Understanding Coding with MedDRA

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ICH
harmonisation for better health

MedDRA was developed under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Committee, which is composed of the ICH parties, the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the WHO (as Observer).

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Course Overview

- What is MedDRA?
- Gain knowledge of MedDRA's scope, structure, and characteristics
- Medical Device terms in MedDRA
- IMDRF and MedDRA
- Learn about MedDRA Term Selection: Points to Consider document
- Watch a demonstration of a MedDRA browser
- See examples of coding using a MedDRA browser

MedDRA Overview

What is MedDRA?

Med = Medical

D = Dictionary for

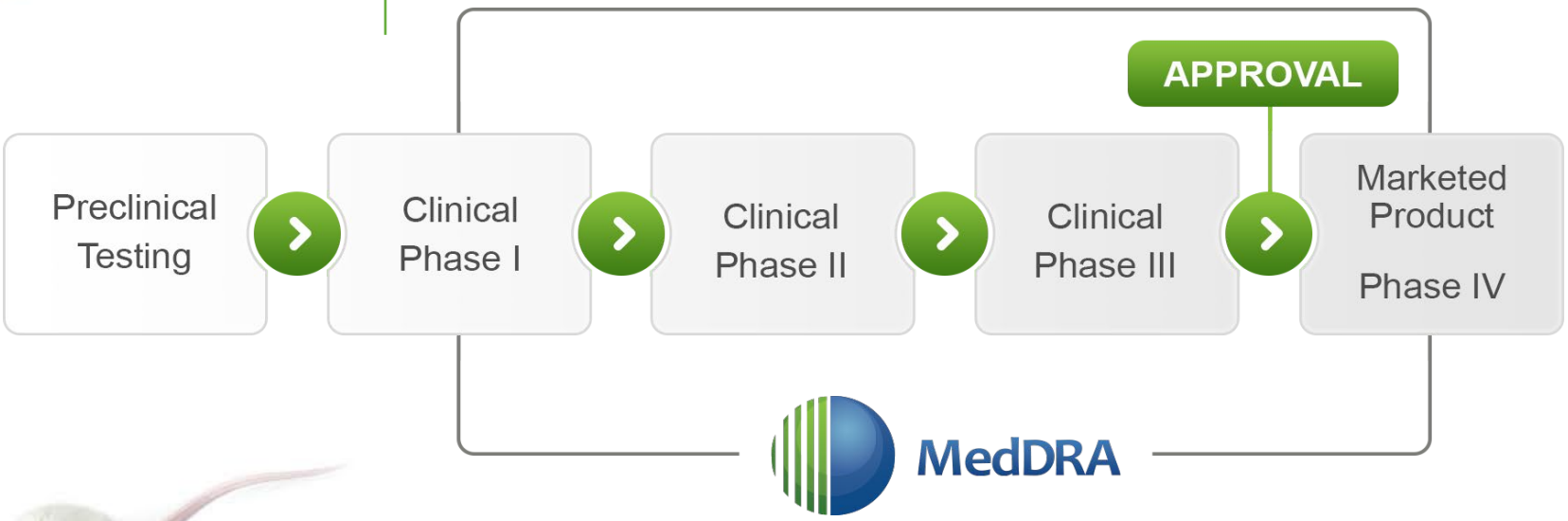
R = Regulatory

A = Activities

MedDRA Definition

MedDRA is a clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation.

