation
- Organization
- Manipulation
- Statistical analysis

MedDRA Structure

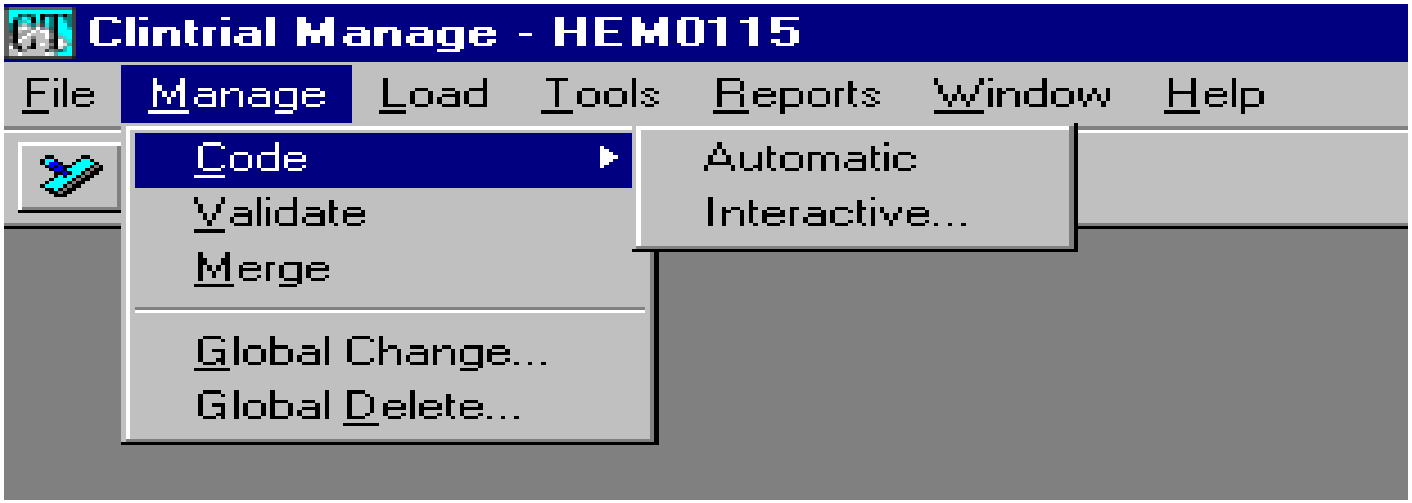


Structural elements in MedDRA terms

- **SOC (System Organ Class)** - Highest level of the terminology, and distinguished by anatomical or physiological system, etiology, or purpose
- **HLGT (High-Level Group Terms)** – Subordinate to SOC, superordinate descriptor for one or more HLTs
- **HLT (High-Level Terms)** – Subordinate to HLGT, superordinate descriptor for one or more PTs (links PTs related to it by anatomy, pathology, physiology, etiology or function)
- **PT (Preferred Term)** – Represents a single medical concept. PT can be connected to a single SOC (Single Axiality) or to SOC through multiple branches (Multiaxiality)
- **LLT (Lower-Level term)** – Lowest level of the terminology. The LLT is the term that most accurately reflects the reporter's words. There is 1:1 correspondence between LLT and VT terms

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

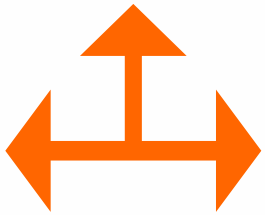


Multiple Code Text

- ‘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

- **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)

Coders and loaders

- In a CDM team the coding responsibility is allocated to certain individuals
- Since coding allows different groups to speak the same language, this team also reconciles the adverse event information gathered by the CDM team and that of the PV team
- Any discrepancies thrown up are addressed by the respective teams.
- Ensure that events residing the clinical database are consistent with the SAE database

Serious Adverse Event Reconciliation

Other reconciliations

- Lab data
- ECG data
- Radiology reports
- Any other data generated at an outside source
  - EEG
  - Echocardiograpgy
  - Lung function tests