



MedDRA Coding Basics



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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 Steering Committee. The MedDRA SC is composed of the EC, Europe; EFPIA; FDA, United States; Health Canada, Canada; JPMA; MHLW/PMDA, Japan; MHRA UK; PhRMA; and WHO (as Observer). In addition, since May 2025, the following representatives have been appointed by the ICH MC to join the MedDRA SC and will serve until the next appointment in 2028: NMPA, China; SFDA, Saudi Arabia; and IFPMA (as Observer).

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MedDRA

Course Overview

- Gain knowledge of MedDRA's scope, structure, and characteristics
- Discuss coding conventions
- Learn about the MedDRA Term Selection: Points to Consider (MTS:PTC) document
- Learn about MedDRA browsers
- Watch a demonstration of coding with browser
- Use browser to code with MedDRA
- Conclude with question and answer session

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MedDRA Overview




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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.



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Where MedDRA is Used





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- Regulatory Authority and Industry Databases
- ICSRs and Safety Summaries
- Clinical Study Reports
- Investigators' Brochures
- Core Company Safety Information
- Marketing Applications
- Publications
- Prescribing Information
- Advertising

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Scope of MedDRA

OUT

- Not a drug dictionary
- Patient demographic terms
- Clinical trial/study design terms
- Frequency qualifiers

IN

- Medical conditions
- Indications
- Investigations (tests, results)
- Medical and surgical procedures
- Medical, social, family history
- Pharmacogenetic terms
- Medication errors
- Product quality issues
- Device-related issues
- Product use issues
- Toxicologic issues
- Standardized queries

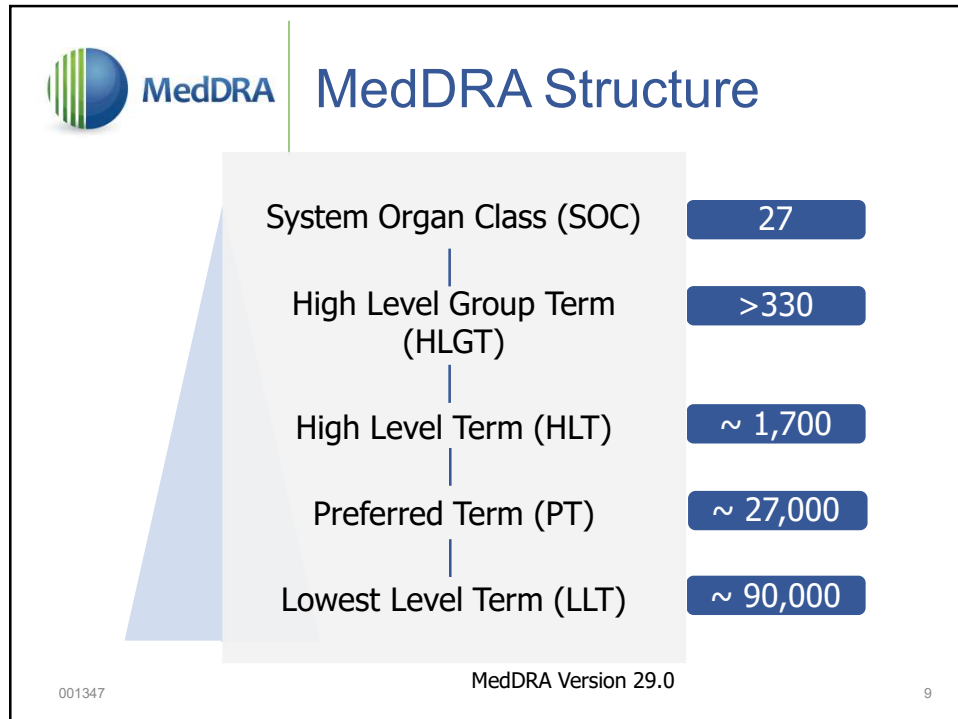
OUT

- Numerical values for results
- Severity descriptors
- Not an equipment, device, diagnostic product dictionary