Where MedDRA is Used



Regulatory Authority and Industry Databases

Individual Case Safety Reports and Safety Summaries

Clinical Study Reports

Investigators' Brochures

Core Company Safety Information

Marketing Applications

Publications

Prescribing Information

Advertising

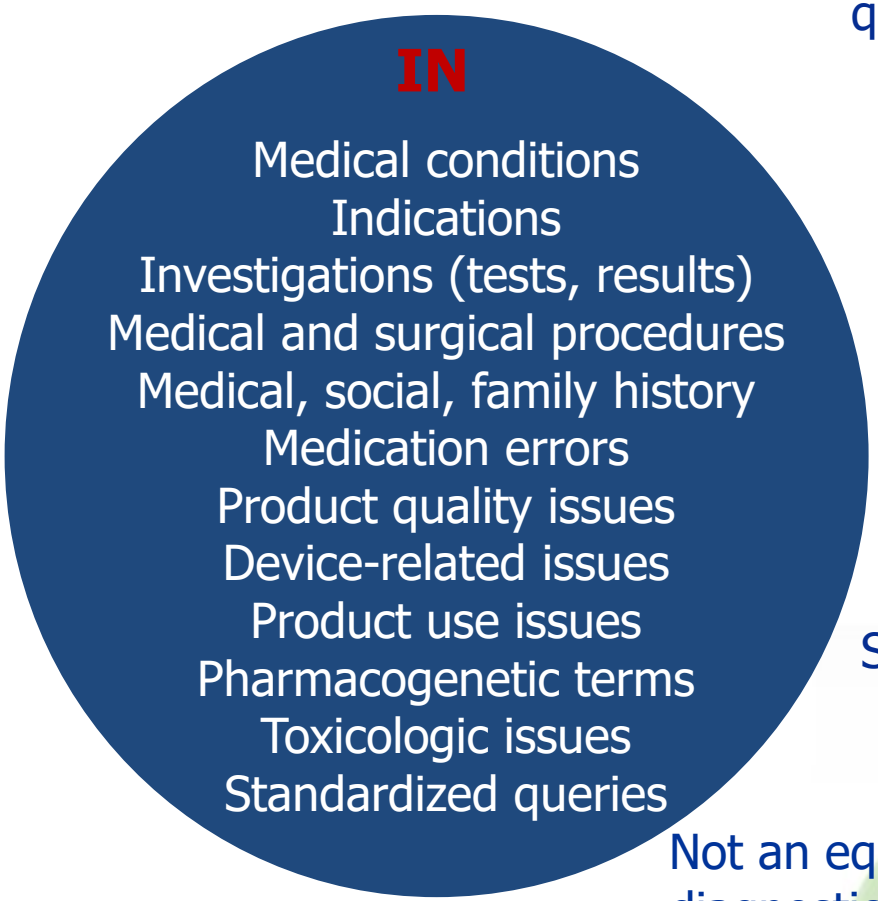
MedDRA's Scope, Structure, and Characteristics

