



MedDRA

Introduction to MedDRA Coding

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National Coordination Centre-Pharmacovigilance Programme of India

Indian Pharmacopoeia Commission





MedDRA

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MedDRA

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Your experience with MedDRA?

Never used MedDRA

6 months to 2 years

3 to 5 years

More than 5 years



MedDRA

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.



MedDRA

MedDRA and the MSSO



International support & development terminology

“Custodians” of the terminology

Foster use of MedDRA

Governed by a Management committee

JMDA for MedDRA Japanese



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

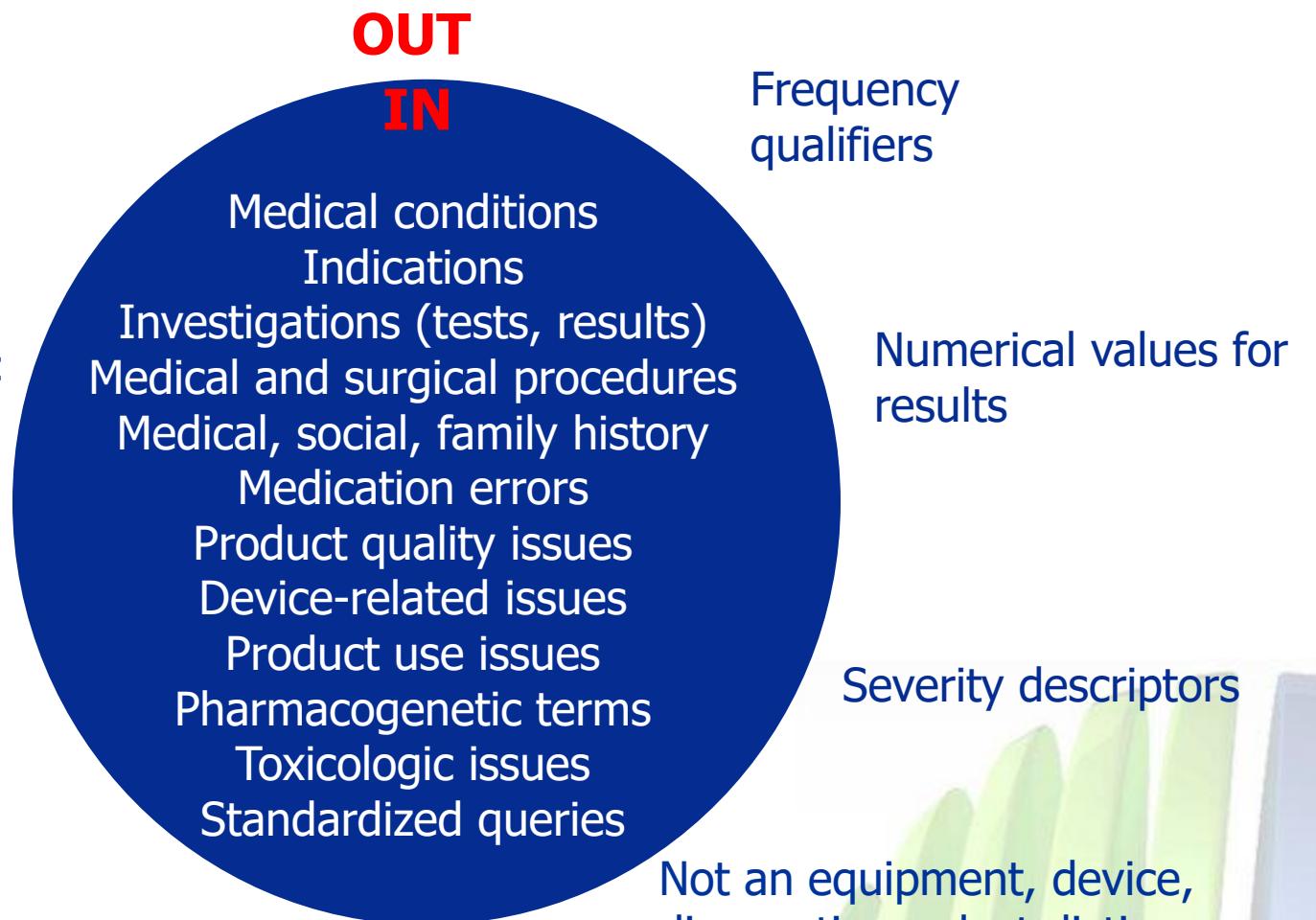
Prescribing Information

Advertising



Scope of MedDRA

Not a drug dictionary
Patient demographic terms
Clinical trial study design terms





MedDRA Codes and Translations



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)