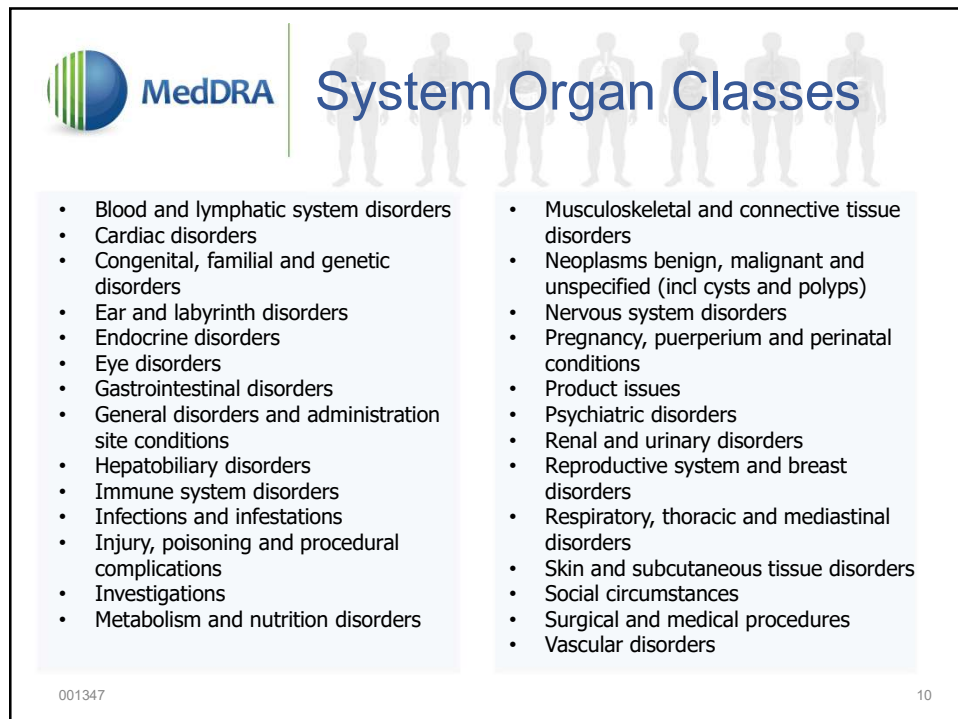
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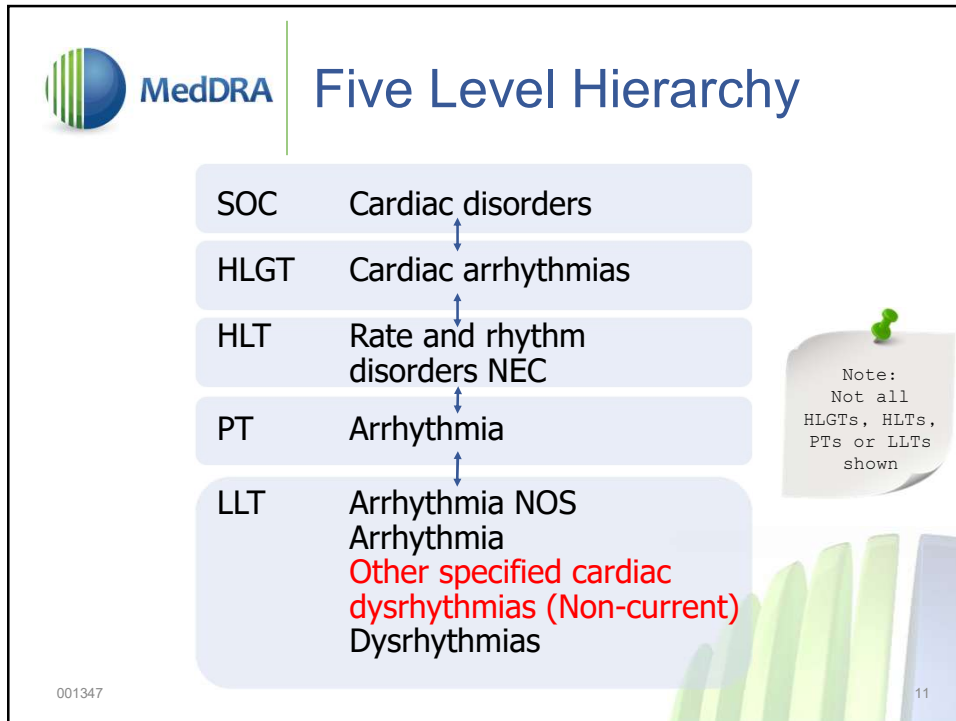
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MedDRA Non-Current Terms LLT

