



Introduction to MedDRA

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Skill Development Programme-23 June 2021
Indian Pharmacopoeia Commission, Ghaziabad





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How To Join Poll Everywhere

- Please join us in making this quiz interactive
- Go to Pollev.com/anamikadutta561
- You may use internet or mobile data
- You could vote using your computer or mobile phones
- Respond to the quiz
- It can be anonymous if you wish!!



Where are you joining from today?

What is Coding? & Why code??





MedDRA

What do you see?



How many cases of Headache??



Head Pain

His head started paining after he woke up from sleep

Cephalgia

Headache recurrent

Hammering pain in Head

Pounding in head

Pain in Head

Dull Headache

Headache

Hedache

Pain head

Throbbing pain in head

My temples are hurting

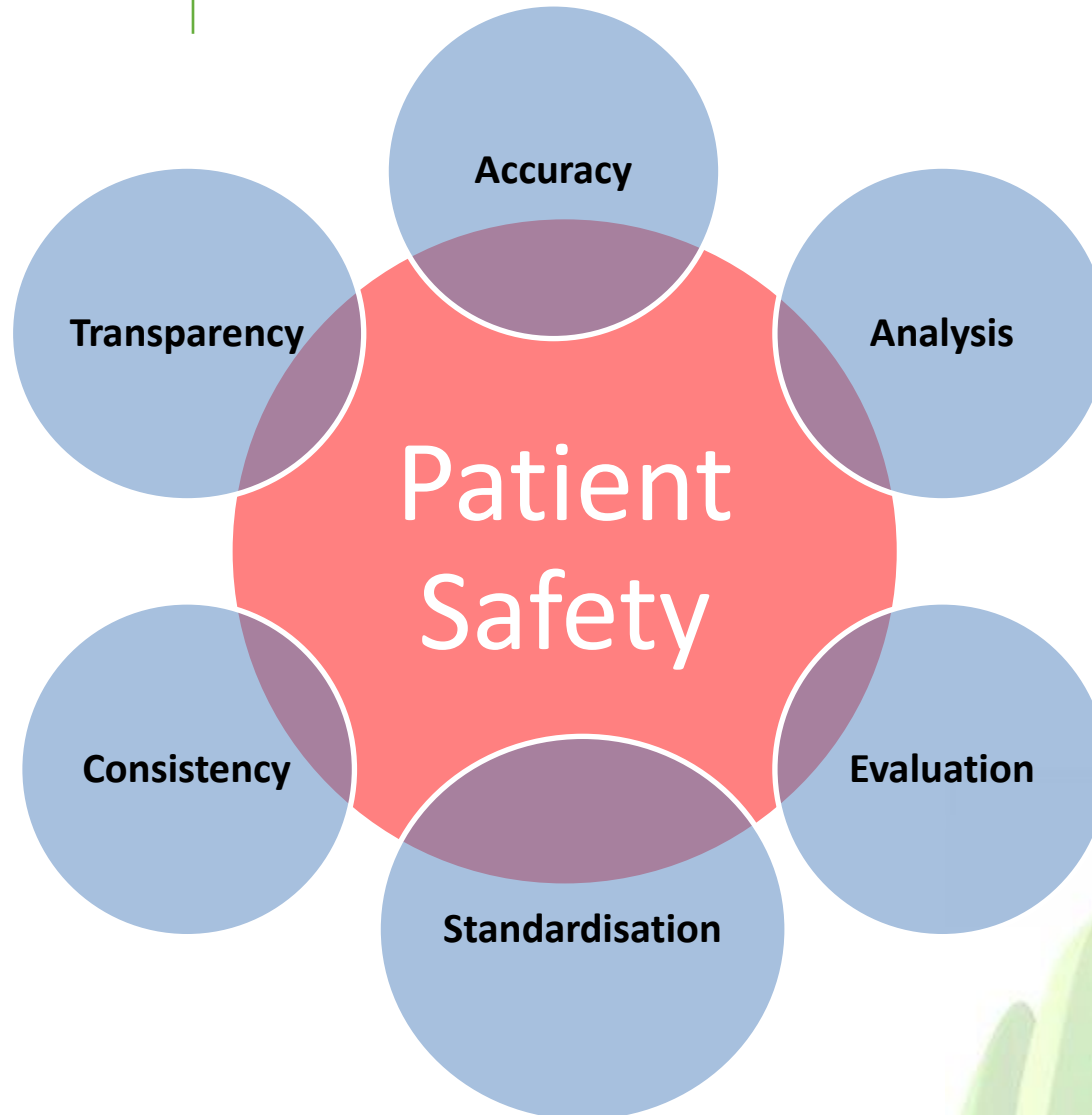


6



MedDRA

Why code?