Scope of MedDRA

OUT

Not a drug dictionary

Frequency qualifiers



Patient demographic terms

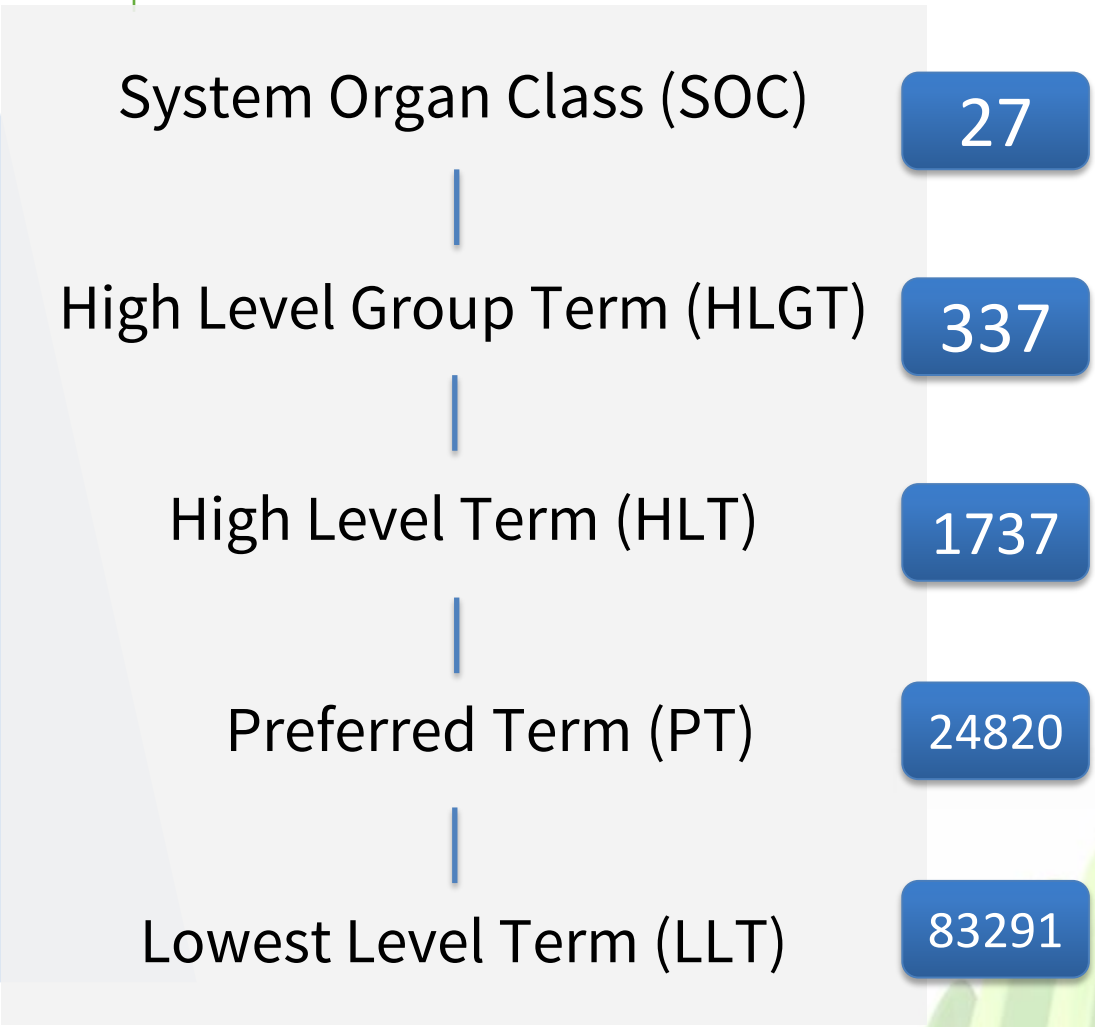
Numerical values for results

Clinical trial study design terms

Severity descriptors

Not an equipment, device, diagnostic product dictionary

MedDRA Structure



System Organ Classes

- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders and administration site conditions
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications
- Investigations
- Metabolism and nutrition disorders
- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Product issues
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
- Vascular disorders

The Five Levels of MedDRA

SOC	Cardiac disorders
HLGT	Cardiac arrhythmias
HLT	Rate and rhythm disorders NEC
PT	Arrhythmia
LLT	LLT Arrhythmia NOS LLT Arrhythmia LLT (Non-current) Other specified cardiac dysrhythmias LLT Dysrhythmias

Note:
Not all HLGTs, HLTs, PTs or LLTs shown

Non-Current Terms

LLT

- Flagged at the LLT level in MedDRA
- Not recommended for continued use
- Retained to preserve historical data for retrieval and analysis
- Terms that are vague, ambiguous, out-dated, truncated, or misspelled
- Terms derived from other terminologies that do not fit MedDRA rules

MedDRA Codes

- Each MedDRA term assigned an 8-digit numeric code starting with "1"
- The code is non-expressive
- Codes can fulfill a data field in various electronic submission types (e.g., E2B)
- New terms are assigned sequentially