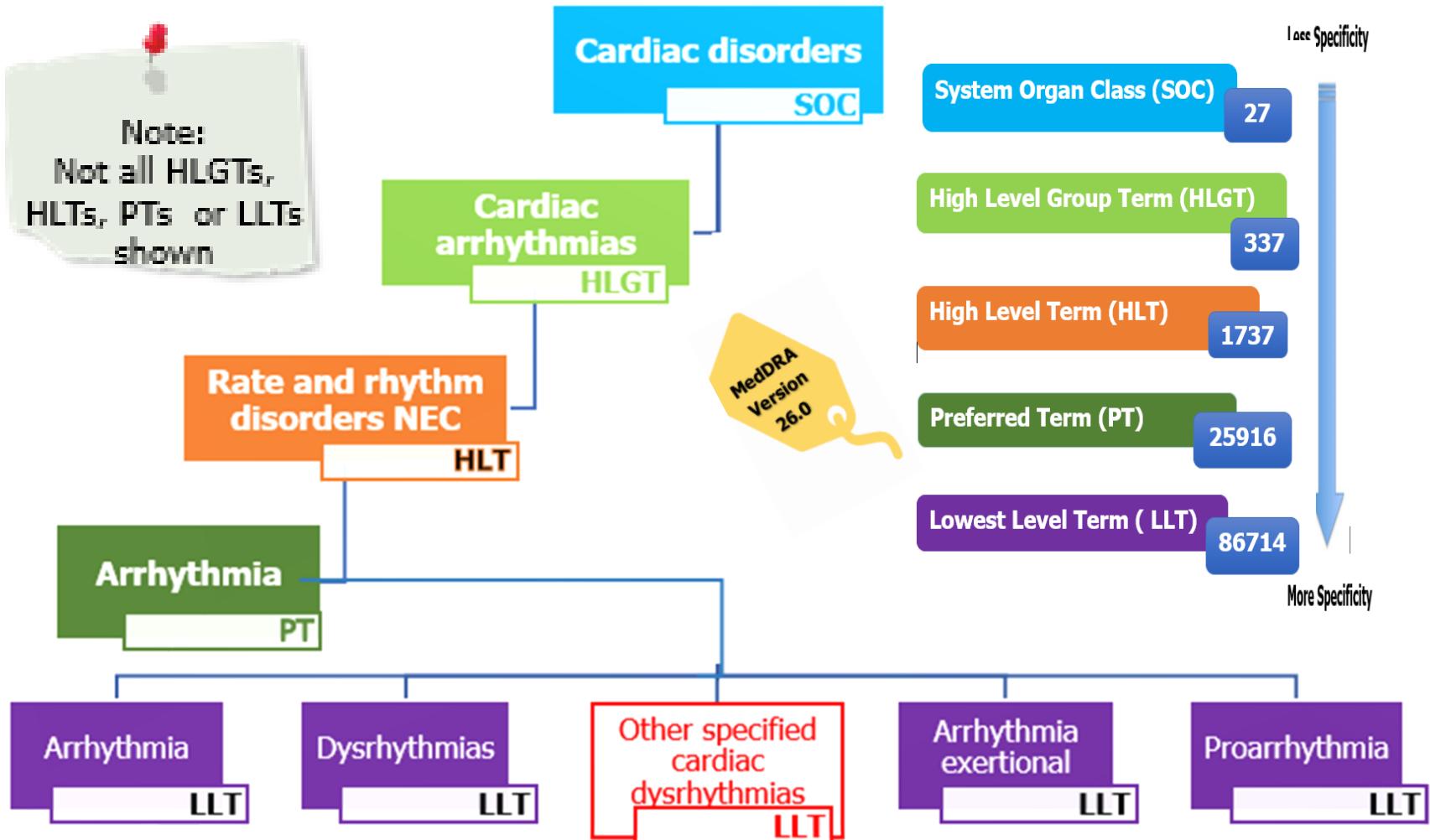
New terms are assigned sequentially



MedDRA

MedDRA Structure

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





MedDRA

System Organ Classes

- + **SOC** Blood and lymphatic system disorders
- + **SOC** Cardiac disorders
- + **SOC** Congenital, familial and genetic disorders
- + **SOC** Ear and labyrinth disorders
- + **SOC** Endocrine disorders
- + **SOC** Eye disorders
- + **SOC** Gastrointestinal disorders
- + **SOC** General disorders and administration site conditions
- + **SOC** Hepatobiliary disorders
- + **SOC** Immune system disorders
- + **SOC** Infections and infestations
- + **SOC** Injury, poisoning and procedural complications
- + **SOC** Investigations
- + **SOC** Metabolism and nutrition disorders
- + **SOC** Musculoskeletal and connective tissue disorders
- + **SOC** Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- + **SOC** Nervous system disorders
- + **SOC** Pregnancy, puerperium and perinatal conditions
- + **SOC** Product issues
- + **SOC** Psychiatric disorders
- + **SOC** Renal and urinary disorders
- + **SOC** Reproductive system and breast disorders
- + **SOC** Respiratory, thoracic and mediastinal disorders
- + **SOC** Skin and subcutaneous tissue disorders
- + **SOC** Social circumstances
- + **SOC** Surgical and medical procedures
- + **SOC** Vascular disorders



27

12



- 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, outdated, truncated, or misspelled
- Terms derived from other terminologies that do not fit MedDRA rules



MedDRA

A Multi-Axial Terminology

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

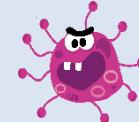


HLGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

PT = Influenza

SOC = Infections and infestations
(Primary SOC)



HLGT = Viral infectious disorders

HLT = Influenza viral infections



Rules for Primary SOC Allocation (cont.)

- 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



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



A Multi-Axial Terminology (cont)

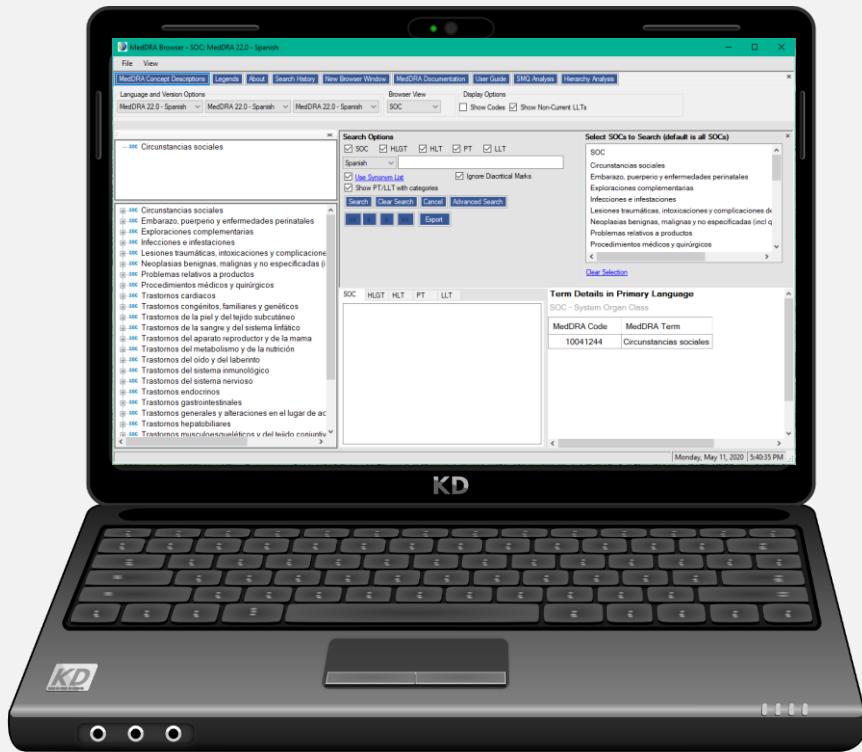
PTs in the following SOCs **only** appear in that particular SOC and not in others, i.e., they are not multi-axial

