



MedDRA Coding Basics



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 six ICH parties (EU, EFPIA, MHLW, JPMA, FDA, PhRMA), the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the WHO (as Observer).



MedDRA

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Course Overview

- Gain knowledge of MedDRA's scope, structure, and characteristics
- Learn about the MedDRA Term Selection: Points to Consider document
- Learn about the available MedDRA browsers
- Watch a demonstration of a MedDRA browser
- See examples of coding using a MedDRA browser
- Conclude with a 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



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

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Scope of MedDRA

Not a drug dictionary

Patient demographic terms

Clinical trial study design terms

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

Frequency qualifiers

Numerical values for results

Severity descriptors

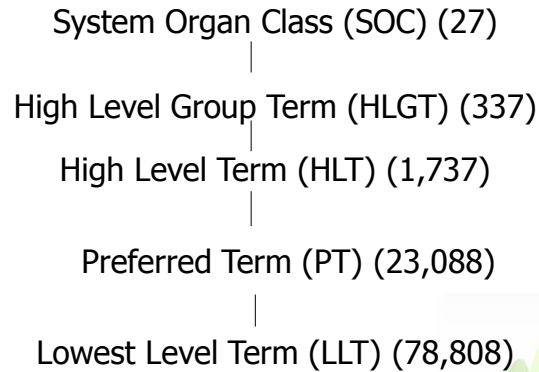
Not an equipment, device, diagnostic product dictionary

