



MedDRA

Introduction to MedDRA

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Induction-cum-Training Programme on Pharmacovigilance -27th August 2021

National Coordination Centre-Pharmacovigilance Programme of India

Indian Pharmacopoeia Commission





MedDRA

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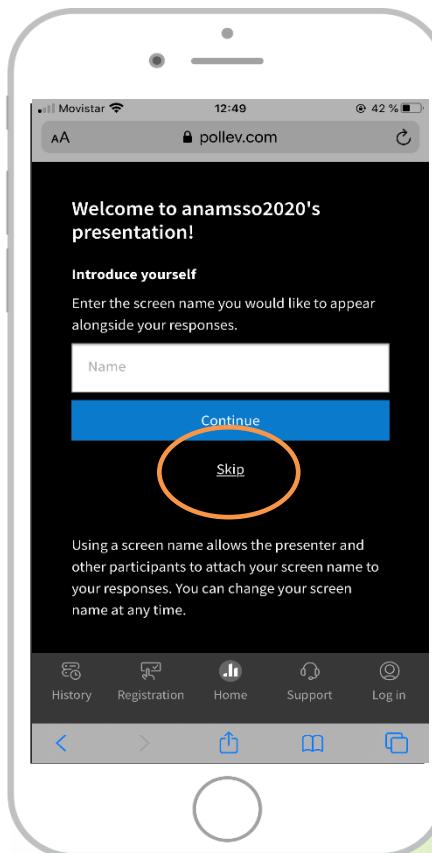
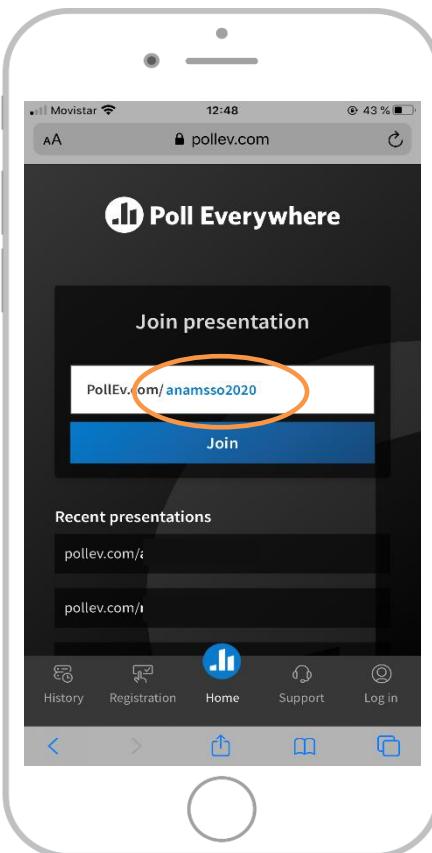
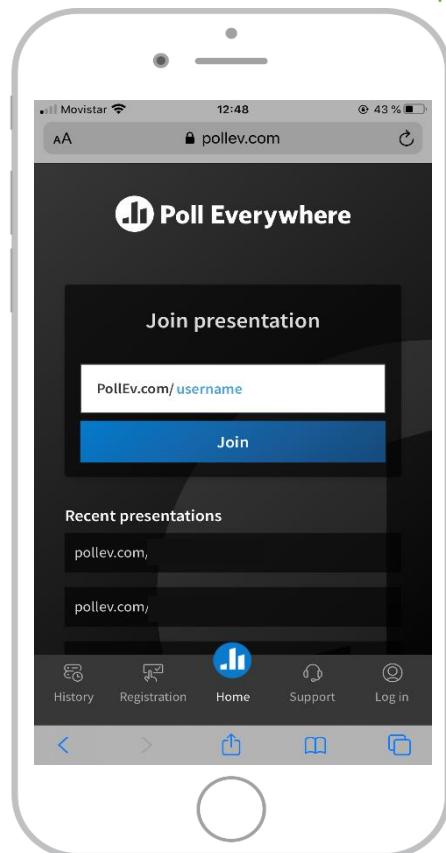


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MedDRA

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2. Go to **PollEv.com**

3. Enter **anamikadutta561** as the "username"
4. Click **Join**

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



MedDRA

Scan me to participate !





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Start the presentation to see live content. For screen share software, share the entire screen. Get help at pollev.com/app



Why code??





What do you see?





How Many Cases of Autoimmune Diseases?

