MedDRA - Terminologies & Coding

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ICH
harmonisation for better health

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Coding?

- What is Coding ?

- Why code?

How does this look to you?

What do you see ?

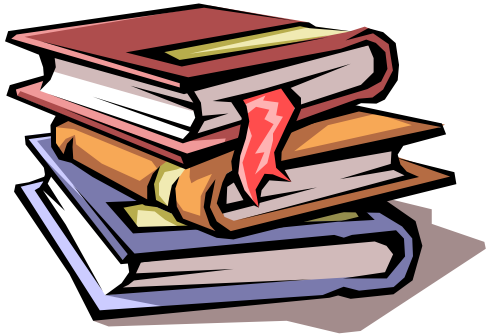
What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities



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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Level 2 (Annual Revenue $10-$20 Million)	$2,496 USD
Level 3 (Annual Revenue $20-$500 Million)	$4,727 USD
Level 4 (Annual Revenue $500 Million-$1 Billion)	$9,918 USD
Level 5 (Annual Revenue $1-$5 Billion)	$41,150 USD
Level 6 (Annual Revenue $5-$20 Billion)	$54,334 USD
Level 7 (Annual Revenue > $20 Billion)	$70,889 USD
System Developer	$2,556 USD

77% of all MedDRA users pay no fee or $654 (or less)

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Online Subscription / Subscription /

Organisation

Organisation Name: *

Organisation Type: *
Select a type

Subscription Type *

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All regulatory authorities are eligible to receive MedDRA at no charge. This includes the English version of each release of MedDRA as well as all available translations.

