MedDRA Coding Basics

ICH
harmonisation for better health

MedDRA

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

MedDRA

- Gain knowledge of MedDRA's scope, structure, and characteristics
- Learn about MedDRA Term Selection: Points to Consider document
- Discuss need for coding conventions when using MedDRA
- Learn about the available MedDRA browsers
- Watch a demonstration of a MedDRA browser
- See examples of coding using a MedDRA browser
- Use Poll Everywhere application to allow you to try to do some coding with MedDRA
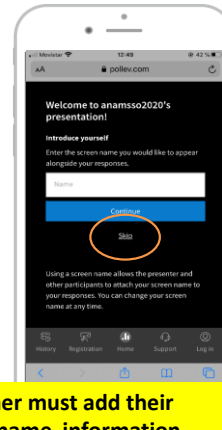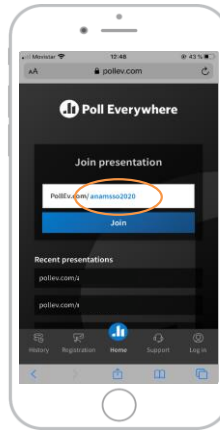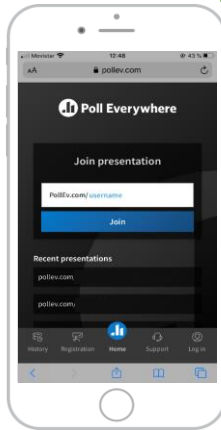- Conclude with a question and answer session

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Slide 5

MedDRA | Get ready to participate !

Trainer must add their username information

1. Open an internet browser on your computer or cell phone
2. Go to **PollEv.com**
3. Enter **xxxxxxxx** as the "username"
4. Click **Join**
5. Click **Skip**
6. Respond to activity

Slide 6

MedDRA

MedDRA Overview

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.
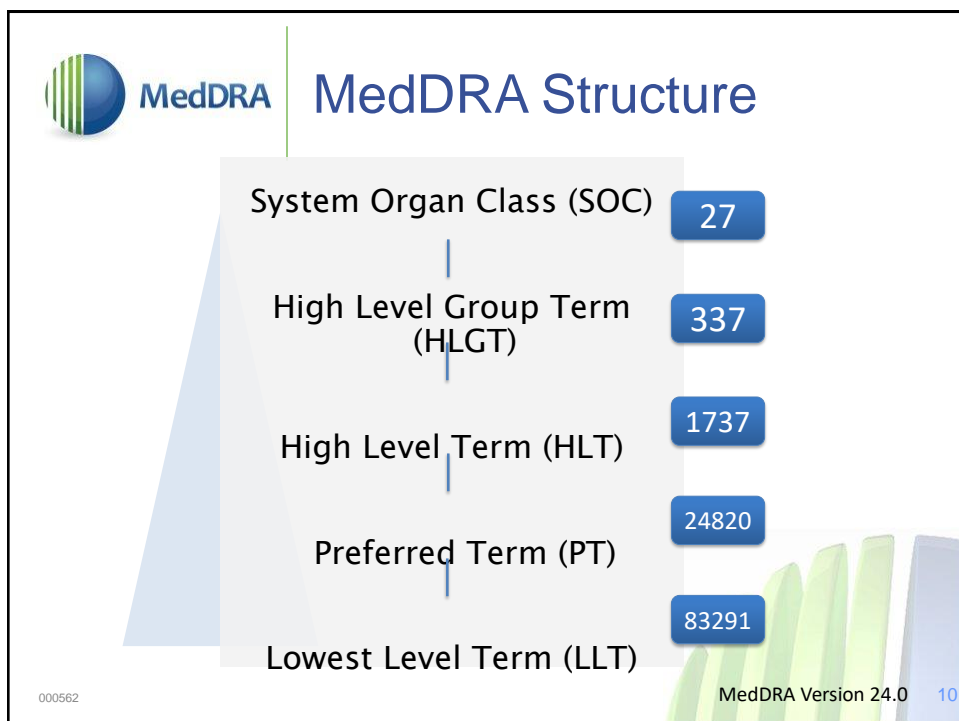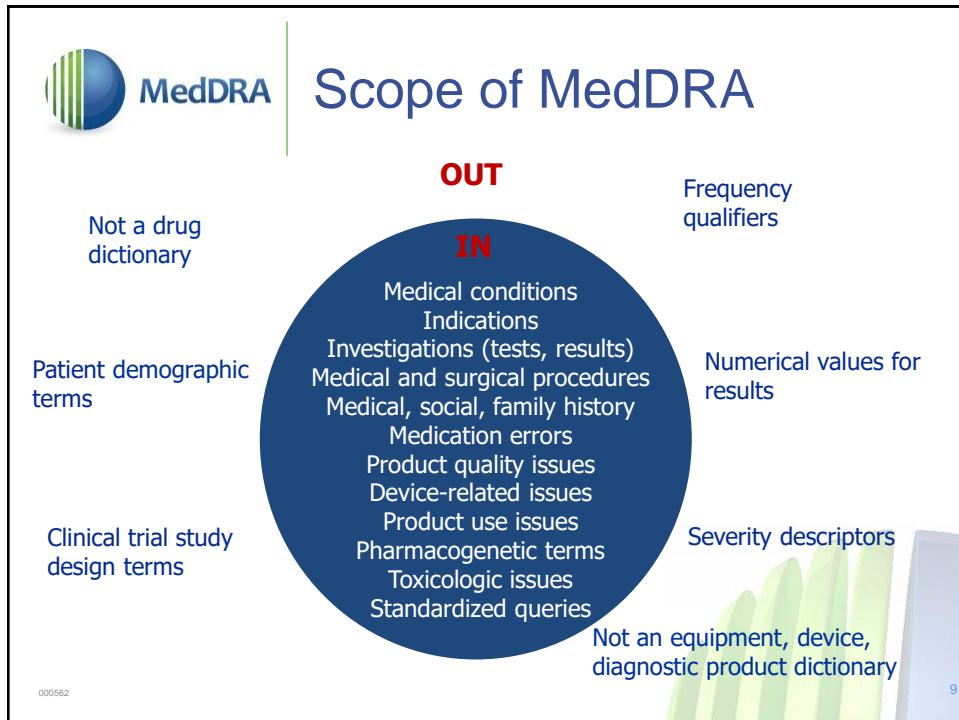
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Where MedDRA is Used