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



MedDRA

MSSO's MedDRA Browsers

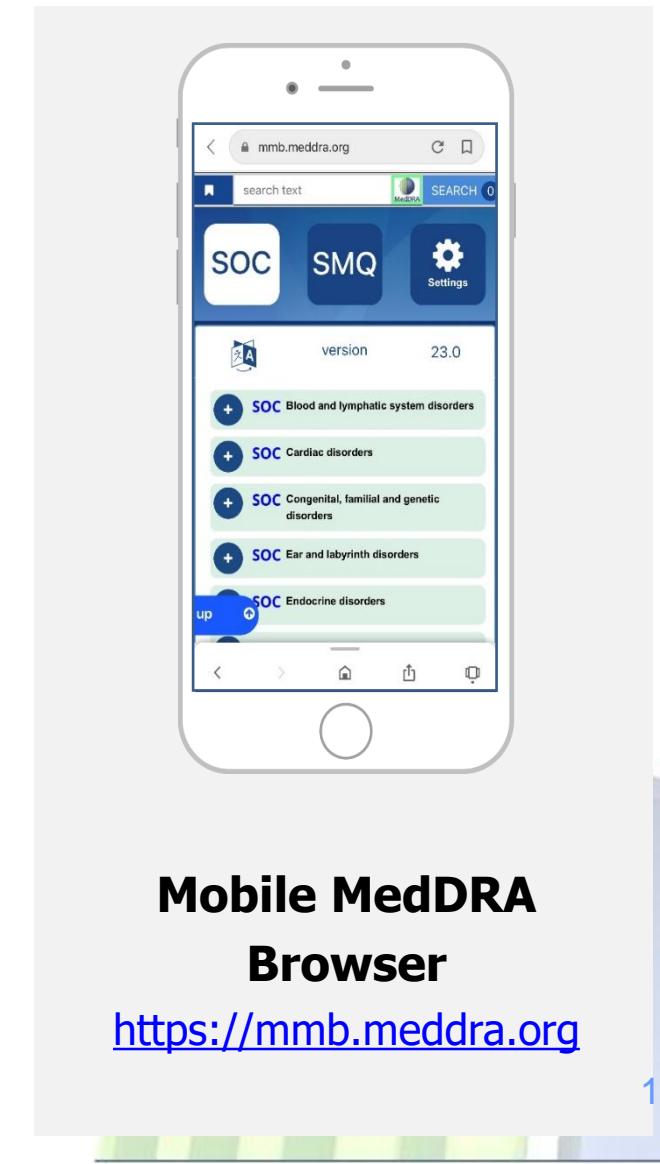


MedDRA Desktop Browser (MDB)

Download MDB and release files from MedDRA website

MedDRA Web-Based Browser (WBB)

<https://tools.meddra.org/wbb/>



Mobile MedDRA Browser

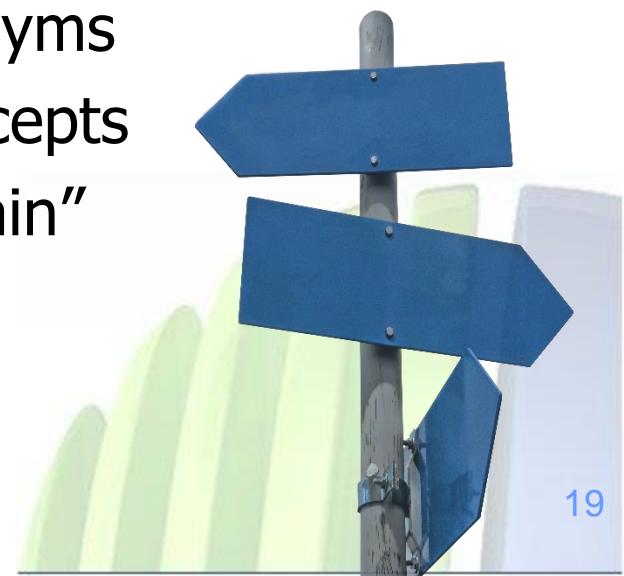
<https://mmb.meddra.org>



MedDRA

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

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

Provides term selection advice for industry and regulatory purposes

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)

SECTION 2 – GENERAL TERM SELECTION PRINCIPLES	
2.1 Quality of Source Data	
2.2 Quality Assurance	
2.3 Do Not Alter MedDRA	
2.4 Always Select a Lowest Level Term	
2.5 Select Only Current Lowest Level Terms	
2.6 When to Request a Term	
2.7 Use of Medical Judgment in Term Selection	
2.8 Selecting More than One Term	
2.9 Check the Hierarchy	
2.10 Select Terms for All Reported Information, Do Not Add Information	
SECTION 3 – TERM SELECTION POINTS	
3.1 Definitive and Provisional Diagnoses with or without Signs and Symptoms	
3.2 Death and Other Patient Outcomes	
3.2.1 Death with ARs/AEs	
3.2.2 Death as the only reported information	
3.2.3 Death terms that add important clinical information	
3.2.4 Other patient outcomes (non-fatal)	
3.3 Suicide and Self-Harm	
3.3.1 If overdose is reported	
3.3.2 If self-injury is reported	
3.3.3 Fatal suicide attempt	
3.4 Conflicting/Ambiguous/Vague Information	
3.4.1 Conflicting information	
3.4.2 Ambiguous information	
3.4.3 Vague information	
3.5 Combination Terms	
3.5.1 Diagnostic and sign/symptom	
3.5.2 One reported condition is more specific than the other	
3.5.3 A MedDRA combination term is available	
3.5.4 When to “split” into more than one MedDRA term	
3.5.5 Event reported with pre-existing condition	
3.6 Age vs. Event Specificity	
3.6.1 MedDRA term includes age and event information	
3.6.2 No available MedDRA term includes both age and event information	
3.7 Body Site vs. Event Specificity	
3.7.1 MedDRA term includes body site and event information	
3.7.2 No available MedDRA term includes both body site and event information	
3.7.3 Event occurring at multiple body sites	
3.8 Location-Specific vs. Microorganism-Specific Infection	
3.8.1 MedDRA term includes microorganism and anatomic location	
3.8.2 No available MedDRA term includes both microorganism and anatomic location	
3.9 Modification of Pre-existing Conditions	
3.10 Exposures during Pregnancy and Breast Feeding	
3.10.1 Events in the mother	