What happens when we code?

- A standard code is assigned to each verbatim
- 8-digit MedDRA code gets assigned to the verbatim term

Verbatim Text	Low Level Term (LLT)	LLT Code	Preferred Term (PT)	PT Code	System Organ Class (SOC)	SOC Code
Pain in eye	Pain in eyes	10033426	Eye pain	10015958	Eye disorders	10015919
Sore eyes	Sore eyes	10041357	Eye pain	10015958	Eye disorders	10015919
Pyrexia	Pyrexia	10037660	Pyrexia	10037660	General disorders and administration site conditions	10018065
Spiking temperature	Spiking temperature	10041523	Pyrexia	10037660	General disorders and administration site conditions	10018065
Suffering from fever	Fever	10016558	Pyrexia	10037660	General disorders and administration site conditions	10018065



MedDRA

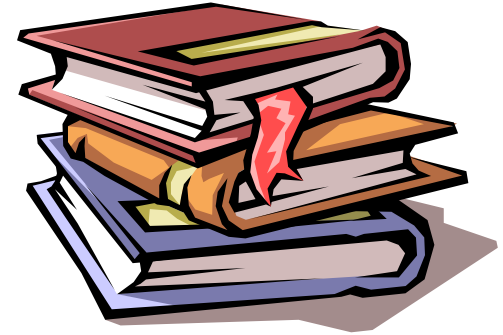
Definition

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities

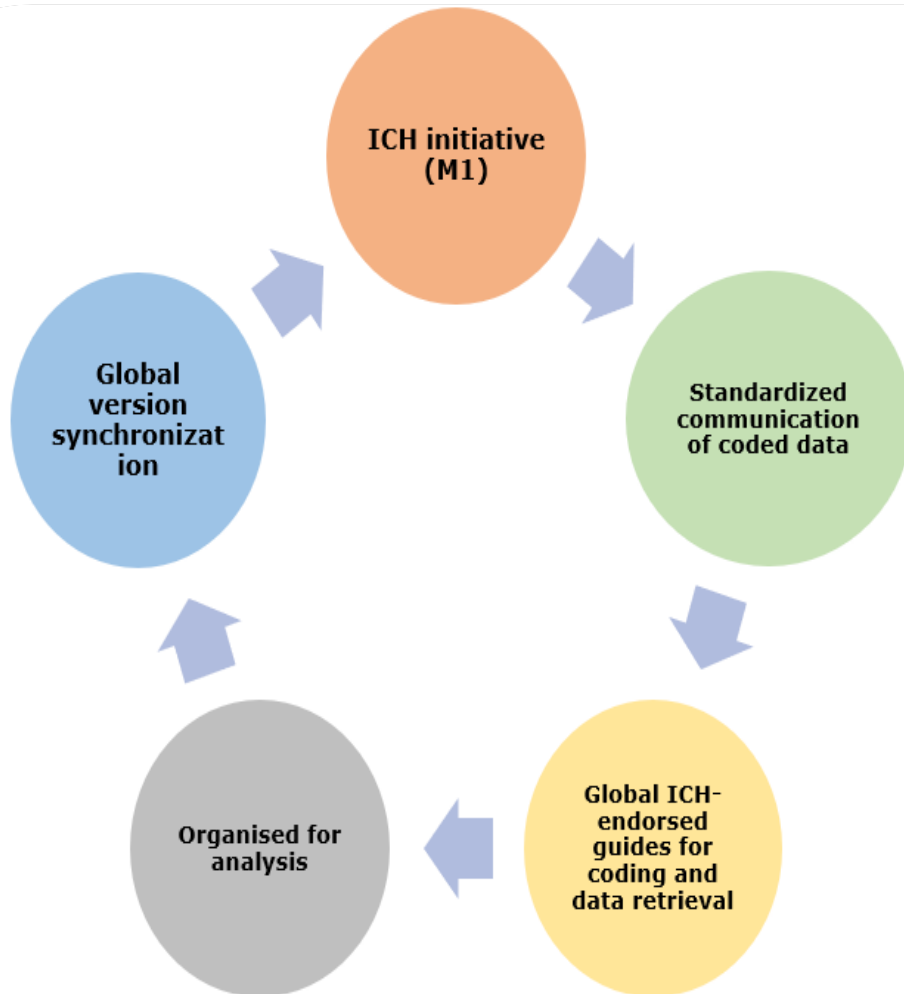


MedDRA is a clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation.