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

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MedDRA Codes


PT *Anaemia*

[10002034]

- Each MedDRA term is assigned an 8-digit numeric code
 - Non-expressive, assigned sequentially
 - Each term has a unique code
 - Codes link terms across versions and translations
- Codes can fulfill a data field in various electronic submission types (e.g., E2B (R3))

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A Multi-Axial Terminology

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

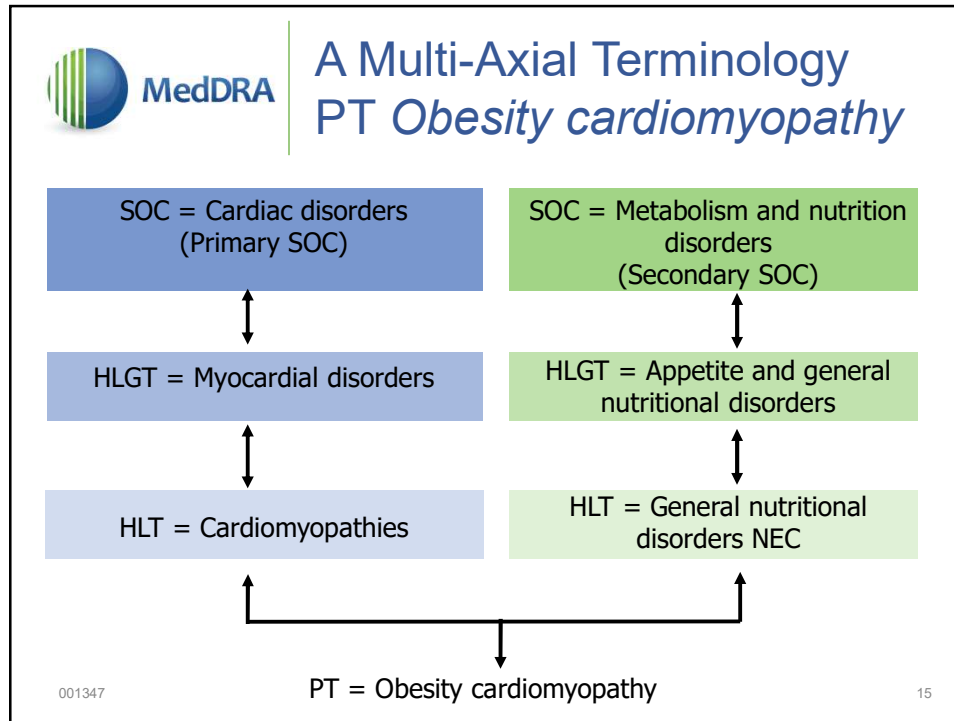
- ✓ Allows grouping by different classifications
- ✓ Allows retrieval and presentation via different data sets