Detailed coding instructions

3.10.2 Events in the child or foetus	
3.11 Congenital Terms	
3.11.1 Congenital conditions	
3.11.2 Acquired conditions (not present at birth)	
3.11.3 Conditions not specified as either congenital or acquired	
3.12 Neoplasms	
3.12.1 Do not infer malignancy	
3.13 Medical and Surgical Procedures	
3.13.1 Only the procedure is reported	
3.13.2 Procedure and diagnosis are reported	
3.14 Investigations	
3.14.1 Results of investigations as ARs/AEs	
3.14.2 Investigation results are consistent with diagnosis	
3.14.3 Investigation results not consistent with diagnosis	
3.14.4 Investigation result terms	
3.14.5 Investigation terms without qualifiers	
3.15 Medication Errors, Accidental Exposures and Occupational Exposures	
3.15.1 Medication errors	
3.15.2 Accidental exposures and occupational exposures	
3.16 Misuse, Abuse and Addiction	
3.16.1 Misuse	
3.16.2 Abuse	
3.16.3 Addiction	
3.16.4 Drug diversion	
3.17 Transmission of Infectious Agent via Product	
3.18 Overdose, Toxicity and Poisoning	
3.18.1 Overdose reported with clinical consequences	
3.18.2 Overdose reported without clinical consequences	
3.19 Device-related Terms	
3.19.1 Device-related event reported with clinical consequences	
3.19.2 Device-related event reported without clinical consequences	
3.20 Drug Interactions	
3.20.1 Reporter specifically states an interaction	
3.20.2 Reporter does not specifically state an interaction	
3.21 No Adverse Effect and “Normal” Terms	
3.21.1 No adverse effect	
3.21.2 Use of “normal” terms	
3.22 Unexpected Therapeutic Effect	
3.23 Modification of Effect	
3.23.1 Lack of effect	
3.23.2 Do not infer lack of effect	
3.23.3 Increased, decreased and prolonged effect	
3.24 Social Circumstances	
3.24.1 Use of terms in this SOC	
3.24.2 Illegal acts of crime or abuse	
3.25 Medical and Social History	
3.26 Indication for Product Use	
3.26.1 Medical conditions	
3.26.2 Complex indications	
3.26.3 Indications with genetic markers or abnormalities	
3.26.4 Prevention and prophylaxis	
3.26.5 Procedures and diagnostic tests as indications	
3.26.6 Supplementation and replacement therapies	
3.26.7 Indication not reported	
3.27 Off Label Use	
3.27.1 Off label use when reported as an indication	
3.27.2 Off label use when reported with an AR/AE	
3.28 Product Quality Issues	
3.28.1 Product quality issue reported with clinical consequences	
3.28.2 Product quality issue reported without clinical consequences	
3.28.3 Product quality issue vs. medication error	
SECTION 4 – APPENDIX	
4.1 Versioning	
4.1.1 Versioning methodologies	
4.1.2 Timing of version implementation	
4.2 Links and References	





MedDRA

General term selection principles



Lowest Level Term that most accurately reflects the reported verbatim information should be selected



Select current LLTs only



Degree of specificity may be challenging



Use medical judgment when appropriate



Avoid company-specific “work-arounds” for MedDRA deficiencies



Submit change request to MSSO



MedDRA

General term selection principles



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



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	





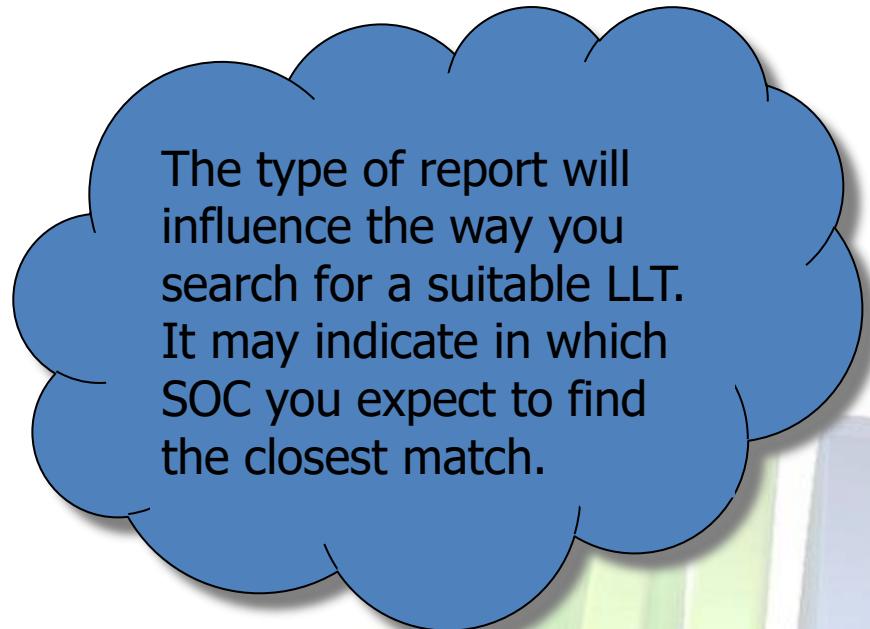
Coding: Translating into MedDRA

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



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?**



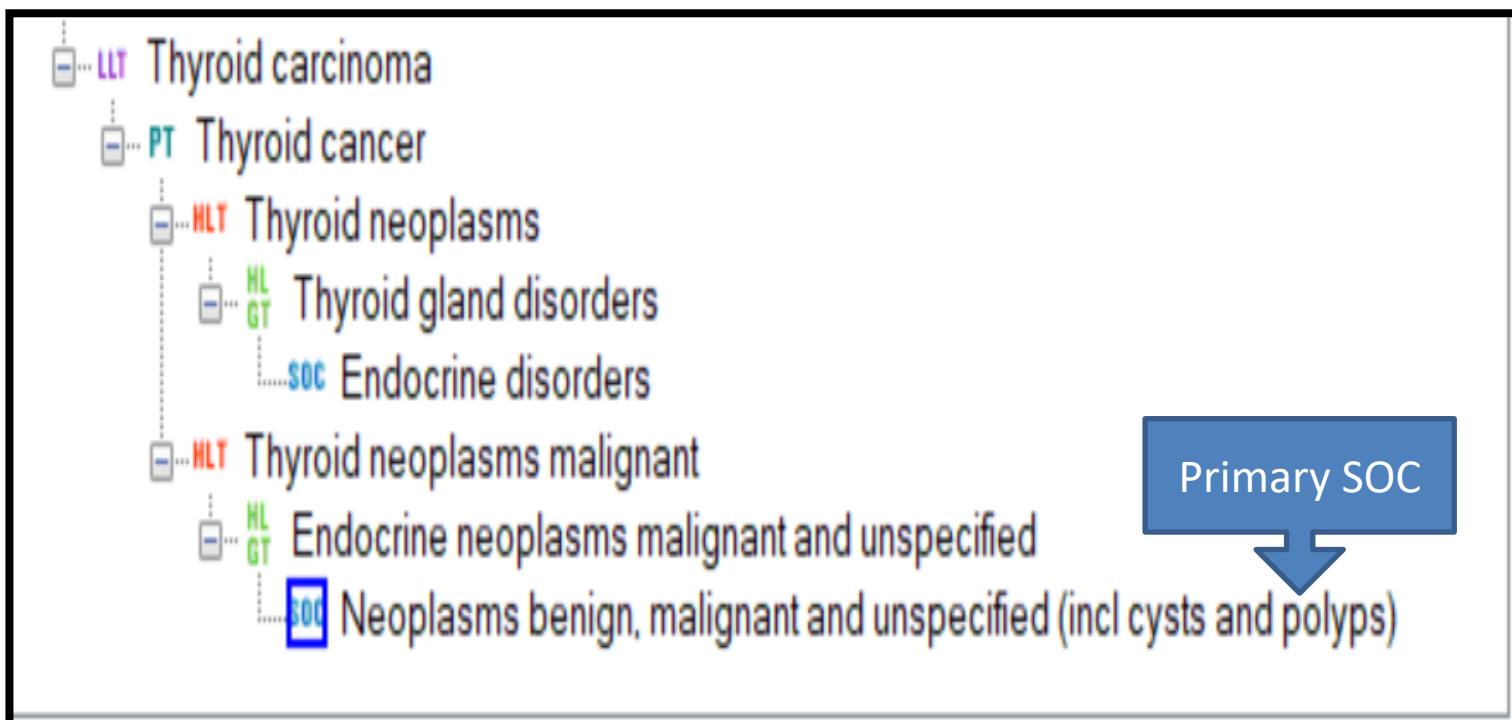
The type of report will influence the way you search for a suitable LLT. It may indicate in which SOC you expect to find the closest match.