Preclinical Testing	Clinical Phase I	Clinical Phase II	Clinical Phase III	Marketed Product Phase IV

APPROVAL

MedDRA

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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4

Scope of MedDRA

OUT

Frequency qualifiers

Not a drug dictionary

IN

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

Patient demographic terms

Numerical values for results

Clinical trial study design terms

Severity descriptors

Not an equipment, device, diagnostic product dictionary

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MedDRA Structure

System Organ Class (SOC)	27
High Level Group Term (HLGT)	337
High Level Term (HLT)	1737
Preferred Term (PT)	24820
Lowest Level Term (LLT)	83291

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MedDRA Version 24.0   10

System Organ Classes

MedDRA

- 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
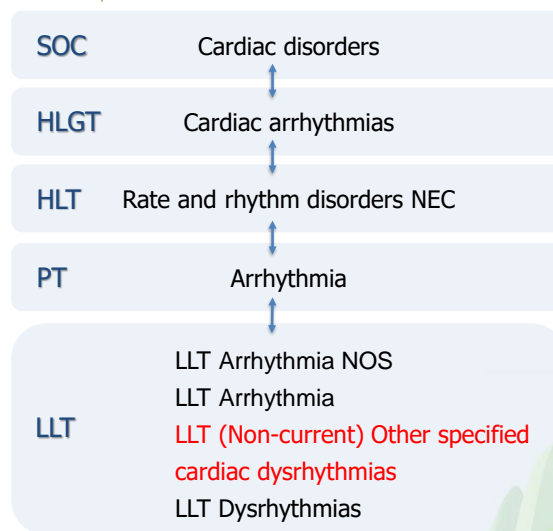- Vascular disorders