All PTs assigned a primary SOC

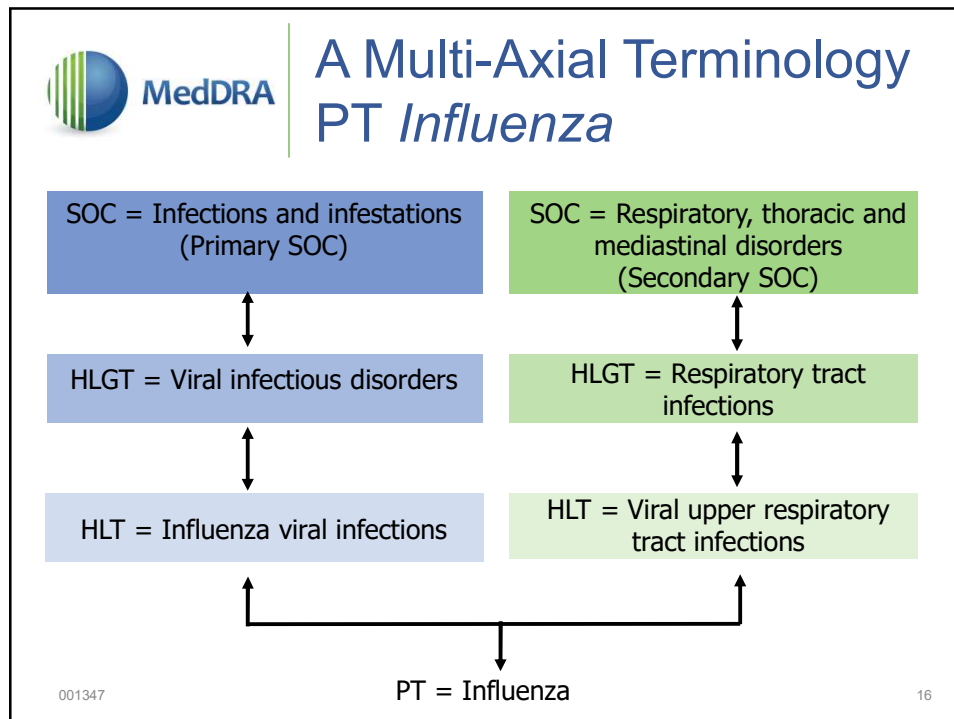
- ✓ Determines which SOC will represent a PT during cumulative data outputs
- ✓ Prevents “double counting”
- ✓ Supports standardized data presentation
- ✓ Pre-defined allocations should not be changed by users

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Rules for Primary SOC Allocation

- 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




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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*

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Non Multi-axial SOC's

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

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

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Coding Conventions

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Quality coding considerations

- Processes
 - Make sure that all relevant information is available for term selection
 - Coding conventions
- Appropriately trained and qualified individuals
- Tools
 - Autoencoding tools
 - Synonym lists
 - Quality assurance reports
 - Unqualified test name term list

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What are Coding Conventions?

- Written guides and sets of principles for using MedDRA that help achieve consistency in coding and data retrieval
- Conventions harmonize exchange of MedDRA coded data worldwide
- Common topics
 - Misspellings, abbreviations and acronyms
 - Combination terms and “due to” concepts
 - “Always query” terms, e.g., “Chest pain”

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Why Do We Need Coding Conventions?

- Differences in medical aptitude of coders
- Consistency concerns (many more “choices” in MedDRA versus older terminologies)
- Autoencoded data need human oversight and may still need manual coding



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Autoencoder Pitfalls

- Inappropriate terms may be selected by autoencoder
 - Review all autoencoding carefully
 - “Allergic to CAT scan” autoencoded as:
LLT *Allergic to cats*
 - “Myocardial infarction in the fall of 2000” autoencoded as:
LLT *Myocardial infarction*
LLT *Fall*
- Autoencoded data needs human oversight

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

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

**MedDRA® TERM SELECTION:
POINTS TO CONSIDER**
ICH-Endorsed Guide for MedDRA Users

Release X.XX

Month Year

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

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MedDRA Term Selection: PTC (cont)


- Developed by a working group of the ICH Management Committee
- Released annually in March
- Complete versions available in
 - English, Japanese, Brazilian Portuguese, Chinese, French, Korean, Spanish, and Russian
- Condensed versions available for other MedDRA languages*
- Available on MedDRA and JMO websites



*Arabic, Czech, Dutch, German, Hungarian, Italian, Portuguese

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MTS:PTC Points of Note

- MTS:PTC sometimes provides more than one option for selecting terms
 - “Preferred option” is identified
- MedDRA users can decide which option to apply
 - Organizations should be consistent with their choice of option
 - Organizations should document their decision on an option in coding conventions

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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

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Quality of Source Data

- 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

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Quality Assurance

- Organizations' coding guidelines should be consistent with MTS:PTC
- Processes ensuring that all relevant information is available during term selection
- Review of term selection by qualified individuals
- Human oversight of automated coding results

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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

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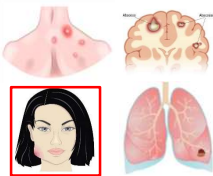