MedDRA

How to code? Example:

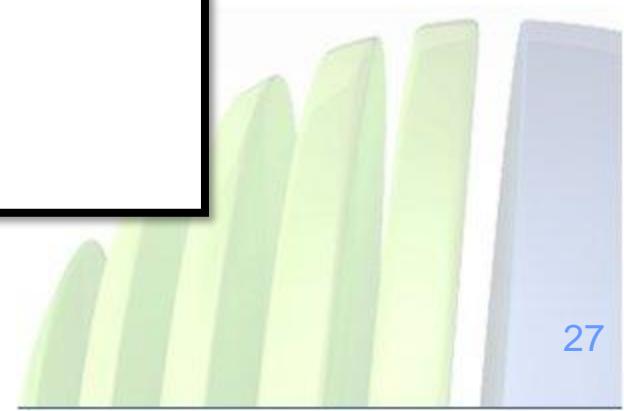
- Verbatim: THYROID CARCINOMA
 - Coded to LLT : Thyroid carcinoma





How to code? Example:

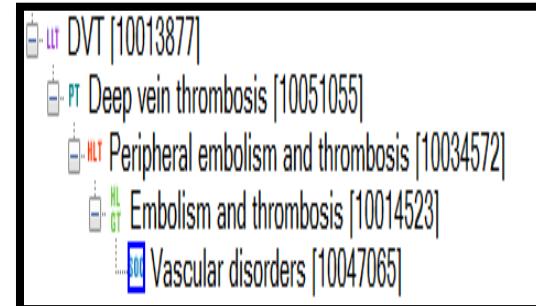
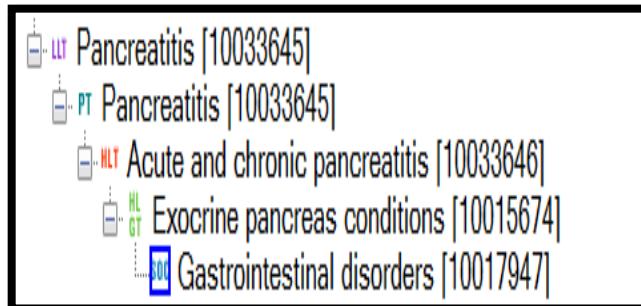
- Verbatim: The patient suffered from an allergic reaction to an antibiotic
 - Coded to LLT : Allergic reaction to antibiotics





How to code? Example:

- Verbatim: 03/19/2012: Patient was hospitalized with severe upper abdominal burning pain radiating to the back, nausea, and vomiting that worsened with eating. Upon further investigation her serum amylase levels were found to be elevated and was diagnosed with Pancreatitis. During the hospitalization she was also found to have DVT.
 - Coded to
 - 1. LLT : Pancreatitis
 - 2. LLT : DVT





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



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How to code? Example:

Symptoms

The patient states she has been experiencing cold
sweats



Investigations

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



MedDRA

What LLT would you Select ? "A 2 day old baby was noted to have a mild fever"