Subject ID	Adverse Event	Subject ID	Adverse Event	Subject ID	Adverse Event	Subject ID	Adverse Event
10000	Antiphospholipid syndrome	10026	Hashimoto's	10024	Inclusion body myositis	10069	Periorbital lupus
10001	Cold type haemolytic anaemia	10027	Marine Lenhart syndrome	10025	Type 1 diabetes mellitus	10070	Neuropsychiatric lupus
10002	Coombs positive haemolytic anaemia	10028	Polymyositis	10026	Hashitoxicosis	10071	Lupus myocarditis
10003	Pernicious anaemia	10029	Hashimoto's encephalopathy	10027	Marine Lenhart syndrome	10072	Lupus hepatitis
10004	Warm type haemolytic anaemia	10030	Basedow's disease	10028	Autoimmune pancreatitis	10073	Lupus enteritis
10005	Evans syndrome		Atrophic thyroiditis	10029	Hashimoto's encephalopathy	10074	Shrinking lung syndrome
10006	Addison's disease	10031	Polyglandular autoimmune syndrome type I	10029	Marine Lenhart syndrome	10075	Lupus pancreatitis
10007	Autoimmune pancytopenia	10017	Polyglandular autoimmune syndrome type II	10030	Atrophic thyroiditis	10076	Butterfly rash
10008	Cholangitis sclerosing	10018	Juvenile polymyositis	10031	Myasthenia gravis	10077	Lupus pleurisy
10009	Autoimmune haemolytic anaemia	10020	Diabetic mastopathy	10033	Silent thyroiditis	10078	Lupus cystitis



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

What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities

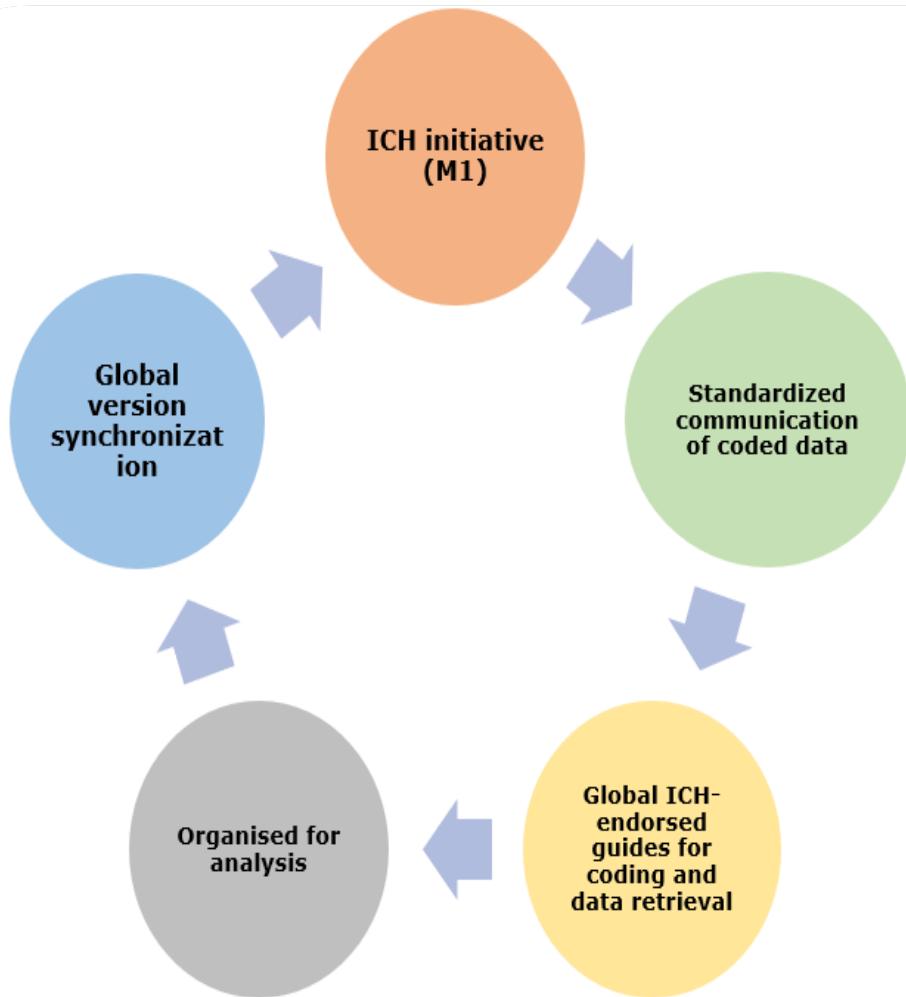


MedDRA is a clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation.