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MedDRA

MedDRA Structure



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MedDRA Version 21.0

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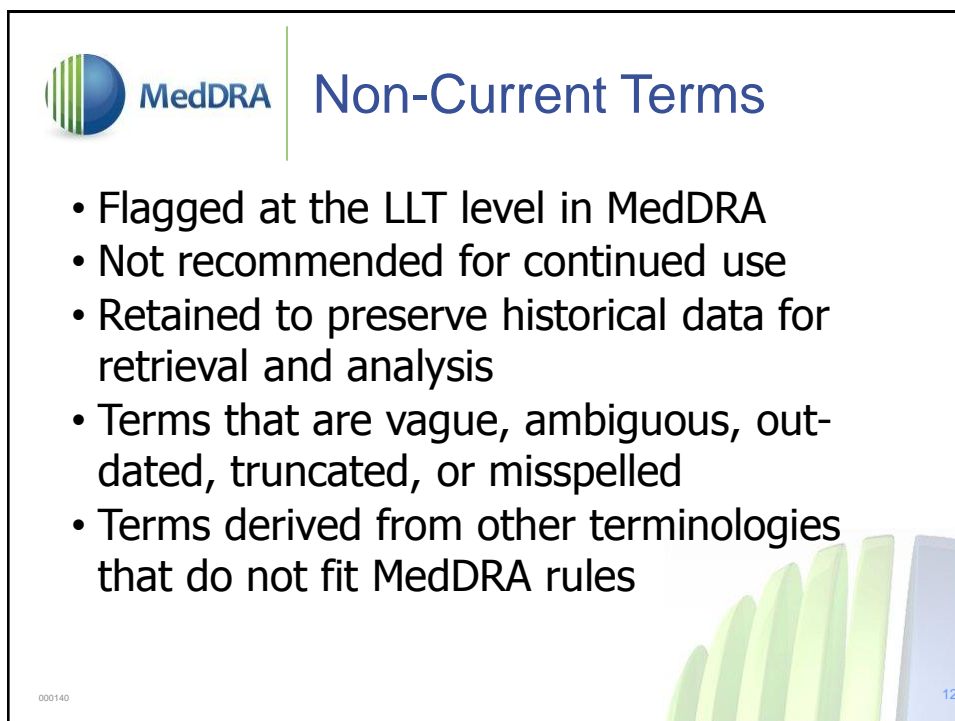
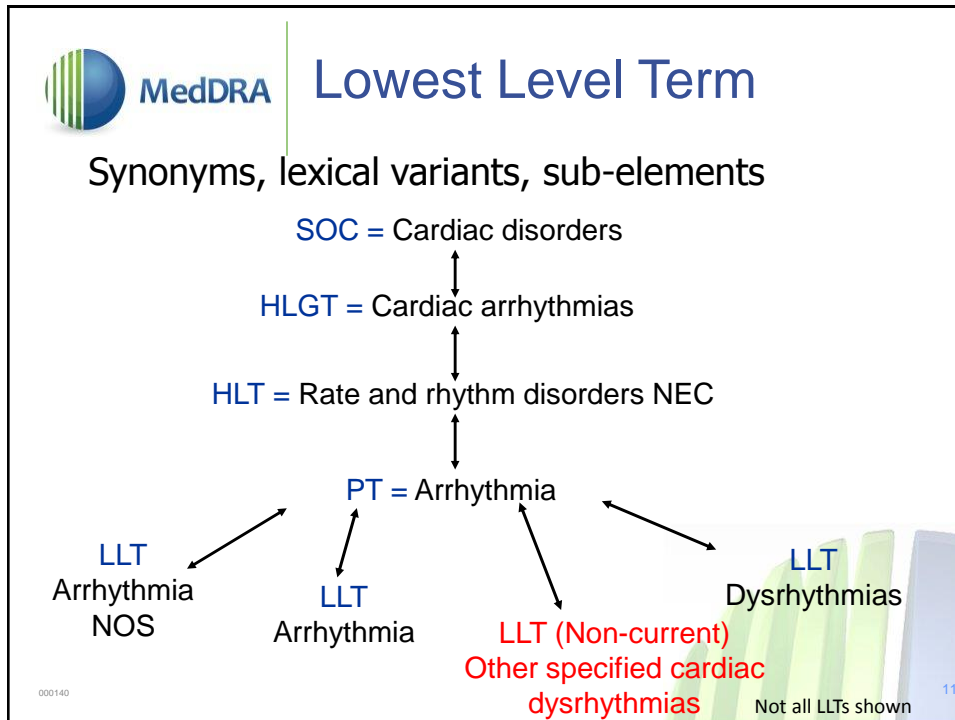
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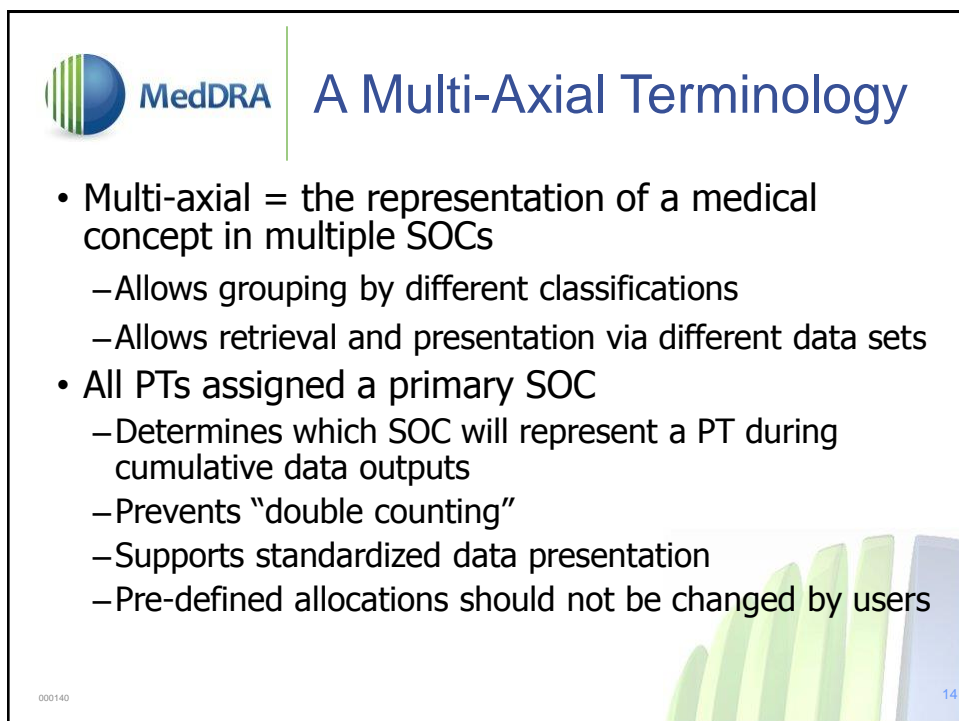
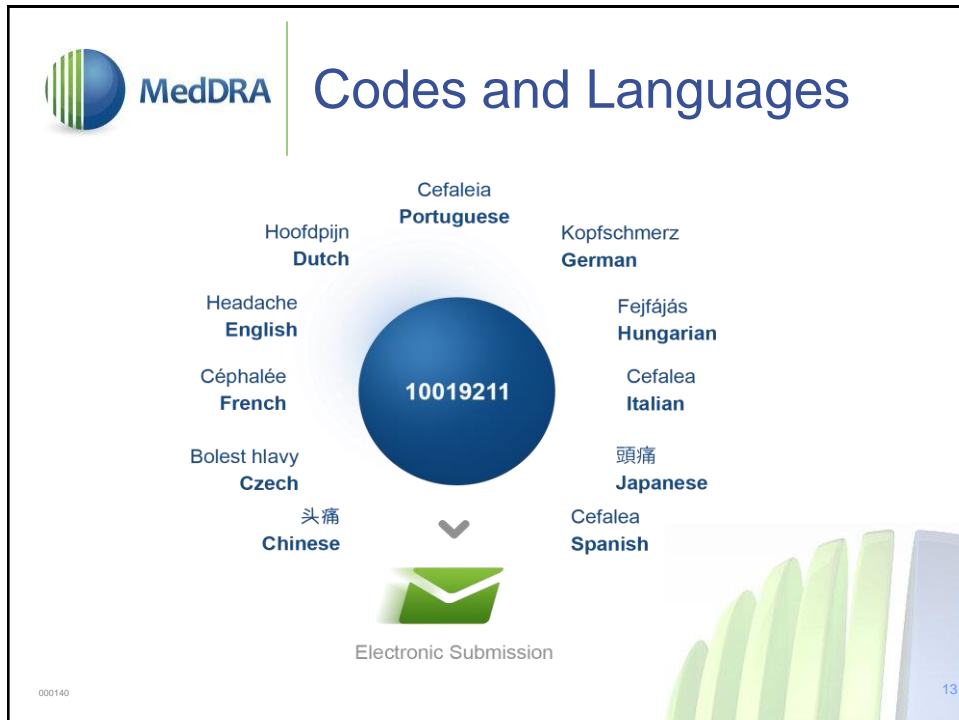
System Organ Classes