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Contact Information

Main point of contact

First Name: *

Last Name: *

Street, No: *

City: *

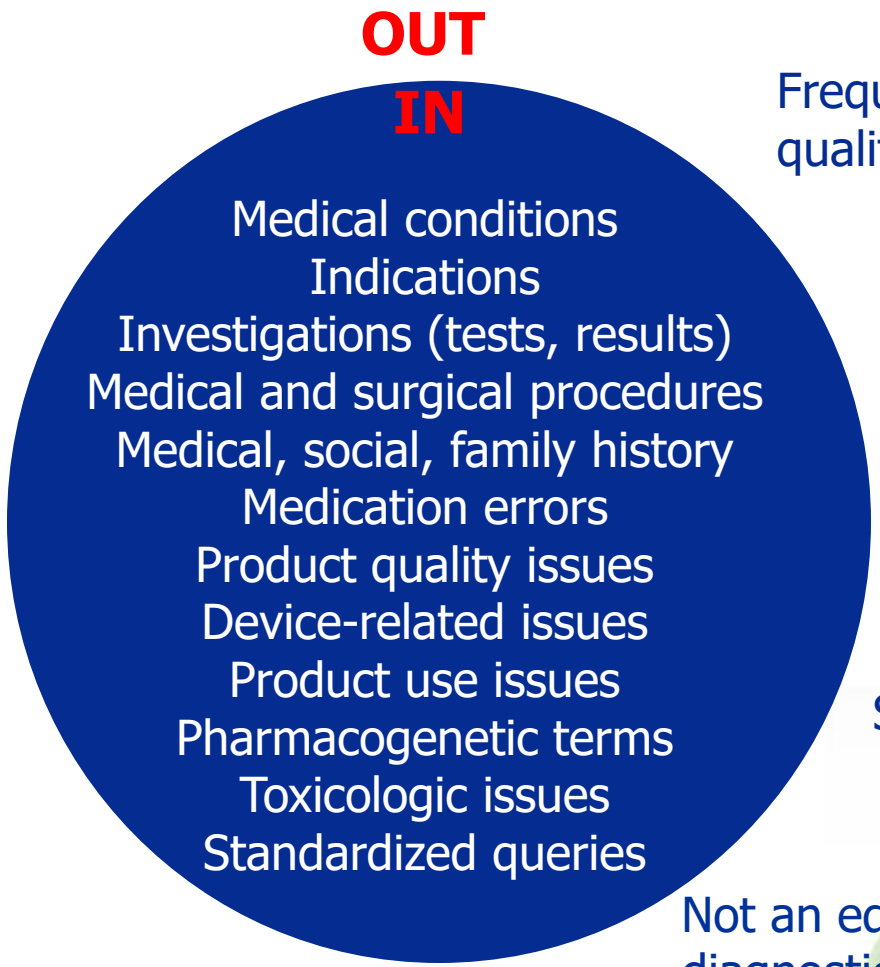
Province/State: *

Postal/Zip Code:

Country: *

Phone: *

Scope of MedDRA



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 Class (SOC) (27)

High Level Group Term (HLGT) (337)

High Level Term (HLT) (1,737)

Preferred Term (PT) (23,708)

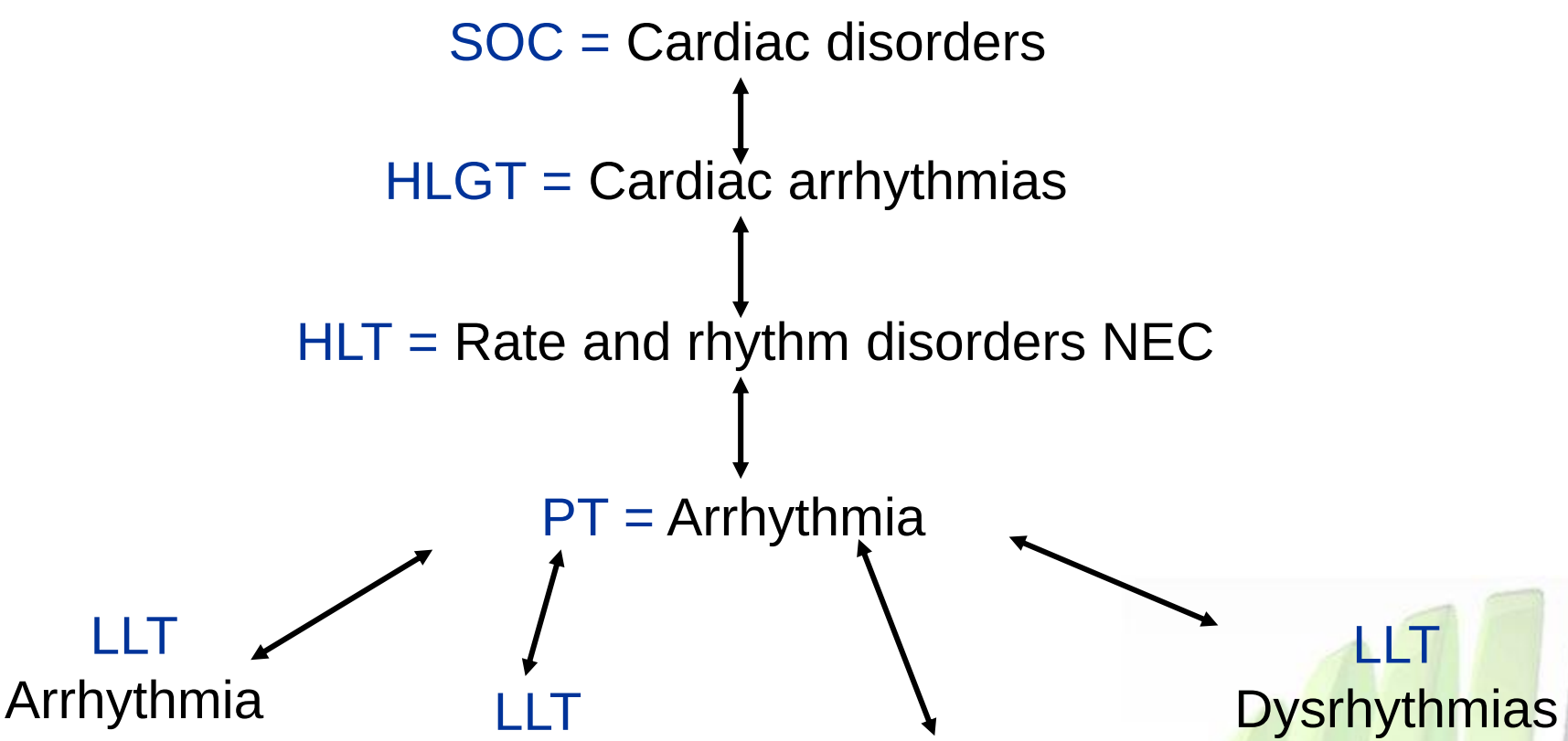
Lowest Level Term (LLT) (80,262)