MedDRA

Why MedDRA?





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



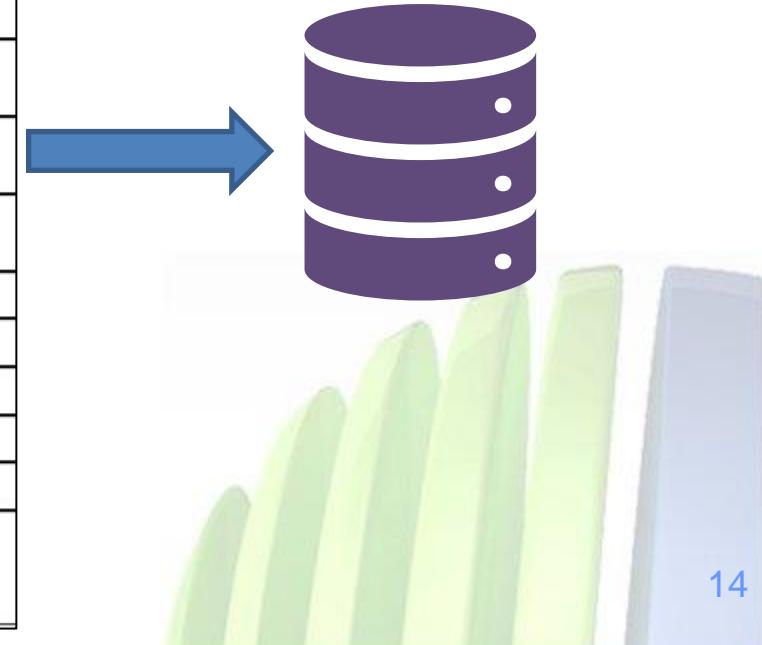
MedDRA

Where MedDRA is Used (Contd)

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

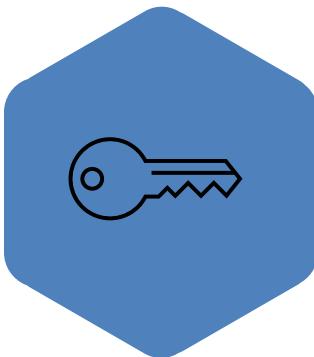
Element id	Element Name
D.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code)
D.8.r.6b	Indication (MedDRA code)
D.8.r.7b	Reaction (MedDRA code)
D.9.2.r.1b	Reported Cause(s) of Death (MedDRA code)
D.9.4.r.1b	Autopsy-determined Cause(s) of Death (MedDRA code)
D.10.7.1.r.1b	Medical 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



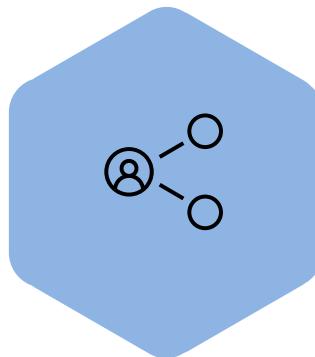


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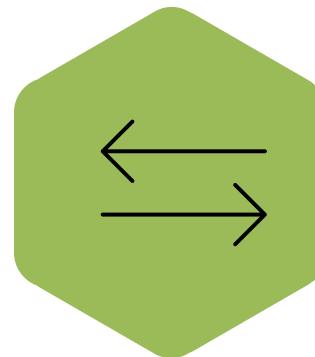
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Contact Information

Main point of contact

First Name: *

Last Name: *

Street, No: *

City: *

Province/State: *

Postal/Zip Code:

Country: *

Phone: *



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)