MTS:PTC General Principle

- Always Select a Lowest Level Term
Select Only Current LLTs

✓ Select the Lowest Level Term that **most accurately reflects the reported verbatim** information


"Abscess on face"
 → Do not simply select LLT *Abscess*
 → Select a term with greater specificity
LLT *Facial abscess*



✓ Select current LLTs only
 – Non-current terms for legacy conversion/historical purposes

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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

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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

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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	

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MedDRA Term Selection Points

Section 3

- Diagnoses and Provisional Diagnoses with or without Signs and Symptoms
- Death and Other Patient Outcomes
- Suicide and Self-Harm
- Conflicting/Ambiguous/Vague Information
- Combination Terms
- Age vs. Event Specificity
- Body Site vs. Event Specificity
- Location-Specific vs. Microorganism-Specific Infection
- Modification of Pre-existing Conditions
- Exposures During Pregnancy and Breast Feeding
- Congenital Terms
- Neoplasms
- Medical and Surgical Procedures
- Investigations

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MedDRA Term Selection Points

Section 3


- Medication Errors, Accidental Exposures and Occupational Exposures
- Misuse, Abuse and Addiction
- Transmission of Infectious Agent via Product
- Overdose, Toxicity and Poisoning
- Device-related Terms
- Drug Interactions
- No Adverse Effect and "Normal" Terms
- Unexpected Therapeutic Effect
- Modification of Effect
- Social Circumstances
- Medical and Social History
- Indication for Product Use
- Off Label Use
- Product Quality Issues

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Introduction to MedDRA Browsers




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MSSO's MedDRA Browsers



MedDRA Desktop Browser (MDB)
Download MDB and release files from MedDRA website


MedDRA Web-Based Browsers (WBB)
New WBB:
<https://wbb.meddra.org>
Legacy WBB:
<https://tools.meddra.org/wbb/>



Mobile MedDRA Browser
<https://mmb.meddra.org>



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MSSO's MedDRA Browsers - Features

- Each require MedDRA ID and password
- View/search MedDRA and SMQs
- Support for all MedDRA languages
- Language specific interface
- Ability to export search results and Research Bin to local file system (MDB and WBB only)

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MDB and WBB Special Features

- View primary and secondary link information
- Upload terms to run against SMQs
- Advanced search options (e.g., NOT, OR)
- Preview upcoming (supplemental) changes in next release*
- For more information:
 - Instructional videos:
<https://www.meddra.org/instructional-videos>

**Supplemental view not available on MDB*


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MedDRA Browser Demonstration



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Approach to Finding Best LLTs



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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?**



The type of report will influence the way you search for a suitable LLT. It may indicate in which SOC you expect to find the closest match.

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Coding Example 1 Specificity

The patient suffered from an allergic reaction to an antibiotic



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Coding Example 2 Symptoms

The patient states she has been experiencing cold
sweats



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Coding Example 3 Investigations

Lab results indicate the patient has increased troponin
and increased CPK-MB



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Coding Example 4 Medication errors

Patient accidentally took drug Y instead of drug X and became short of breath



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Coding Example 5 Patient demographics

A 2-day old **baby** was noted to have a mild fever



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Coding Example 6 Indications

A 35 year old woman was taking Drug X to prevent relapses of multiple sclerosis



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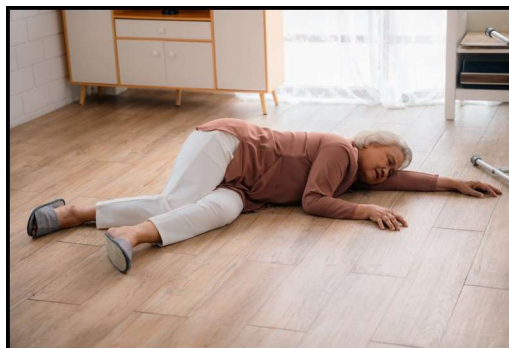
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Coding Example 7 Specificity

She had a pathologic fracture of the neck of the left femur



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Coding Example 8 Specificity

Following the **procedure**, the patient experienced several days of **constipation**



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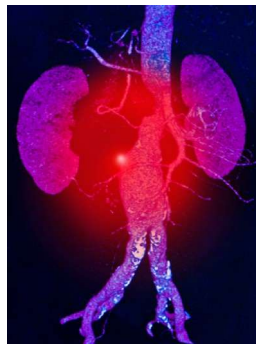
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Coding Example 9 Death and Other Patient Outcomes

The 66-year-old man **died** from a **ruptured aortic aneurysm**



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Coding Example 10 Product quality issues

It was determined that the product was counterfeit.