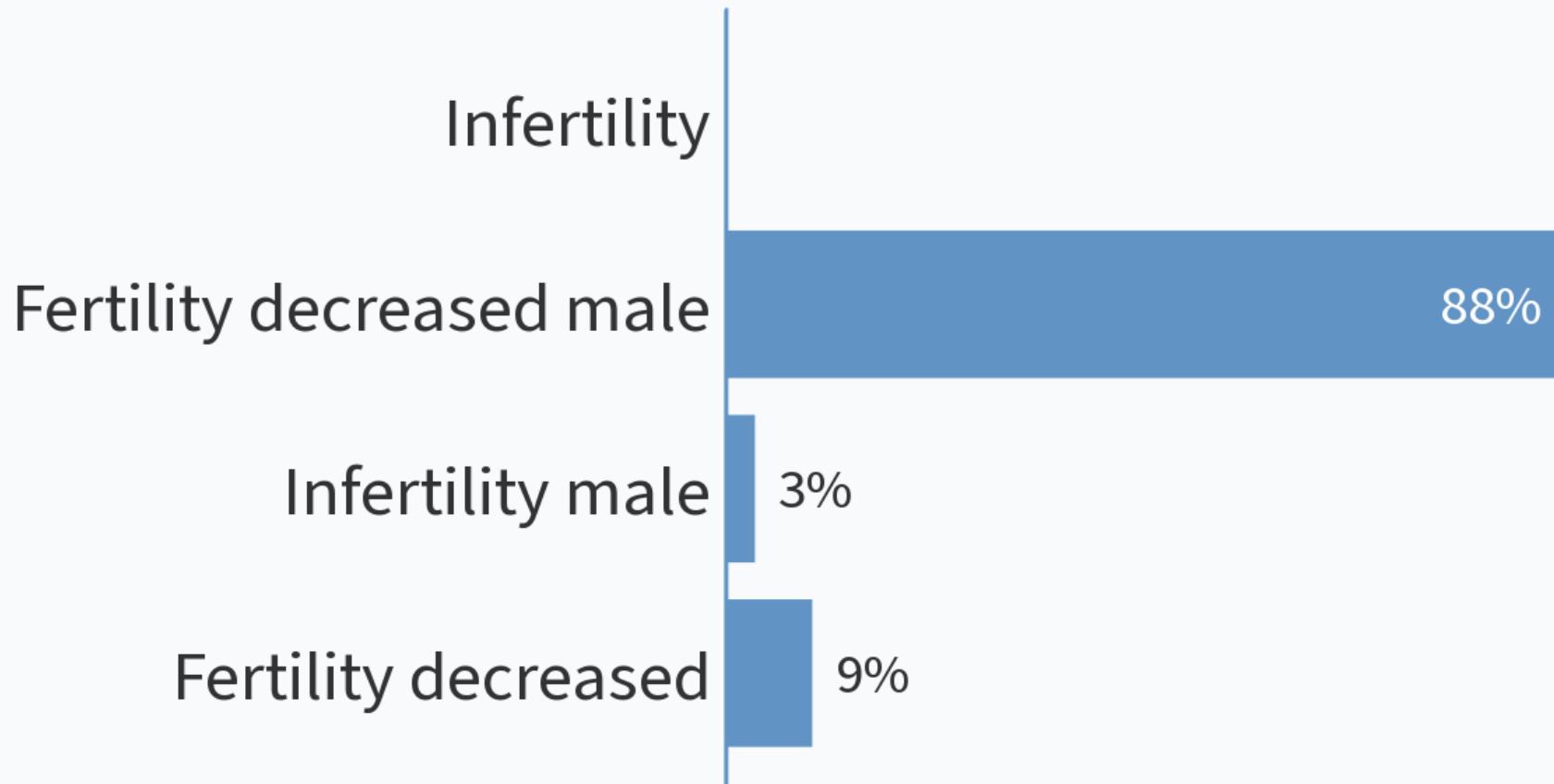


Reported term: 'Abuse'

Code
Seek
clarification



"Man with decreased fertility."





Deliberately took an overdose

Intentional overdose

16%

Suicide attempt

Deliberate overdose

81%

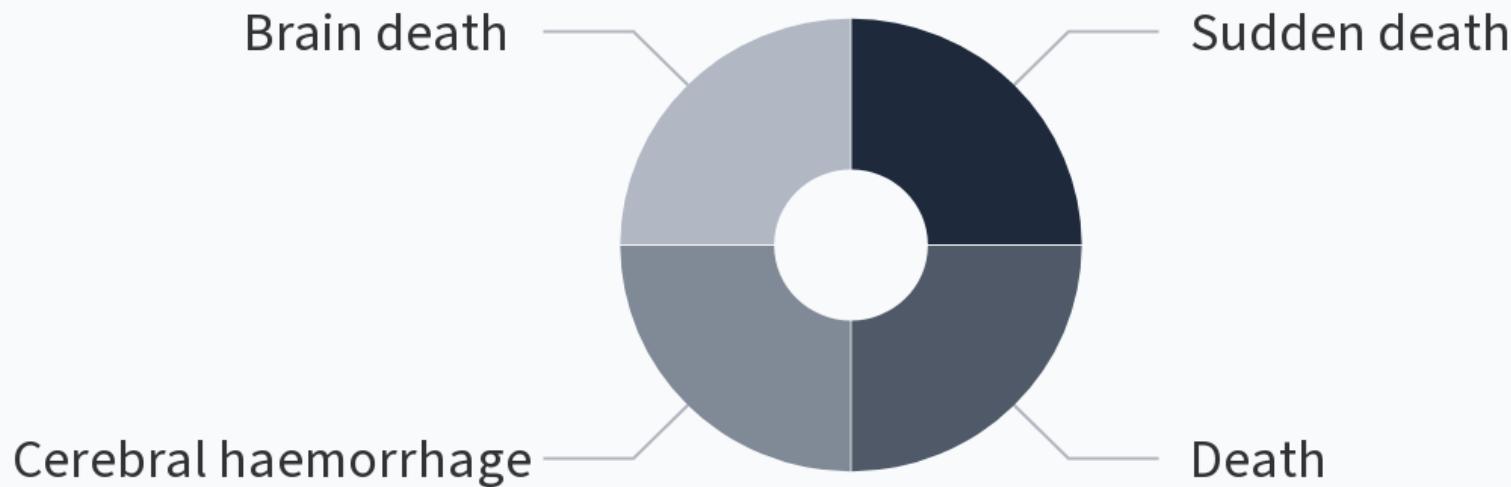
Overdose NOS

3%



Verbatim: "Death from cerebral haemorrhage"

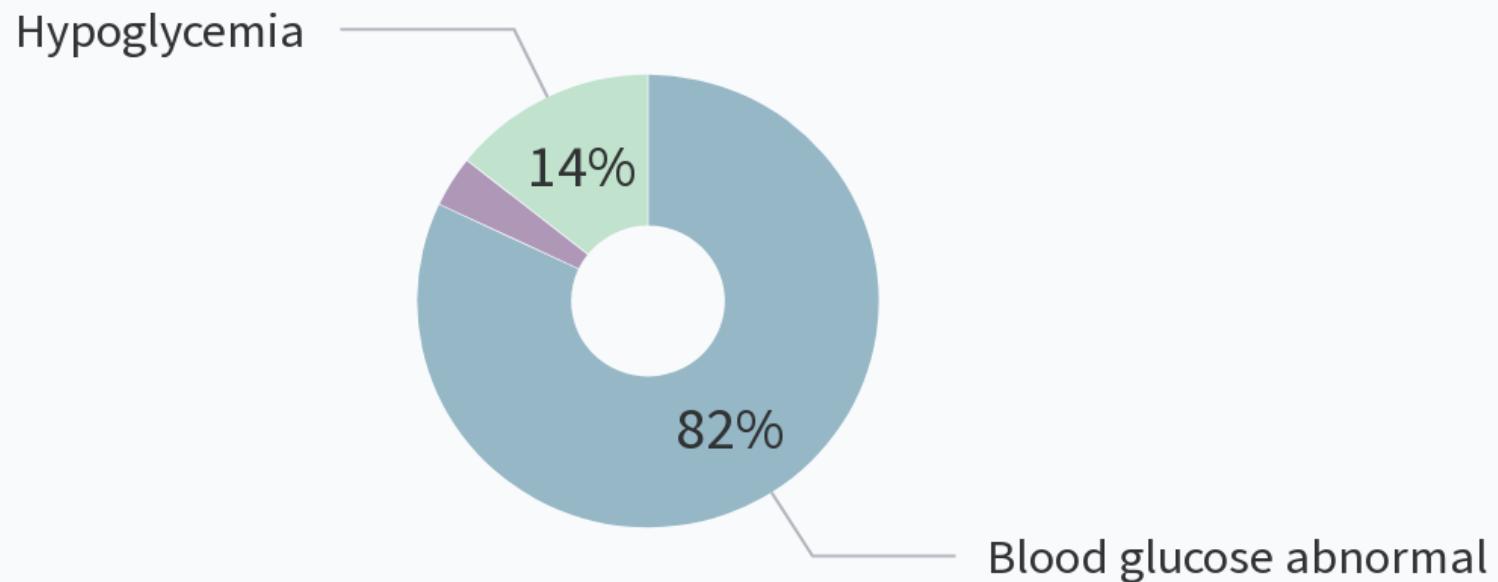
Sudden death Death Cerebral haemorrhage Brain death