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The Five Levels of MedDRA

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

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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
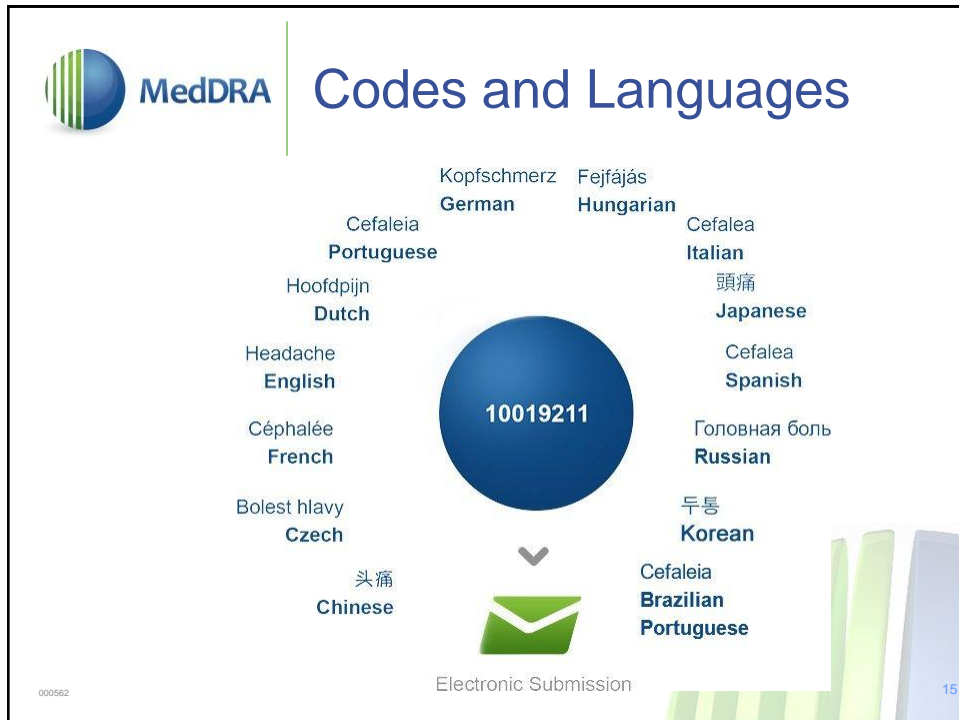
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MedDRA Codes

- 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

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Codes and Languages

Kopfschmerz — **German**
Fejfájás — **Hungarian**
Cefaleia — **Portuguese**
Cefalea — **Italian**
Hoofdpijn — **Dutch**
頭痛 — **Japanese**
Headache — **English**
Cefalea — **Spanish**
10019211
Céphalée — **French**
Головная боль — **Russian**
Bolest hlavy — **Czech**
두통 — **Korean**
头痛 — **Chinese**
Cefaleia — **Brazilian Portuguese**

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Electronic Submission
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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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A Multi-Axial Terminology (cont)

MedDRA

SOC = Respiratory, thoracic and mediastinal disorders (Secondary SOC)

SOC = Infections and infestations (Primary SOC)

HLGT = Respiratory tract infections

HLGT = Viral infectious disorders

HLT = Viral upper respiratory tract infections

HLT = Influenza viral infections

PT = Influenza

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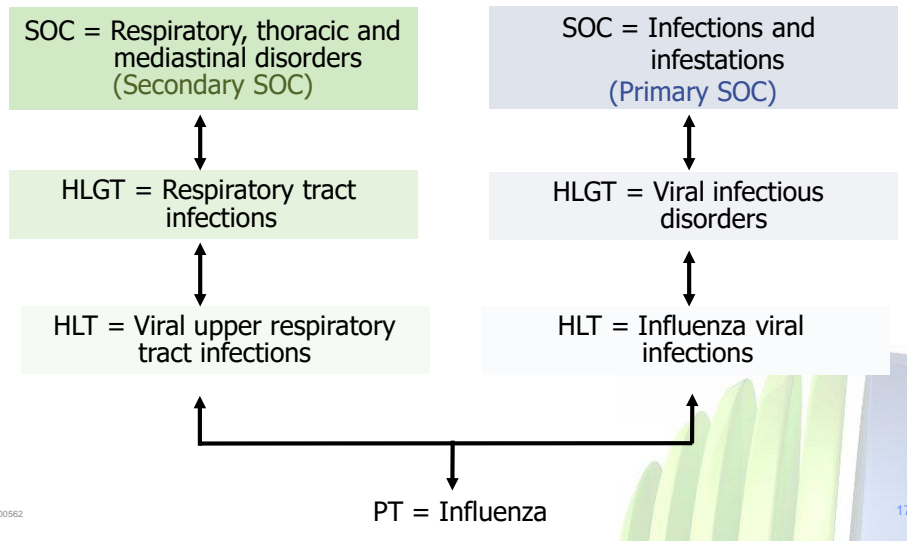
Rules for Primary SOC Allocation (cont.)

MedDRA

- 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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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

Coding Conventions

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MedDRA | 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"

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MedDRA | 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 | 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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MedDRA Term Selection:
Points to Consider Document

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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 4.21

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

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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

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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

MedDRA

- 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 Assurance

MedDRA

- 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

MedDRA

- 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

MedDRA

- 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

MedDRA

- 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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Term Selection Points

MedDRA

- 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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Term Selection Points (cont)

MedDRA

- 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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MedDRA

Introduction to the MedDRA Browsers

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

MedDRA Web-Based Browser (WBB)
https://tools.meddra.org/wbb/

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

MSSO's MedDRA Browsers (cont)

• 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)

MedDRA

MedDRA Browser Demonstration

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MedDRA

Approaches to Finding the Best LLT

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Assessing the Reported Information