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

Lowest Level Term

Synonyms, lexical variants, sub-elements



Not all LLTs shown

Non-Current Terms

- 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

Codes and Languages

Cefaleia
Portuguese

Hoofdpijn
Dutch

Kopfschmerz
German

Headache
English

Fejfájás
Hungarian

10019211

Céphalée
French

Cefalea
Italian

Bolest hlavy
Czech

頭痛
Japanese

头痛
Chinese

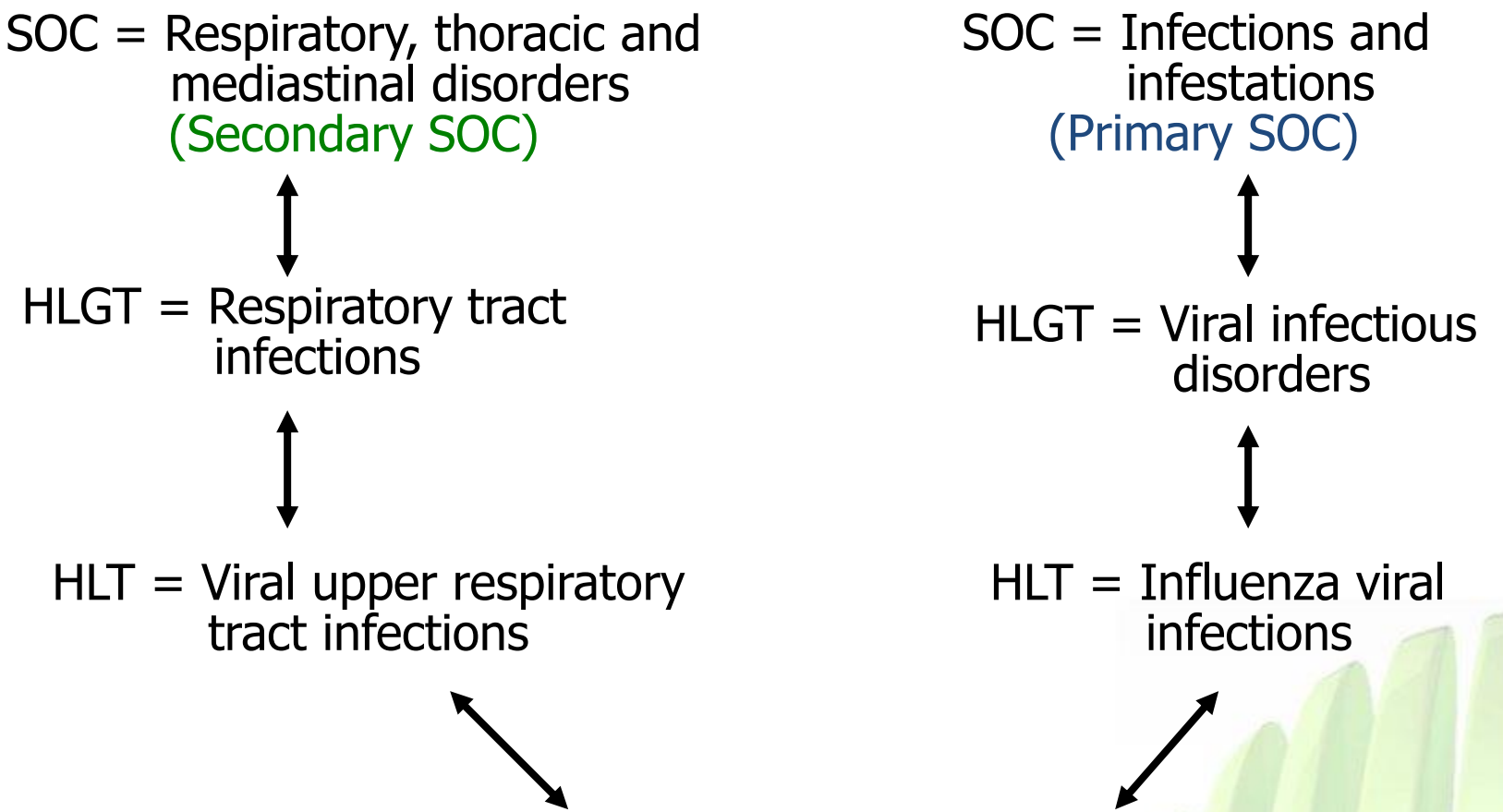
Cefalea
Spanish

Electronic Submission

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

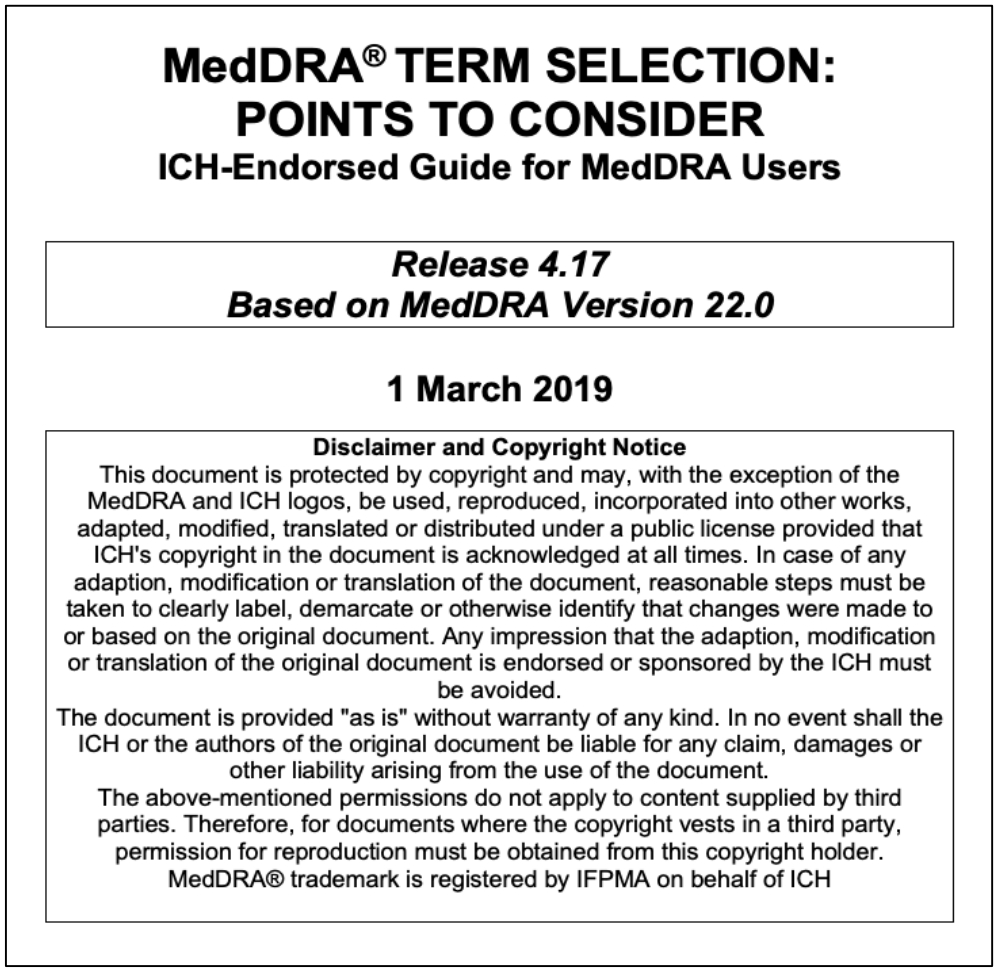
A Multi-Axial Terminology (cont)