Hypoglycemia (blood glucose = 200 mg/dL)

Blood glucose abnormal Blood glucose increased Hypoglycemia



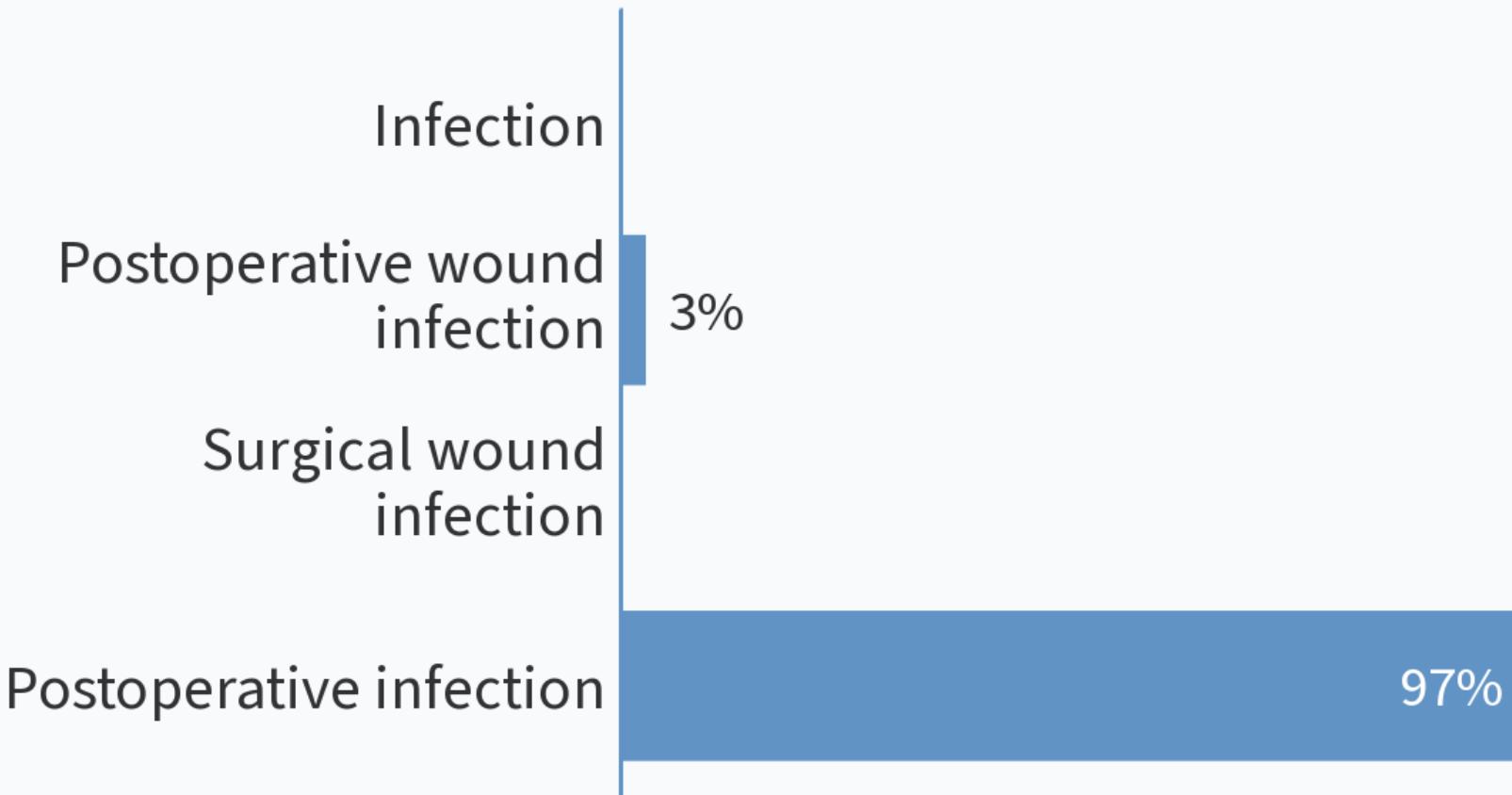


Took intramuscular drug by mouth

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



"Infection after surgery"





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What LLT would you Choose ? "The patient was confined to a wheelchair"



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How would you handle this report?

A diabetic patient is anxious about his XXXX vaccination appointment, so he forgets that he took his morning insulin and administers a second dose. At the vaccination clinic, the diabetic patient seems confused, looks pale, and is sweaty.





How would you handle this report?

1. Select 4 LLTs: Extra dose administered AND Confusion AND Looked pale AND Sweating
2. Select LLT Hypoglycemic attack
3. Select LLT Medication error
4. Select LLT Vaccination adverse reaction
5. Select LLT Panic attack
6. Query the site



MedDRA

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



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

“ Accidental exposure of drug ”

“ Accidental ingestion of product ”

“ Accidental ingestion of drug ”

“ Accidental ingestion of drug ”



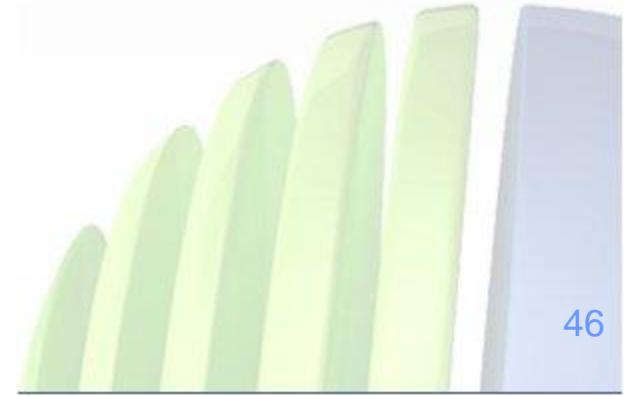
"The patient developed hyponatraemia while hospitalised"



MedDRA

What Terms to Select?