MedDRA

Why MedDRA?



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

Where MedDRA is Used

Individual Case Safety Reports (ICSRs) - ICH E2B (R3) Data Elements in MedDRA

Element id	Element Name
D.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code)
D.8.r.6b	Indication (MedDRA code)
D.8.r.7b	Reaction (MedDRA code)
D.9.2.r.1b	Reported Cause(s) of Death (MedDRA code)
D.9.4.r.1b	Autopsy-determined Cause(s) of Death (MedDRA code)
D.10.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code)
D.10.8.r.6b	Indication (MedDRA code)
D.10.8.r.7b	Reactions (MedDRA code)
E.i.2.1b	Reactions / Event (MedDRA code)
F.r.2.2b	Test Name (MedDRA code)
G.k.7.r.2b	Indication (MedDRA code)
H.3.r.1b	Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA code)

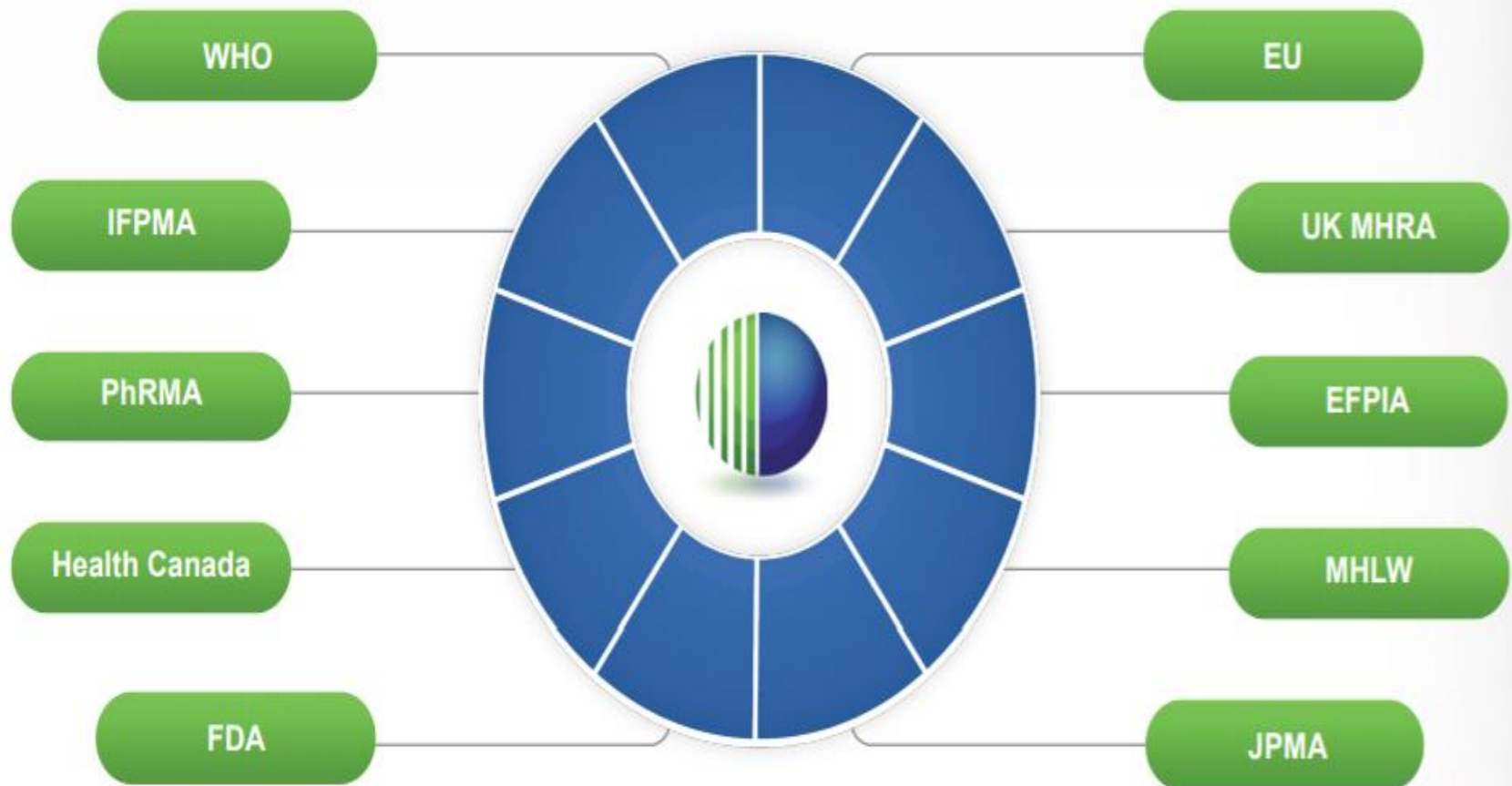
Regulator Database





MedDRA

MedDRA Governance





MedDRA

MedDRA and the MSSO

International
support &