Scope of MedDRA

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



Frequency qualifiers

Numerical values for results

Severity descriptors

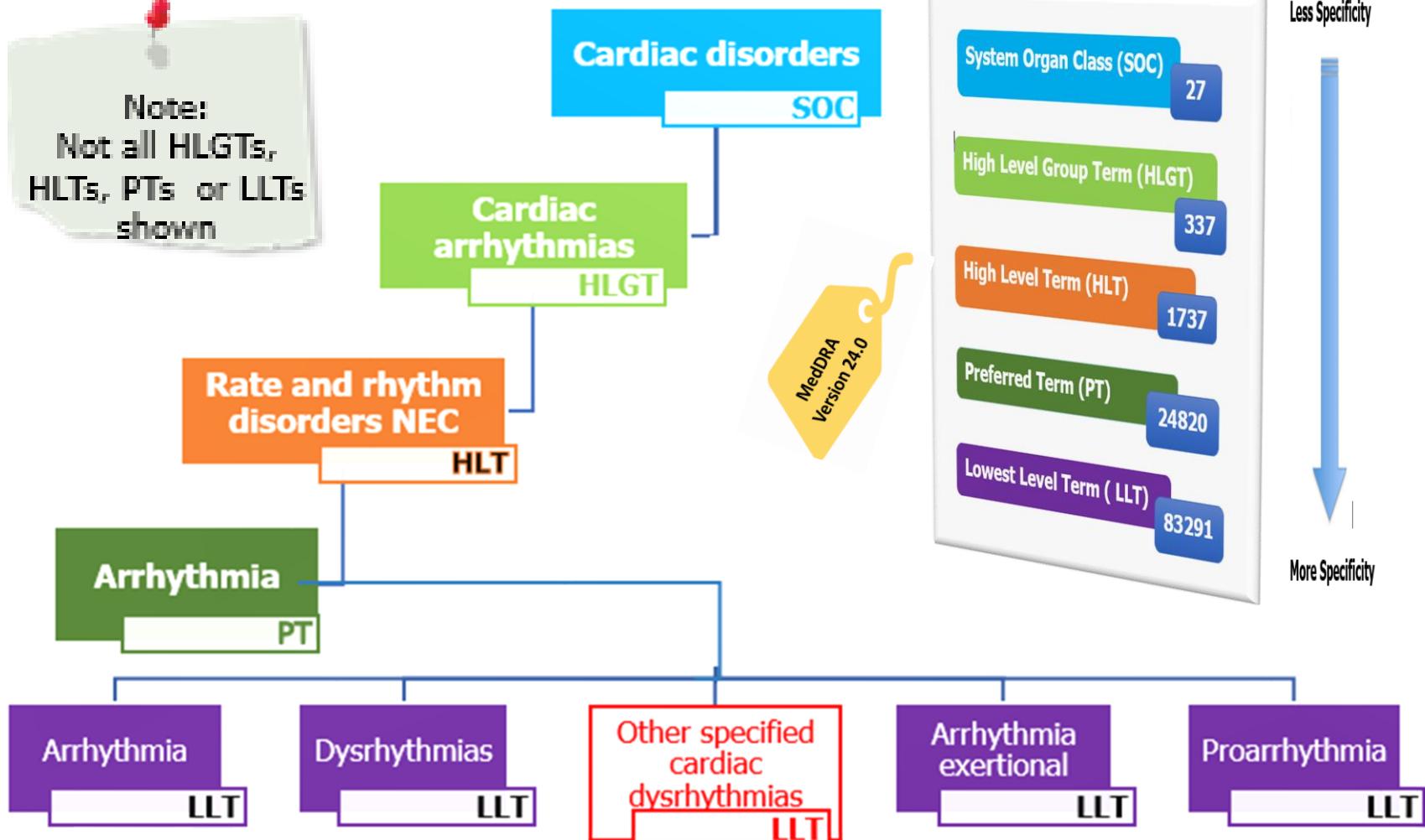
Not an equipment, device, diagnostic product dictionary



MedDRA

MedDRA Structure

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

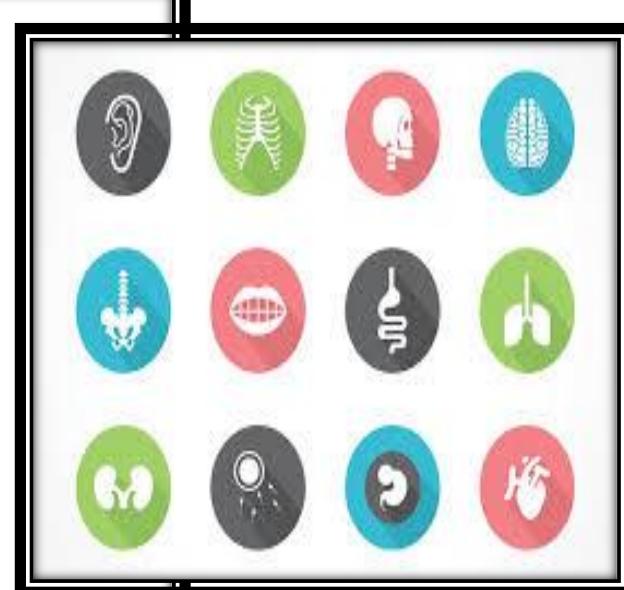




MedDRA

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



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MedDRA

MedDRA Codes and Languages

	Kopfschmerz	Fejfájás
	German	Hungarian
Cefaleia		
Portuguese		
Hoofdpijn		
Dutch		
Headache		
English		
Céphalée		
French		
Bolest hlavy		
Czech		
头痛		
Chinese		