“Spray it in the nose as much as you can, and the septum is gone !! ”





One of this terms was not reported for coding. Guess which one :)

- Recurrent fatal stroke
- Barely visible posterior
- Normally normal after drinking coffee
- Seeing people in room, seeing chickens at window
- Wanting to crawl out of your skin
- Went to hell
- Died of cancer of the placebo



MedDRA Data Retrieval and Presentation: Points to Consider (DRP:PTC)

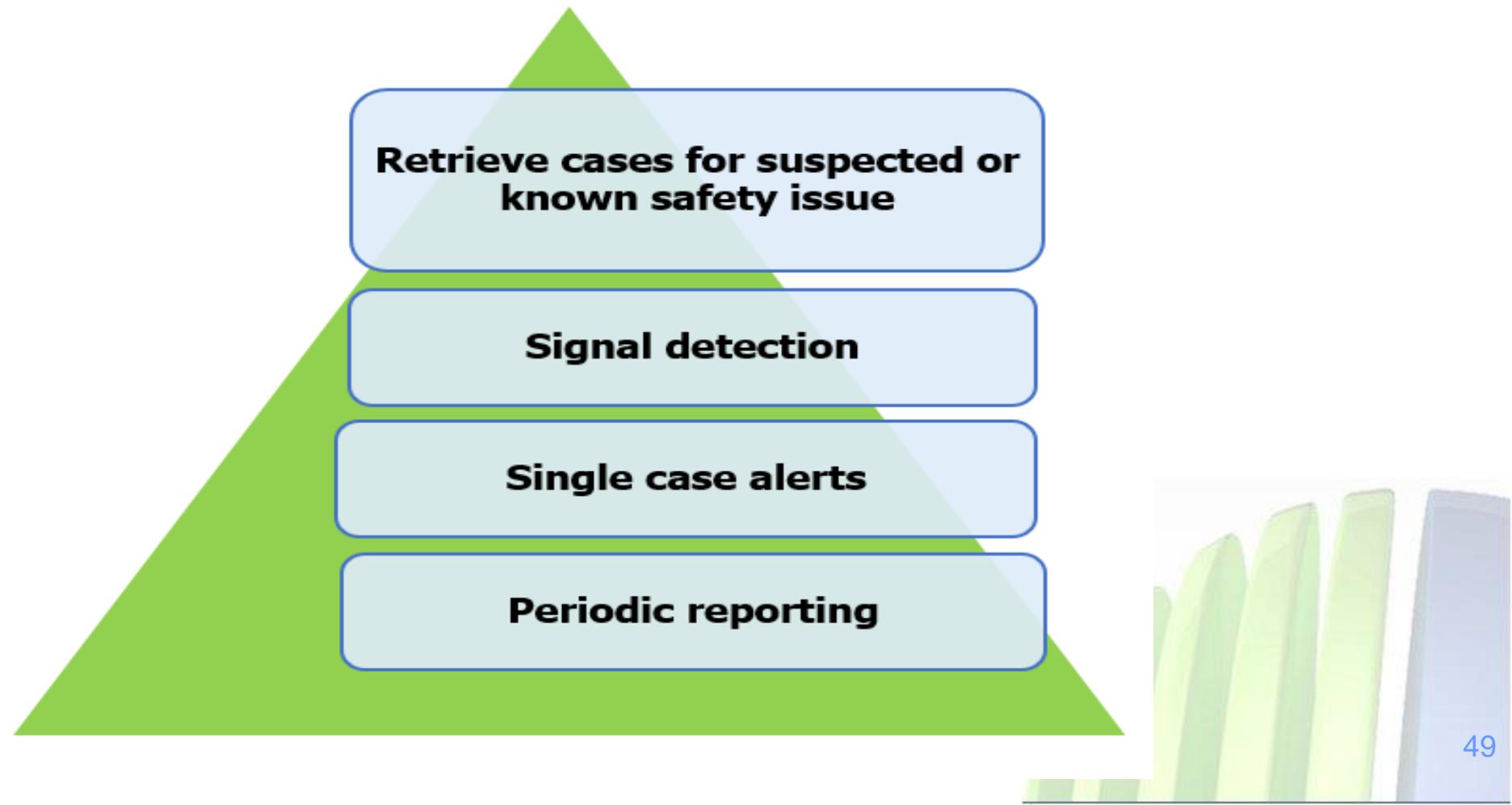
Provides data retrieval and presentation options for industry or regulatory purposes

Most effective when used in conjunction with MedDRA Term Selection: PTC document

Recommended to be used as basis for individual organization's own data retrieval conventions



Standardised MedDRA Queries (SMQs) in Pharmacovigilance



Periodic reporting



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Know more?

www.meddra.org



**MedDRA**

Medical Dictionary for
Regulatory Activities

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Select a language: **English**

Additional Points to Consider Documents and MedDRA Best Practices Document (click here)

MedDRA Version 24.0 March 2021

MedDRA Version 23.1 September 2020

MedDRA Version 23.0 English March/April 2020

MedDRA Version 22.1 English September 2019

MedDRA Version 22.0 English March 2019

MedDRA Version 21.1 English September 2018

MedDRA Version 21.0 English March 2018

MedDRA Version 20.1 English September 2017

MedDRA Version 20.0 English March 2017

MedDRA Version 19.1 English September 2016

MedDRA Version 19.0 English March 2016

MedDRA Version 18.1 English September 2015

Training Materials / [Training](#) / [Home](#)

MedDRA training materials are available as presentations and videocasts for streaming to your computer (.wmv) or for downloading (.zip).

General / Basics

> Topic

Coding

> Topic

Retrieval / Analysis (SMQs)

> Topic

MedDRA Versioning

> Topic

Tools

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Contributions from MedDRA User Groups

A number of useful training materials (presentations and recordings) are developed for User Groups and are available for download on the User Group page.

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