development of
terminology

**“Custodians” of
the terminology**

Foster use of
MedDRA

JMO for Japanese-
language

Governed by a
Management
Committee



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MedDRA

2021 MedDRA Subscription Rate Table

MedDRA Subscription Types	2021 Annual Subscription Rates
Regulatory Authority	\$0 USD
Non-Commercial / Non-Profit	\$0 USD
Commercial (Parent Company Annual Revenue or Turnover)	
Level 0 (Annual Revenue < \$1 Million)	\$154 USD
Level 1 (Annual Revenue \$1-\$10 Million)	\$654 USD
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)





MedDRA

Scope of MedDRA

OUT
IN

Not a drug
dictionary

Frequency
qualifiers

Patient demographic
terms

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

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)

1737



Preferred Term (PT)

24820



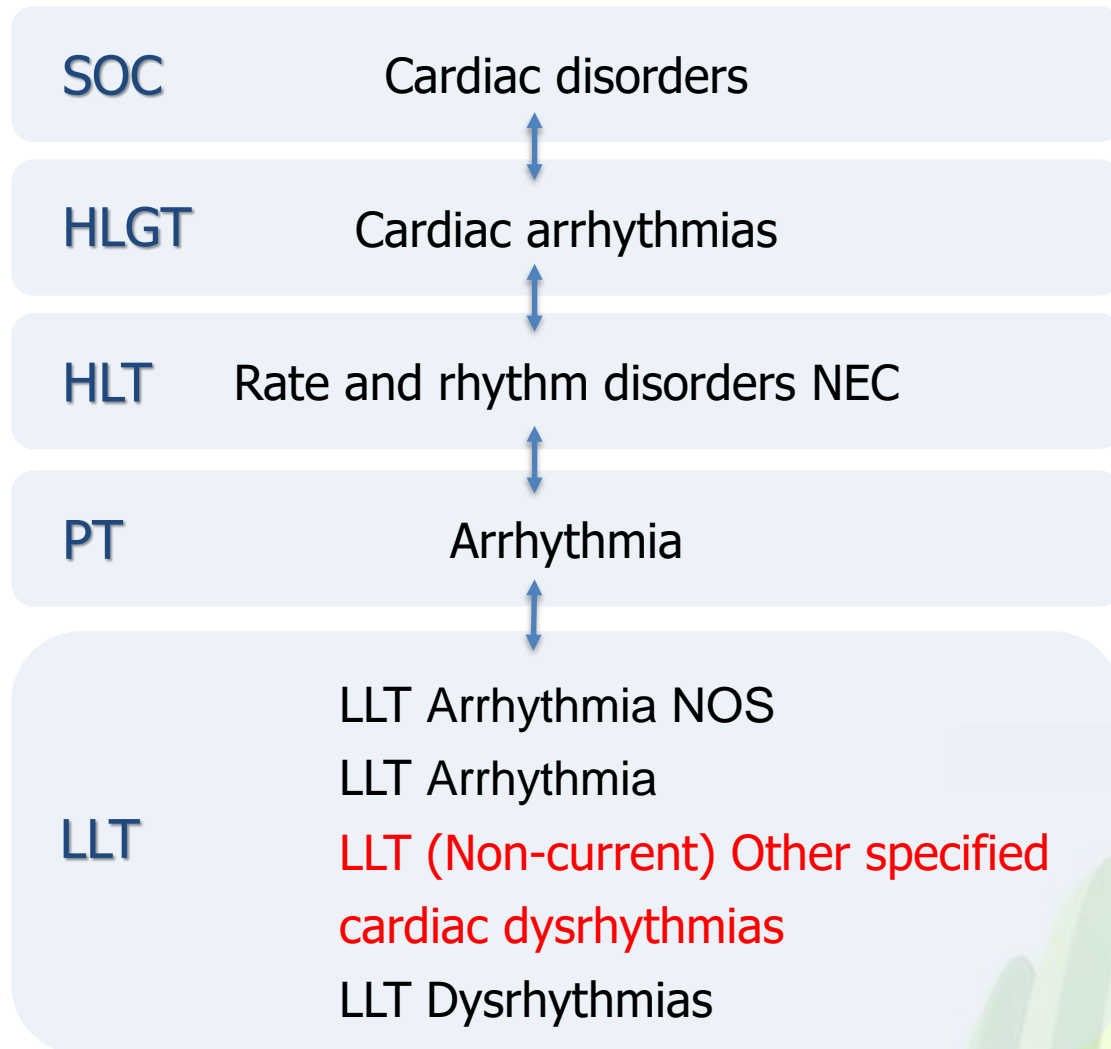
Lowest Level Term (LLT)