Electronic Submission

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

A Multi-Axial Terminology

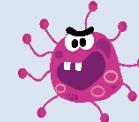
SOC = Respiratory, thoracic and mediastinal disorders
(Secondary SOC)



HLGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

SOC = Infections and infestations
(Primary SOC)



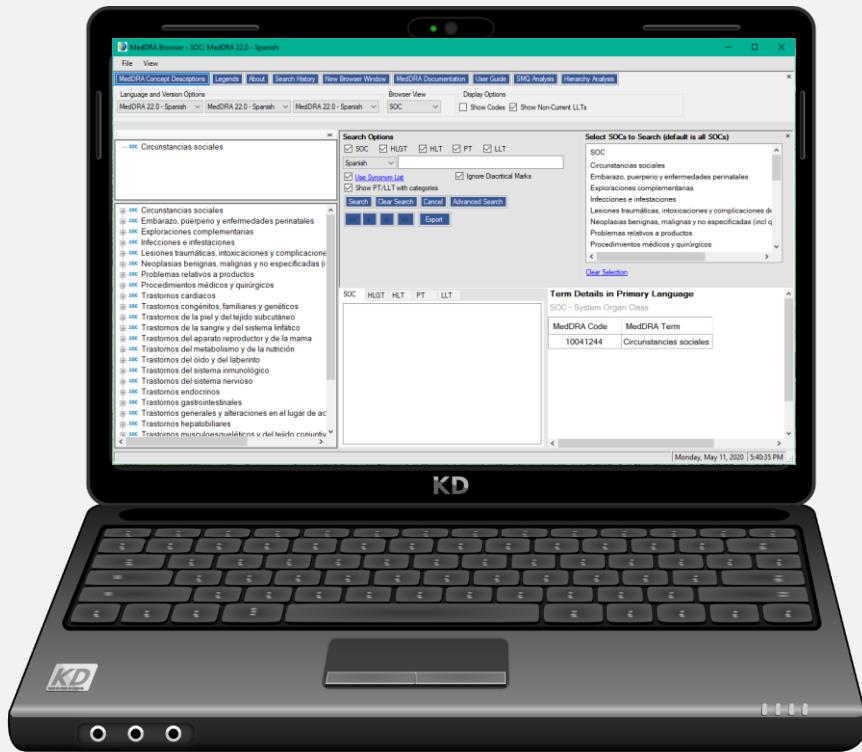
HLGT = Viral infectious disorders

HLT = Influenza viral infections



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/>



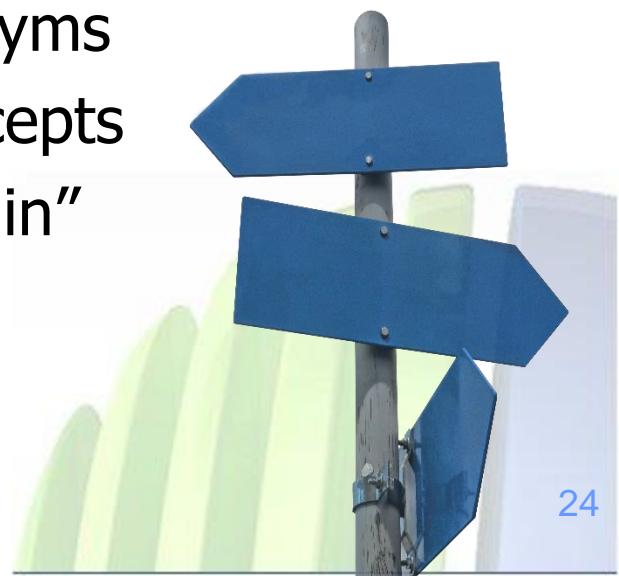
Mobile MedDRA Browser

<https://mmb.meddra.org>



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)

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

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 that are not 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	