What are coding conventions?

ICH MedDRA Coding Guide

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



MedDRA® TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Release 4.17
Based on MedDRA Version 22.0

1 March 2019

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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

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

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

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

Some Points to consider

- Obtain clarification of data that are ambiguous, confusing, or unintelligible
- Do Not Alter MedDRA :Users must not make ad hoc structural alterations, including changing the primary SOC allocation
- Avoid company-specific "work-arounds" for MedDRA deficiencies, submit change request to MSSO
- Select current LLTs only
  - Non-current terms for legacy conversion/historical purposes

Some Points to consider

- 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*"
- If no exact match in MedDRA, use medical judgment to match to an existing term that adequately represents the concept
- Check the hierarchy above a selected LLT (PT, HLT, HLGT, SOC) to ensure placement accurately reflects meaning of reported term

Some Points to consider

- Can select more than one LLT to represent reported information. Document procedures.
- 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 make diagnosis if only signs/symptoms reported

MedDRA Browser & Demonstration

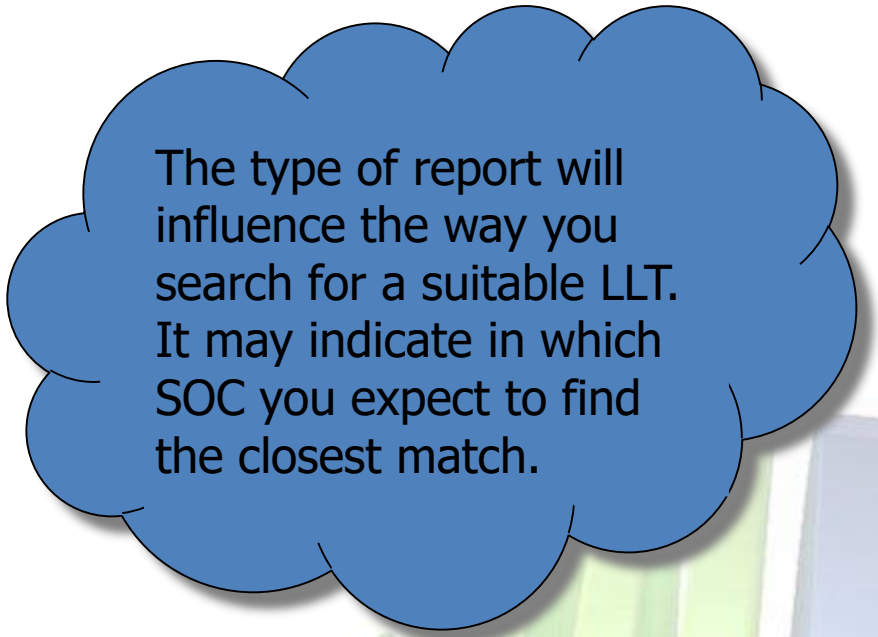
MSSO's MedDRA Browsers

- 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

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

Investigations

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

Coding Example 4

Patient demographics

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

Coding Example 5

Indications

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

Coding Example 6

Product quality issues

It was determined that the product was counterfeit

Coding Example 7

Social circumstances

The patient was confined to a wheelchair

Coding Example 8

Medication errors/Product use errors and issues

The pharmacist made a mistake in compounding the medication

MedDRA Coding Exercise

Which LLT Would You Select?