83291



The Five Levels of MedDRA

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





MedDRA

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



MedDRA

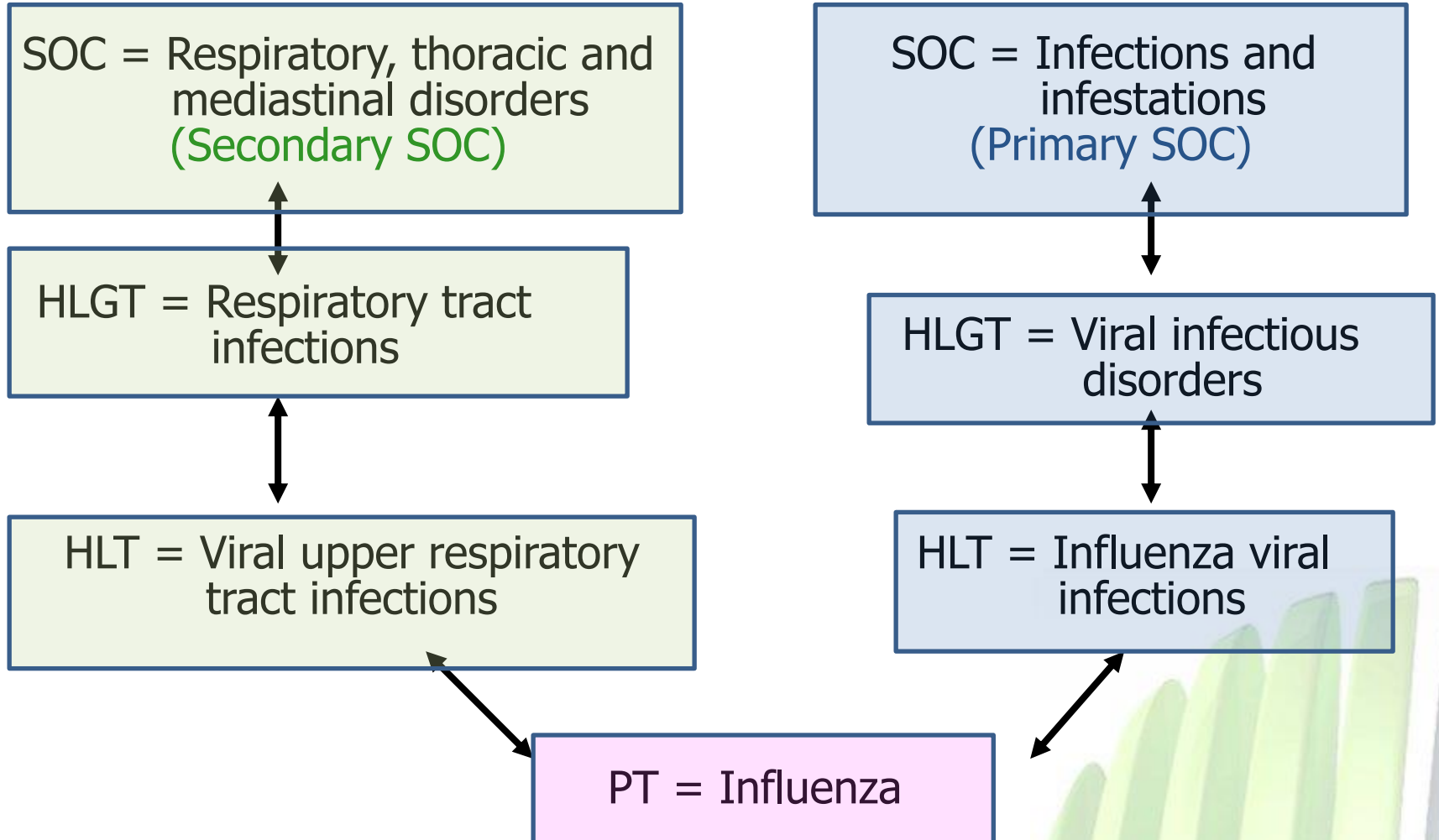
MedDRA Codes and Languages



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



A Multi-Axial Terminology





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”