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



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



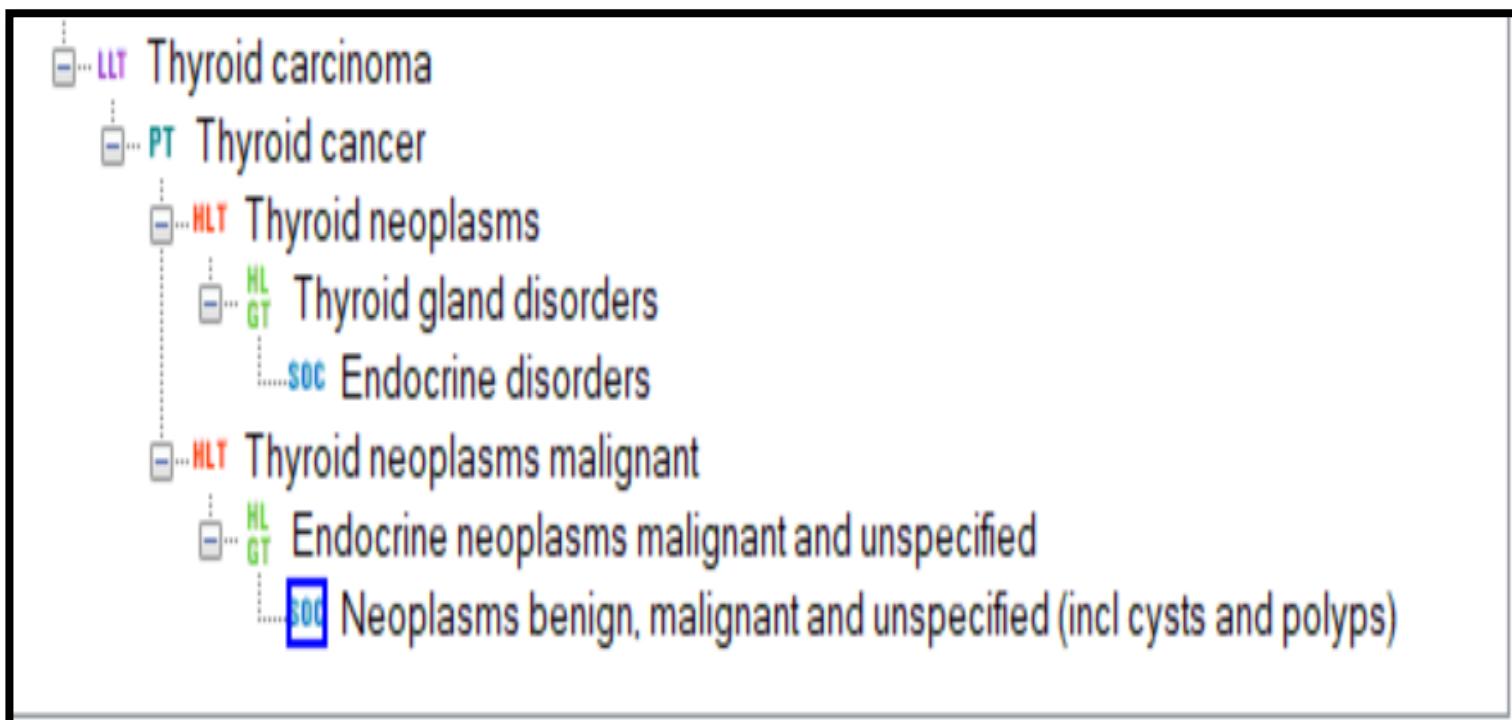
Submit change request to MSSO



MedDRA

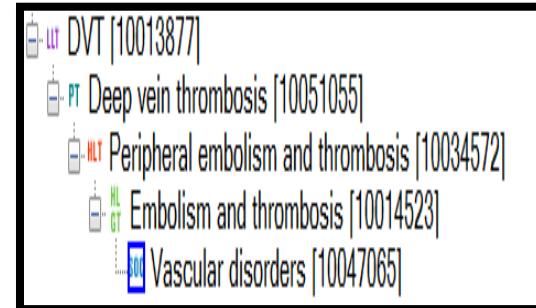
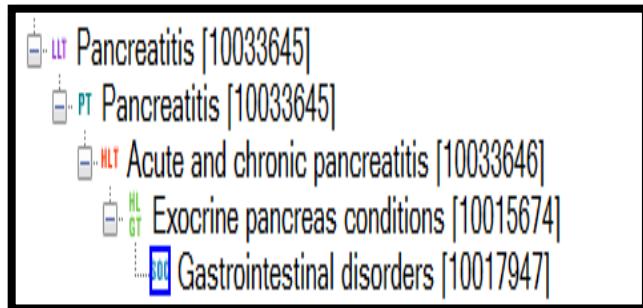
How to code with MedDRA? Example:

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



How to code with MedDRA? Example:

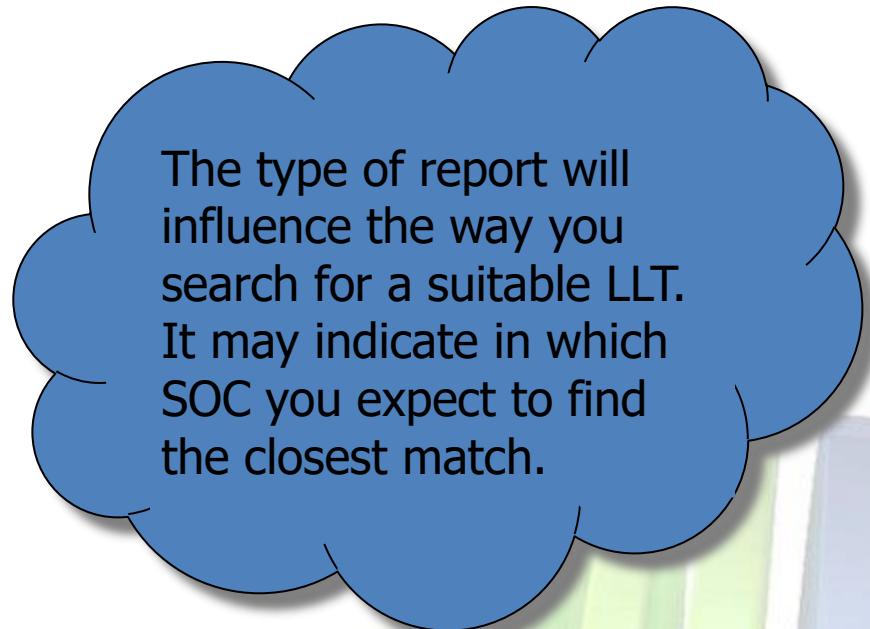
- Verbatim: 03/19/2012: Patient was hospitalized with severe upper abdominal burning pain radiating to the back, nausea, and vomiting that worsened with eating. Upon further investigation her serum amylase levels were found to be elevated and was diagnosed with Pancreatitis. During the hospitalization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





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.