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Coding Example 11 Social circumstances

The patient was confined to a wheelchair



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Coding Example 12 Medication Errors/Product Use Errors and Issues

The pharmacist made a mistake in compounding the medication



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Coding Example 13 Narrative vignette

A 75-year-old male receiving Drug X for rheumatoid arthritis developed symptomatic aortic valve stenosis. The patient's medical history is significant for colon cancer and cigarette smoking. He underwent an aortic valve replacement and developed a sternal wound infection three days post-surgery.

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Additional Coding Exercises

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Try to Code Some Verbatims

- Open either the Desktop or Web-Based Browser
- Try to find the best LLT to code several short verbatims
- Select an LLT from MedDRA using either a "top down" or "bottom up" approach
- Correct LLTs for each verbatim will be discussed

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Short Verbatim #1

"She was diagnosed with pneumonia caused by COVID-19 infection"



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Short Verbatim #2

"Woman ingested her husband's blood pressure drug by mistake"



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Short Verbatim #3

“The patient developed hyponatraemia while hospitalised”



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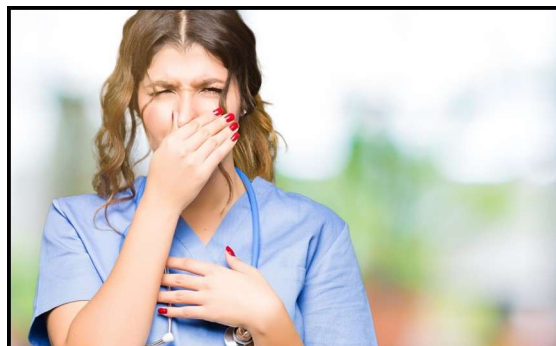
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Short Verbatim #4

“Nurse noticed that the injection solution had an unusual odor”



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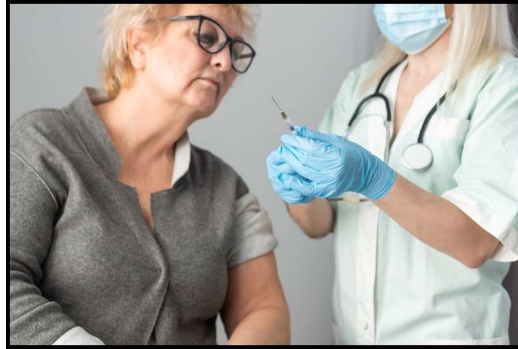
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Short Verbatim #5

"Elderly woman complained her arm was tender where she had received her seasonal flu vaccine"



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Summary

- ✓ Discussed scope, structure, and characteristics of MedDRA
- ✓ Discussed coding conventions
- ✓ Introduced the MedDRA Term Selection: Points to Consider document
- ✓ Introduced the MedDRA browser and showed how it is used for coding
- ✓ Performed some coding exercises on your own

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MSSO Contacts

- Website
 - www.meddra.org
- Email
 - mssohelp@meddra.org
- Frequently Asked Questions
 - www.meddra.org/faq

MedDRA Browsers

- Desktop –
 - <https://www.meddra.org/meddra-desktop-browsers>
- Web-Based
 - New WBB: <https://wbb.meddra.org>
 - Legacy WBB: <https://tools.meddra.org/wbb/>
- Mobile
 - <https://mmb.meddra.org>

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MSSO Contacts (cont)

- Change Request Submission
 - <https://www.meddra.org/how-to-use/change-requests>
- Training Schedule
 - <https://www.meddra.org/training/schedule>
- MedDRA Support Documentation
 - <https://www.meddra.org/how-to-use/support-documentation>


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Question and Answer Session



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MedDRA | Medical Dictionary
for Regulatory Activities

Thank you!



ICH
harmonisation for better health

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