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: Points to Consider (MTS:PTC)

- Detailed coding instructions**

SECTION 2 – GENERAL TERM SELECTION PRINCIPLES		
2.1 Quality of Source Data	3.10.2 Events in the child or foetus	3.18.1 Overdose reported with clinical consequences
2.2 Quality Assurance	3.11 Congenital Terms	3.18.2 Overdose reported without clinical consequences
2.3 Do Not Alter MedDRA	3.11.1 Congenital conditions	3.19 Device-related Terms
2.4 Always Select a Lowest Level Term	3.11.2 Acquired conditions (not present at birth)	3.19.1 Device-related event reported with clinical consequences
2.5 Select Only Current Lowest Level Terms	3.11.3 Conditions not specified as either congenital or acquired	3.19.2 Device-related event reported without clinical consequences
2.6 When to Request a Term	3.12 Neoplasms	3.20 Drug Interactions
2.7 Use of Medical Judgment in Term Selection	3.12.1 Do not infer malignancy	3.20.1 Reporter specifically states an interaction
2.8 Selecting More than One Term	3.13 Medical and Surgical Procedures	3.20.2 Reporter does not specifically state an interaction
2.9 Check the Hierarchy	3.13.1 Only the procedure is reported	3.21 No Adverse Effect and "Normal" Terms
2.10 Select Terms for All Reported Information, Do Not Add Information	3.13.2 Procedure and diagnosis are reported	3.21.1 No adverse effect
SECTION 3 – TERM SELECTION POINTS		
3.1 Definitive and Provisional Diagnoses with or without Signs and Symptoms	3.14 Investigations	3.21.2 Use of "normal" terms
3.2 Death and Other Patient Outcomes	3.14.1 Results of investigations as ARs/AEs	3.22 Unexpected Therapeutic Effect
3.2.1 Death with ARs/AEs	3.14.2 Investigation results consistent with diagnosis	3.23 Modification of Effect
3.2.2 Death as the only reported information	3.14.3 Investigation results not consistent with diagnosis	3.23.1 Lack of effect
3.2.3 Death terms that add important clinical information	3.14.4 Grouped investigation result terms	3.23.2 Do not infer lack of effect
3.2.4 Other patient outcomes (non-fatal)	3.14.5 Investigation terms without qualifiers	3.23.3 Increased, decreased and prolonged effect
3.3 Suicide and Self-Harm	3.15 Medication Errors, Accidental Exposures and Occupational Exposures	3.24 Social Circumstances
3.3.1 If overdose is reported	3.15.1 Medication errors	3.24.1 Use of terms in this SOC
3.3.2 If self-injury is reported	3.15.2 Accidental exposures and occupational exposures	3.24.2 Illegal acts of crime or abuse
3.3.3 Fatal suicide attempt	3.16 Misuse, Abuse and Addiction	3.25 Medical and Social History
3.4 Conflicting/Ambiguous/Vague Information	3.16.1 Misuse	3.26 Indication for Product Use
3.4.1 Conflicting information	3.16.2 Abuse	3.26.1 Medical conditions
3.4.2 Ambiguous information	3.16.3 Addiction	3.26.2 Complex indications
3.4.3 Vague information	3.16.4 Drug diversion	3.26.3 Indications with genetic markers or abnormalities
3.5 Combination Terms	3.17 Transmission of Infectious Agent via Product	3.26.4 Prevention and prophylaxis
3.5.1 Diagnosis and sign/symptom	3.18 Overdose, Toxicity and Poisoning	3.26.5 Procedures and diagnostic tests as indications
3.5.2 One reported condition is more specific than the other		3.26.6 Supplementation and replacement therapies
3.5.3 A MedDRA combination term is available		3.26.7 Indication not reported
3.5.4 When to "split" into more than one MedDRA term		3.27 Off Label Use
3.5.5 Event reported with pre-existing condition		3.27.1 Off label use when reported as an indication
3.6 Age vs. Event Specificity		3.27.2 Off label use when reported with an AR/AE
3.6.1 MedDRA term includes age and event information		3.28 Product Quality Issues
3.6.2 No available MedDRA term includes both age and event information		3.28.1 Product quality issue reported with clinical consequences
3.7 Body Site vs. Event Specificity		3.28.2 Product quality issue reported without clinical consequences
3.7.1 MedDRA term includes body site and event information		3.28.3 Product quality issue vs. medication error
3.7.2 No available MedDRA term includes both body site and event information		SECTION 4 – APPENDIX
3.7.3 Event occurring at multiple body sites		4.1 Versioning
3.8 Location-Specific vs. Microorganism-Specific Infection		4.1.1 Versioning methodologies
3.8.1 MedDRA term includes microorganism and anatomic location		4.1.2 Timing of version implementation
3.8.2 No available MedDRA term includes both microorganism and anatomic location		4.2 Links and References
3.9 Modification of Pre-existing Conditions		
3.10 Exposures during Pregnancy and Breast Feeding		
3.10.1 Events in the mother		