Codes and Languages

A Multi-Axial Terminology

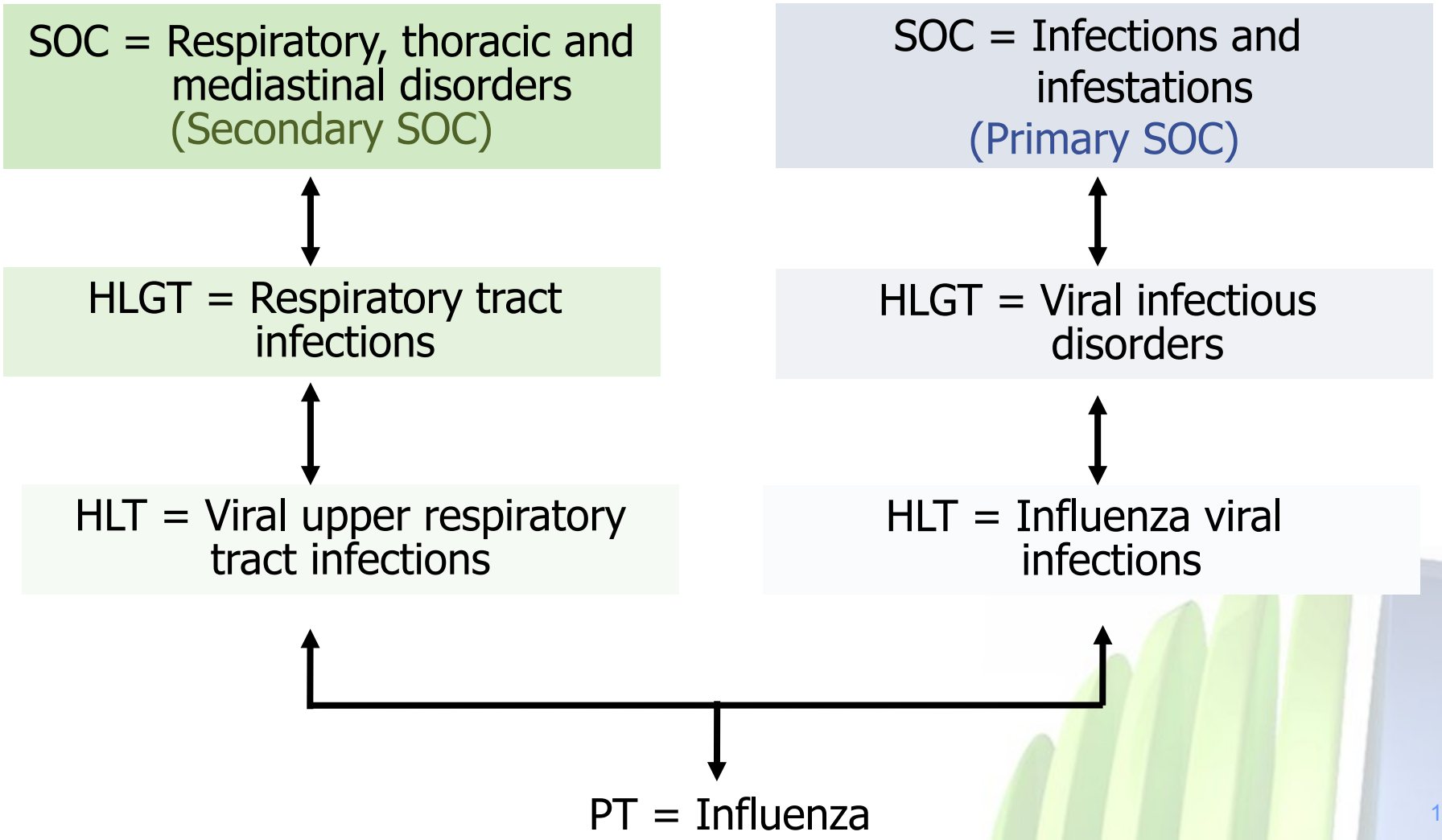
Multi-axial = the representation of a medical concept in multiple SOCs

- ✓ Allows grouping by different classifications
- ✓ Allows retrieval and presentation via different data sets

All PTs assigned a primary SOC

- ✓Determines which SOC will represent a PT during cumulative data outputs
- ✓Prevents "double counting"
- ✓Supports standardized data presentation
- ✓Pre-defined allocations should not be changed by users

A Multi-Axial Terminology (cont)



Rules for Primary SOC Allocation (cont.)

- PTs represented in only one SOC are automatically assigned that SOC as primary

- PTs for diseases, signs and symptoms are assigned to prime manifestation site SOC

- Congenital and hereditary anomalies terms have SOC *Congenital, familial and genetic disorders* as Primary SOC
- Neoplasms terms have SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* as Primary SOC
  - **Exception:** Cysts and polyps have prime manifestation site SOC as Primary SOC
- Infections and infestations terms have SOC *Infections and infestations* as Primary SOC

Primary SOC Priority

If a PT links to more than one of the exceptions, the following priority will be used to determine primary SOC:

Congenital, familial and genetic disorders

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Infections and infestations

A Multi-Axial Terminology (cont)

PTs in the following SOCs **only** appear in that particular SOC and not in others, i.e., they are not multi-axial

- *Investigations*
- *Surgical and medical procedures*
- *Social circumstances*

Can You Select the Primary SOC for This PT?