Verbatim: "Man with decreased fertility."

A. Infertility
B. Fertility decreased male
C. Infertility male
D. Fertility decreased

Which LLT Would You Select?

Verbatim: "Became color blind in adolescence"

A. Color blindness
B. Blindness color
C. Colour blindness acquired
D. Color blindness acquired

Which LLT Would You Select?

Verbatim: "Turned very greasy"

A. Ill-defined disorder
B. Unevaluable event
C. Skin greasy
D. Unevaluable reaction

Which LLT Would You Select?

Verbatim: "Deliberately took an overdose"

A. Intentional overdose
B. Overdose NOS
C. Deliberate overdose
D. Overdose

Which LLT Would You Select?

Verbatim: "Toddler accidentally took her mother's medication"

A. Accidental overdose
B. Accidental exposure to product by child
C. Accidental drug intake by child
D. Accidental ingestion

Which LLT Would You Select?

Verbatim: "Infection after surgery"

A. Infection
B. Postoperative wound infection
C. Surgical wound infection
D. Postoperative infection

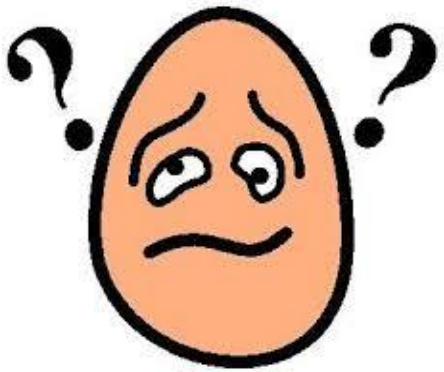
Which LLT Would You Select?

Verbatim: "He sold his father's medication"

A. Drug diversion
B. Intentional product misuse
C. Drug use for unapproved indication
D. Intentional drug misuse

Which LLT Would You Select?

Verbatim: "Had MI"



A. Myocardial infarction
B. Ill-defined disorder
C. MI
D. Unevaluable event

Which LLT Would You Select?

Verbatim:

"Hypernatraemia (Serum sodium = 115 mEq/L)"

A. Serum sodium abnormal
B. Hypernatraemia
C. Hyponatraemia
D. Serum sodium decreased

Which LLT Would You Select?

Verbatim: "Took intramuscular drug by mouth"

A. Wrong route of administration
B. Drug administered via inappropriate route
C. Medication error
D. Intramuscular formulation administered by other route

Which LLT Would You Select?

Verbatim: "The doctor mistakenly prescribed the wrong drug; the pharmacist noticed the error before dispensing the drug"

A. Wrong drug dispensed
B. Medication error
C. Intercepted drug prescribing error
D. Intercepted drug dispensing error

Which LLT Would You Select?

Verbatim: Patient attempted to commit suicide by walking into the sea; unfortunately, he could swim

A. Suicidal behaviour
B. Attempted suicide
C. Completed suicide
D. Death

Which LLT Would You Select?

Verbatim: "Dose taken was below the minimum recommended dose in the product label"

A. Underdose
B. Drug administration error
C. Accidental underdose
D. Incorrect dosage administered

Which LLT Would You Select?

Verbatim: "After taking an antihistamine along with her prescribed proton pump inhibitor, a 53-year-old woman developed vertigo."

A. Drug interaction NOS
B. Vertigo subjective
C. Vertigo
D. Drug interaction

Which LLT Would You Select?

Verbatim: "The medication was stored at room temperature instead of in the refrigerator where it belonged."

A. Incorrect storage of drug
B. Improper storage of unused product
C. Intercepted medication error
D. Product storage error temperature too high

Which LLTs Would You Select?