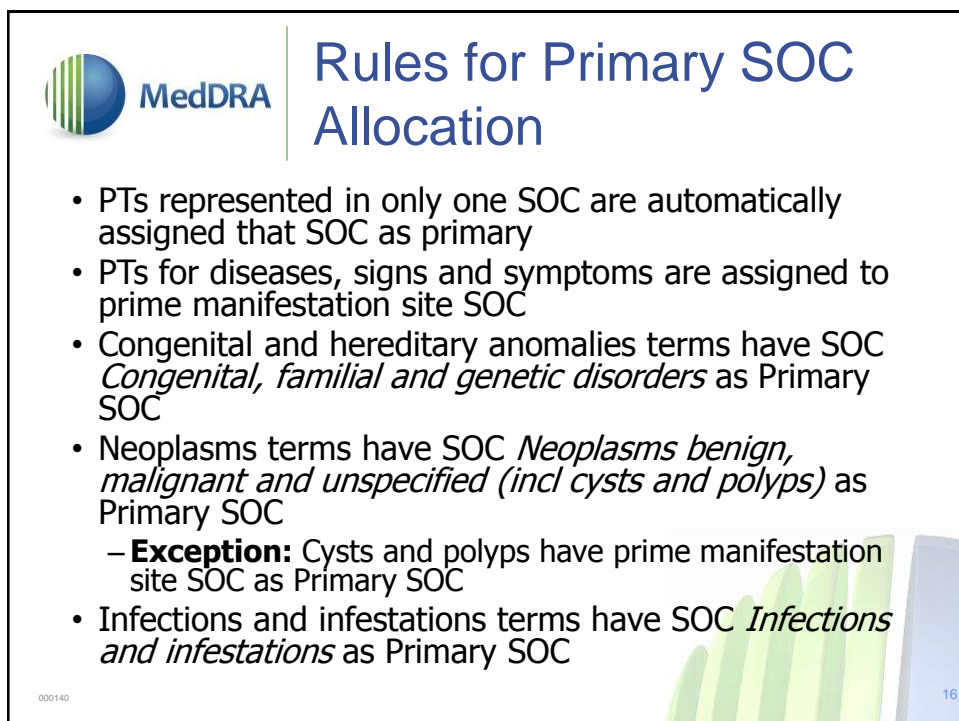
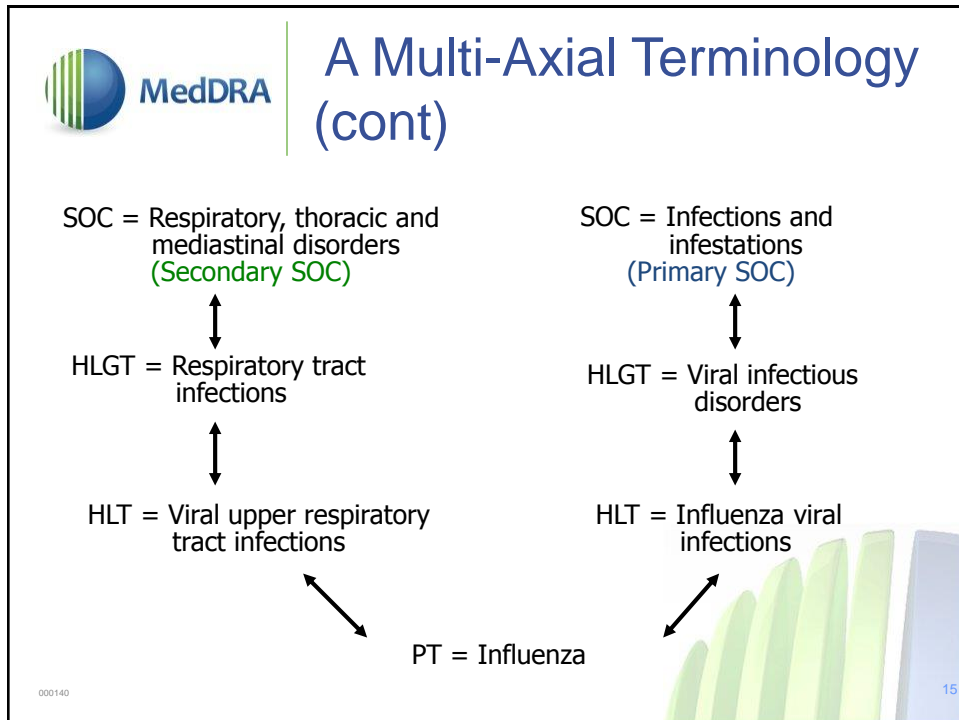
- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders and administration site conditions
- Hepatobiliary disorders
- Immune system disorders
- 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