PT	HLT	HLGT	SOC
Congenital HIV infection	Viral infections congenital	Infections and infestations congenital	Congenital, familial and genetic disorders
	Congenital neonatal infections	Neonatal and perinatal conditions	Pregnancy, puerperium and perinatal conditions
	Retroviral infections	Viral infectious disorders	Infections and infestations
	Acquired immunodeficiency syndromes	Immunodeficiency syndromes	Immune system disorders

Medical Device Terms in MedDRA

Device Terms in MedDRA

- Device specific terms included from the inception of MedDRA
  - Currently over 700 device specific terms in MedDRA
  - Can be found in various SOCs
- The scope of MedDRA encompasses medical, health-related, and regulatory concepts pertaining to medical products for human use and these include the health effects and malfunction of devices
  - e.g., PT *Device related infection* and PT *Device failure*
- Device names/components are out of scope

Device Terms in MedDRA : Important Grouping Levels

- SOC General disorders and administration site conditions
  - HLGT Administration site reactions
  - HLGT Body temperature conditions
  - HLGT Complications associated with device
    - HLT Breast complications associated with device
    - HLT Cardiac complications associated with device
    - HLT Complications associated with device NEC
    - HLT Eye complications associated with device
    - HLT Reproductive complications associated with device
    - HLT Respiratory complications associated with device
    - HLT Vascular complications associated with device

- SOC Product issues
  - HLGT Device issues
    - HLT Device computer issues
    - HLT Device electrical issues
    - HLT Device incompatibility issues
    - HLT Device information output issues
    - HLT Device issues NEC
    - HLT Device malfunction events NEC
    - HLT Device operational issues NEC
    - HLT Device physical property and chemical issues

- SOC Injury, poisoning and procedural complications
  - HLGT Administration site reactions
  - HLGT Bone and joint injuries
  - HLGT Exposures, chemical injuries and poisoning
  - HLGT Injuries by physical agents
  - HLGT Injuries NEC
  - HLGT Medication errors and other product use errors and issues
  - HLGT Off label uses and intentional product misuses/use issues
  - HLGT Overdoses and underdoses NEC
  - HLGT Procedural related injuries and complications NEC
    - HLT Anaesthetic and allied procedural complications
    - HLT Cardiac and vascular procedural complications
    - HLT Device site reactions
      - PT Medical device site abscess
      - PT Medical device site anaesthesia
      - PT Medical device site atrophy
      - PT Medical device site bruise
      - PT Medical device site burn
      - PT Medical device site calcification
      - PT Medical device site cellulitis

- SOC Surgical and medical procedures
  - HLGT Bone and joint therapeutic procedures
  - HLGT Breast therapeutic procedures
  - HLGT Cardiac therapeutic procedures
    - HLT Cardiac device therapeutic procedures
      - PT Artificial heart implant
      - PT Cardiac contractility modulation therapy
      - PT Cardiac device reprogramming
      - PT Cardiac pacemaker adjustment
      - PT Cardiac pacemaker insertion
      - PT Cardiac pacemaker removal
      - PT Cardiac pacemaker replacement
      - PT Cardiac resynchronisation therapy
      - PT Implantable cardiac monitor insertion
      - PT Implantable cardiac monitor removal
      - PT Implantable cardiac monitor replacement

- These are not all device terms though!

MedDRA use in Medical Device

- For Medical Device reporting, MedDRA is not a standard terminology by regulations.
- However, many organizations choose to use MedDRA internally because of its high level of granularity for patient adverse events and device malfunction terms
  - using the broader FDA/IMDRF codes as required by regulatory
- MSSO mapped IMDRF Annex E Patient Problem Codes to MedDRA LLTs (v21.1) in December 2018

Coding with MedDRA

Coding: Term Selection

Verbatim	LLT
Infection in lungs	Lung infection
Throbbing above temple Aching all over head Pulsing pain in head Really bad headache	Headache
Muscular pain in legs	Myalgia of lower extremities
Patient took Drug A instead of Drug B and experienced hypertension	Wrong drug administered Hypertension

What are Coding Conventions?