Coding: Translating into MedDRA

Reported Information	MedDRA Coding Term (LLT)
Throbbing above temple Aching all over head Pulsing pain in head Really bad headache Headache	Headache
Infection in lungs	Lung infection
Patient took Drug A instead of Drug B and experienced hypertension	Wrong drug administered Hypertension



MedDRA

General term selection principles

- 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
- If no exact match in MedDRA, use medical judgment to match to an existing term that adequately represents the concept
- Avoid company-specific "work-arounds" for MedDRA deficiencies, submit change request to MSSO



Assessing the Reported Information

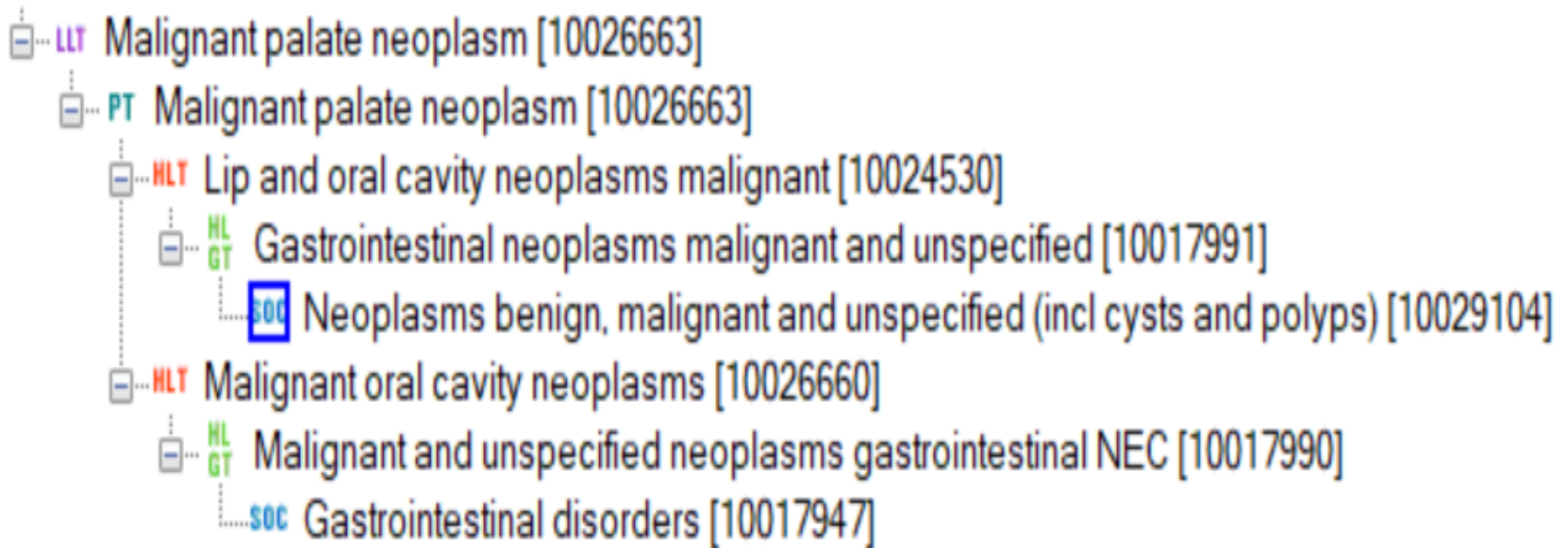
- Consider what is being reported. Is it a:
 - Clinical condition - Diagnosis, sign or symptom?
 - Indication?
 - Test result?
 - Injury?
 - Procedure?
 - Medication error?
 - Product use issue?
 - Product quality issue?
 - Social circumstance?
 - Device issue?
 - Procedural complication?
 - **Is it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