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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:

- 1st: Congenital, familial and genetic disorders*
- 2nd: Neoplasms benign, malignant and unspecified (incl cysts and polyps)*
- 3rd: Infections and infestations*

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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*

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MedDRA Term Selection: Points to Consider Document

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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"
- Should be consistent with the MedDRA Term Selection: Points to Consider document

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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

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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 4.15

Based on MedDRA Version 21.0

1 March 2018

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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



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MedDRA Term Selection: PTC (cont)

- Developed by a working group of the ICH Management Committee
- Updated twice yearly with each MedDRA release
- Available on MedDRA and JMO websites
 - English and Japanese
 - Word (“clean” and “redlined”), PDF, HTML formats
 - “Redlined” document identifies changes made from previous to current release of document

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ICH M1 Points to Consider Working Group (PtC WG)



- Regulators and industry from EU, US, and Japan
- Health Canada
- MSSO
- JMO
- WHO (Observer)

New members 2017/2018

- MFDS, Republic of Korea
- ANVISA, Brazil
- CFDA, China

Meeting 13-15 November 2017, Geneva, Switzerland

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MTS:PTC Points of Note

- In some cases with more than one option for selecting terms, a “preferred option” is identified but this does not limit MedDRA users to applying that option. Organizations should be consistent in their choice of option.
- Section 4.1 – Versioning (Appendix)
 - 4.1.1 Versioning methodologies
 - 4.1.2 Timing of version implementation

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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
- Selecting More than One Term
- Check the Hierarchy
- Select Terms for All Reported Information, Do Not Add Information

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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

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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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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

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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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Selecting More than One Term Check the Hierarchy

- Can select more than one LLT to represent reported information. Document procedures.
 - Selecting one term may lead to loss of specificity
 - Selecting more than one term may lead to redundant counts
- Check the hierarchy above a selected LLT (PT, HLT, HLGT, SOC) to ensure placement accurately reflects meaning of reported term

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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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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*

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Term Selection Points

- 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 Information
- Modification of Pre-existing Conditions
- Exposures During Pregnancy and Breast Feeding
- Congenital Terms
- Neoplasms
- Medical and Surgical Procedures
- Investigations

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Term Selection Points (cont)

- 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 the 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 Browser (WBB)
 - <https://tools.meddra.org/wbb/>
- Features
 - Both 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

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MedDRA Browser Demonstration

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Approaches to Finding the Best LLT

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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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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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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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Summary

In this course, we:

- Reviewed the scope, structure, and characteristics of MedDRA
- Were introduced to the MedDRA Term Selection: Points to Consider document and some of its specific principles
- Were introduced to the MedDRA browsers and saw some examples of how a browser is used for coding

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MSSO Contacts

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

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Question and Answer Session

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