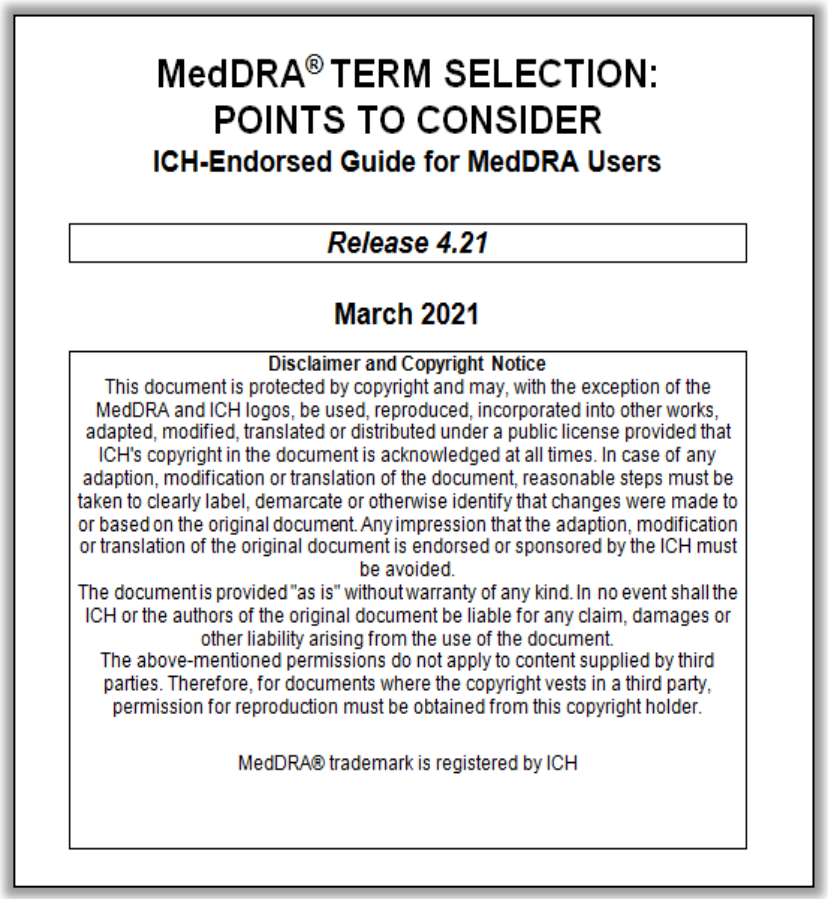
- Written guidelines for coding with MedDRA in your organization
- Support accuracy and consistency
- Common topics
  - Misspellings, abbreviations and acronyms
  - Combination terms and "due to" concepts
  - "Always query" terms, e.g., "Chest pain"

Why Do We Need Coding Conventions?

- Differences in medical aptitude of coders
- Consistency concerns (many more "choices" to manually code terms in MedDRA compared to older terminologies)
- Even with an autoencoder, may still need manual coding

MedDRA Term Selection: Points to Consider Document

MedDRA Term Selection: Points to Consider (MTS:PTC)



MedDRA® TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Release 4.21

March 2021

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- Provides term selection advice for industry and regulatory purposes
- Objective is to promote accurate and consistent term selection to facilitate a common understanding of shared data
- Recommended to be used as basis for individual organization's own coding conventions

MedDRA Term Selection: PTC (cont)

- Developed by a working group of the ICH Management Committee
- Updated annually in step with the March release of MedDRA
- Complete versions available in English, Japanese, Chinese, Korean, and Spanish
- Condensed versions available for other MedDRA languages
- Available on MedDRA and JMO websites

General Term Selection Principles

- Quality of Source Data
- Quality Assurance
- Do Not Alter MedDRA
- Always Select a Lowest Level Term
- Select Only Current Lowest Level Terms
- When to Request a Term
- Use of Medical Judgment in Term Selection
- Select Terms for All Reported Information, Do Not Add Information

Quality of Source Data Quality Assurance

- Quality of original information impacts quality of output
- Obtain clarification of data
- Can be optimized by careful design of data collection forms and proper training of staff
- Organizations' coding guidelines should be consistent with MTS:PTC
- Review of term selection by qualified individuals
- Human oversight of automated coding results