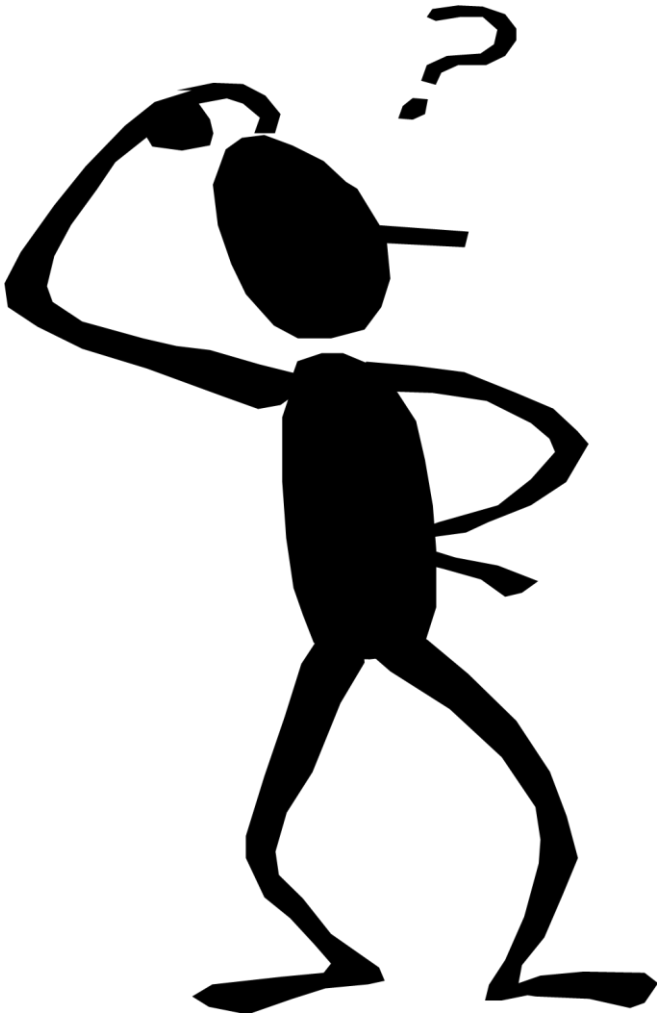
Verbatim: The 66 year old man died from a ruptured aortic aneurysm

A. Aortic aneurysm rupture
B. Ascending aortic aneurysm rupture
C. Dissecting aortic aneurysm, ruptured
D. Death
E. A & D both

Quick Guess?

- Hippo tension
- Mousy feeling in chest
- Patient recently began new job where he works around chicken wings and barbecue sauce
- Loss of brain
- Spray it in the nose as much as you want and the Septum is gone
- Medication messed up with the brain
- Adult teeth came in three different colors – yellow, green and white
- Husband had his uterus scrapped and frozen
- Death-worsened clinically by end of 4 hrs rx
- Even Need to spend more time with my wife (as the subject stated)

After Coding?



How is MedDRA Used for Analysis?

- MedDRA can be used to summarise large volumes of data
  - Standard approach is to list data at PT and SOC levels for overview
- Focused searches can be made using features of MedDRA
  - Searching for specific PTs
  - Summarising at HLT or HLGT levels
  - Using multiaxial links to group diagnoses with signs and symptoms
  - Selecting a set of relevant PTs which reflect the condition of interest
  - Using Standardised MedDRA Queries (SMQs) for signal detection
  - Customized search /Modified MedDRA Queries

More on SMQ and Data Retrieval ?

- Documentation :
  - SMQ Introductory Guide

https://www.meddra.org/how-to-use/support-documentation

- Processes :
  - MedDRA Data Retrieval and Presentation: Points to Consider

https://www.meddra.org/how-to-use/support-documentation

- Training :
  - Face-to-Face Training - MedDRA: Safety Data Analysis and SMQs
  - Webinar
  - Training Videocast

https://www.meddra.org/training/offerings

Know more?

- Visit : www.meddra.org

MedDRA | Medical Dictionary for Regulatory Activities

Thank You!!

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