MedDRA

- 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

MedDRA

Specificity

The patient suffered from an <u>allergic reaction to an antibiotic</u>

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MedDRA | Coding Example 2

Symptoms

The patient states she has been experiencing <u>cold sweats</u>

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MedDRA | Coding Example 3

Investigations

Lab results indicate the patient has <u>increased troponin and increased CPK-MB</u>

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MedDRA | Coding Example 4

Medication errors

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

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MedDRA | Coding Example 5

Patient demographics

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

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MedDRA | Coding Example 6

Indications

A 35 year old woman was taking Drug X to <u>prevent relapses</u> of <u>multiple sclerosis</u>

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MedDRA | Coding Example 7

Specificity

She had a <u>pathologic fracture</u> of the <u>neck of </u>the left <u>femur</u>

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MedDRA | Coding Example 8

Specificity

Following the procedure, the patient experienced several days of constipation

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MedDRA | Coding Example 9

Death and other patient outcomes

The 66 year old man died from a ruptured aortic aneurysm

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MedDRA | Coding Example 10

Product quality issues

It was determined that the <u>product</u> was <u>counterfeit</u>

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MedDRA | Coding Example 11

Social circumstances

The patient was <u>confined to a wheelchair</u>

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MedDRA | Coding Example 12

Medication errors/Product use errors and issues

The pharmacist made a <u>mistake in compounding the medication</u>

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MedDRA | Coding Example 13

Narrative vignette

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

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MedDRA

Additional Coding Exercises

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MedDRA | Try to Code Some Verbatims

- Please open either the Desktop or Web-Based Browser
- I will ask you to try to find the best LLT in MedDRA to code several short verbatims
- You can select an LLT from MedDRA using either a "top down" or "bottom up" approach
- We will use Poll Everywhere to submit your proposed answers
- We will review the correct LLTs for each verbatim

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MedDRA | Get ready to participate !
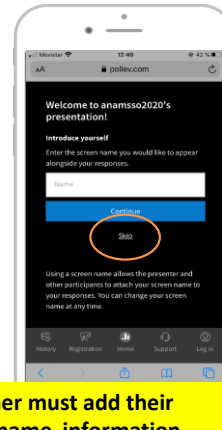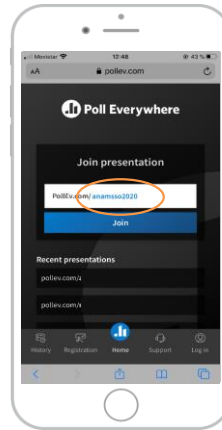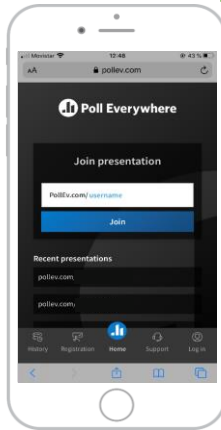
1. Open an internet browser on your computer or cell phone
2. Go to **PollEv.com**

3. Enter **xxxxxxxx** as the "username"
4. Click **Join**

Trainer must add their username information

5. Click **Skip**
6. Respond to activity

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MedDRA | Short Verbatim #1

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

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Enter the Correct LLT

MedDRA

Correct Answer - Verbatim #1

LLT *COVID-19 pneumonia*

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MedDRA | Short Verbatim #2

"Elderly woman ingested her husband's blood pressure drug by mistake"

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Enter the correct LLT

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MedDRA

Correct Answer - Verbatim #2

LLT *Accidental ingestion of drug*

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MedDRA

Short Verbatim #3

"The patient developed hyponatraemia while hospitalised"

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Enter the correct LLT

MedDRA

Correct Answer - Verbatim #3

LLT *Hospital acquired hyponatraemia*

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Short Verbatim #4

MedDRA

"Nurse noticed that the injection solution had
an unusual odor"

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Enter the correct LLT

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MedDRA | Correct Answer - Verbatim #4

LLT *Product odor abnormal*

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MedDRA | Short Verbatim #5

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

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Enter the correct LLT

Start the presentation to see live content. Still no live content? Install the app or get help at **PollEv.com/app**

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MedDRA

Correct Answer -
Verbatim #5

LLT *Vaccination site tenderness*

MedDRA | 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
- Performed some coding exercises on your own

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MedDRA | MSSO Contacts

- Website
  - www.meddra.org
- Email
  - mssohelp@meddra.org
- Frequently Asked Questions
  - www.meddra.org/faq
- MedDRA Browsers
  - https://www.meddra.org/meddra-desktop-browsers (Desktop Browser)
  - https://tools.meddra.org/wbb/ (Web-Based Browser)
  - https://mmb.meddra.org (Mobile Browser)

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MedDRA | 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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MedDRA

Question and Answer Session

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