Do Not Alter MedDRA

- MedDRA is a standardized terminology with a pre-defined term hierarchy
- Users must not make *ad hoc* structural alterations, including changing the primary SOC allocation
- If terms are incorrectly placed, submit a change request to the MSSO

Always Select a Lowest Level Term
Select Only Current LLTs

- Lowest Level Term that most accurately reflects the reported verbatim information should be selected
- Degree of specificity may be challenging
  - Example: "*Abscess on face*" → select "*Facial abscess*," not simply "*Abscess*"
- Select current LLTs only
  - Non-current terms for legacy conversion/historical purposes

When to Request a Term Use of Medical Judgment

- Avoid company-specific "work-arounds" for MedDRA deficiencies. If concept not adequately represented in MedDRA, submit Change Request to MSSO.
- If no exact match in MedDRA, use medical judgment to match to an existing term that adequately represents the concept

Select Terms for All Reported Information

- Select terms for every AR/AE reported, regardless of causal association
- Select terms for device-related events, product quality issues, medication errors, medical and social history, investigations and indications as appropriate

Do Not Add Information

- Do not make diagnosis if only signs/symptoms reported

Reported	LLT Selected	Comment
Abdominal pain, increased serum amylase, and increased serum lipase	Abdominal pain	It is inappropriate to assign an LLT for diagnosis of "pancreatitis"
	Serum amylase increased	
	Lipase increased	

MedDRA Browser Demonstration

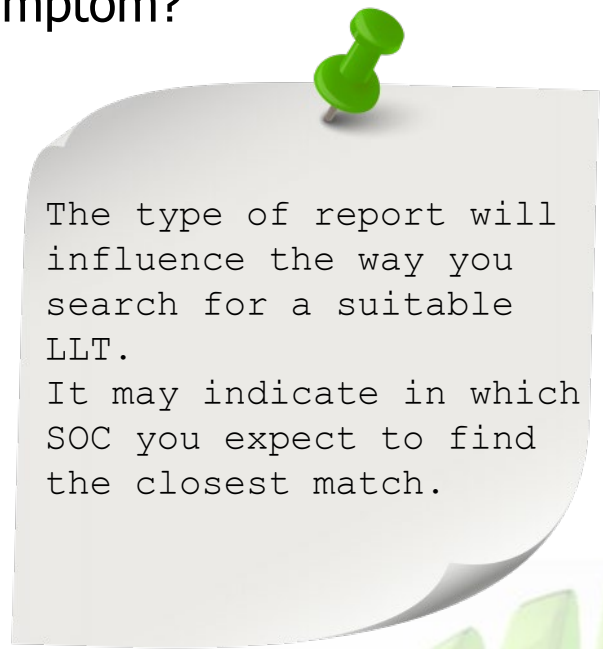
https://tools.meddra.org/wbb/

Approaches to Finding the Best LLT

Assessing the Reported Information

- Consider what is being reported. Is it a:
  - Clinical condition - Diagnosis, sign or symptom?
  - Indication?
  - Test result?
  - Injury?
  - Procedure?
  - Medication error?
  - Product use issue?
  - Product quality issue?
  - Social circumstance?
  - Device issue?
  - Procedural complication?

  - **Is it a combination of these?**



Coding Example 1

Specificity

The patient suffered from an allergic reaction to an antibiotic

Coding Example 2

Symptoms

The patient states she has been experiencing cold sweats

Coding Example 3

Medication errors/Product use errors and issues

The pharmacist made a mistake in compounding the medication

Summary

In this course, we:

- Discussed the scope, structure, and characteristics of MedDRA
- Introduced the MedDRA Term Selection: Points to Consider document
- Discussed need for coding conventions when using MedDRA
- Introduced the MedDRA browser and showed how it is used for coding

MedDRA Coding Practices – CASE STUDY

- Please read through the scenario & Hint to find the right LLTs using the MedDRA Web-based browser.
- It is helpful to first underline the information to be coded.

  – CASE 1,2 : Short verbatim
  – CASE 3,4 : Narrative vignette
  – CASE 5,6 : Narrative vignette - Multiple choice questions

MedDRA | Medical Dictionary for Regulatory Activities

Thank you!

✉ mssohelp@meddra.org

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