How to code? Example:

- Verbatim: Malignant neoplasm of palate
 - Coded to LLT : Malignant palate neoplasm





How to code? Example:

Patient reported severe **eye irritation** after using **eye drops that had a cloudy appearance**. An investigation by the manufacturer revealed that the **batch of eye drops contained foreign material**.

- Coded to LLTs

LLT	PT	Primary SOC
Eye irritation	Eye irritation	Eye disorders
Product appearance cloudy	Liquid product physical issue	Product issues
Product contamination foreign material	Product contamination physical	Product issues



MedDRA

How to code?

- Gastric Boating





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



Clinical complication of IUD

LLT IUD
complication

LLT Intra-uterine
death

LLT 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



Died as a result of a suicide attempt

-
- A. Suicide gesture B. Attempted suicide C. Completed suicide D. Death



Which LLT(s) Would You Select?

Verbatim: “The patient reported a loss of smell and thought that he might have a COVID-19 infection”

- A. Anosmia
- B. Suspected COVID-19
- C. Loss of smell
- D. COVID-19



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



MedDRA

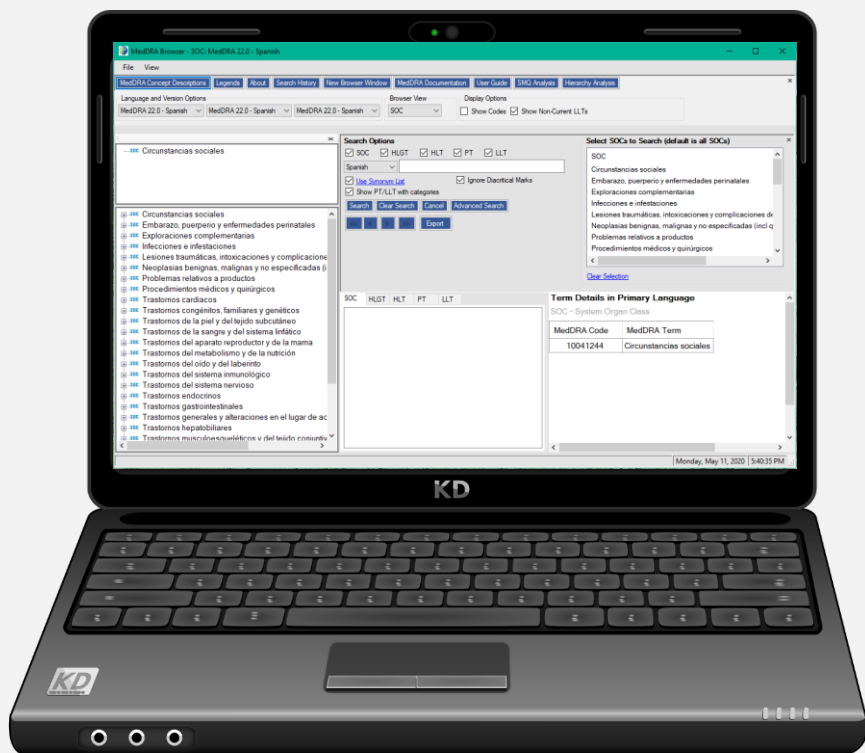
What Terms to Select?

“Husband had his uterus scrapped and frozen”





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/>



Mobile MedDRA Browser

<https://mmb.meddra.org>



MedDRA

Who uses MedDRA?





MedDRA

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MedDRA

Medical Dictionary for Regulatory Activities

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Welcome to MedDRA

In the late 1990s, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) developed MedDRA, a rich and highly specific standardised medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans... (more)

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COVID-19

Please go to the [COVID-19 page](#) for information about COVID-19 terms and revisions in MedDRA 23.0 - 24.0. New SMQ COVID-19 is included in MedDRA 24.0 on the [Downloads](#) page.

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by submitting change requests. Your contribution will be considered by MSSO/JMO.

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MedDRA

Medical Dictionary
for Regulatory Activities

Thank You!!

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