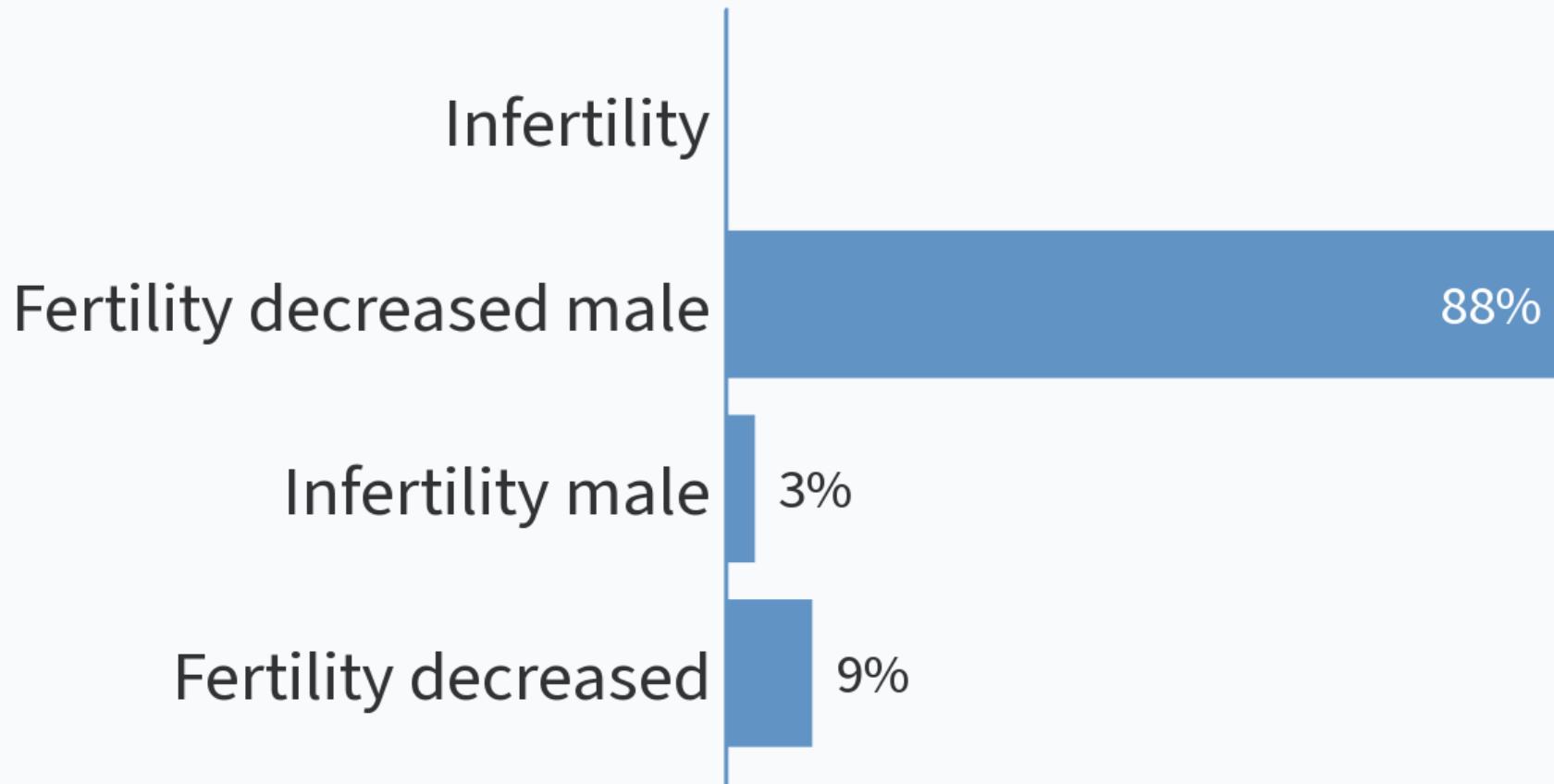


Reported term: 'Abuse'

Code
Seek
clarification



"Man with decreased fertility."





Deliberately took an overdose

Intentional overdose

16%

Suicide attempt

Deliberate overdose

81%

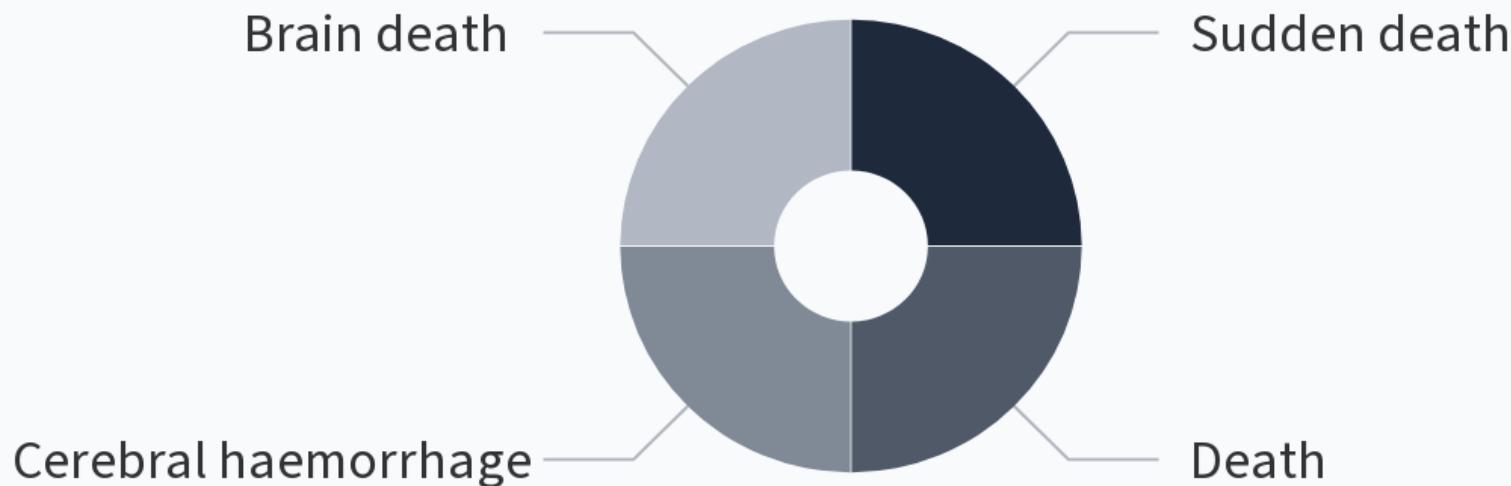
Overdose NOS

3%



Verbatim: "Death from cerebral haemorrhage"

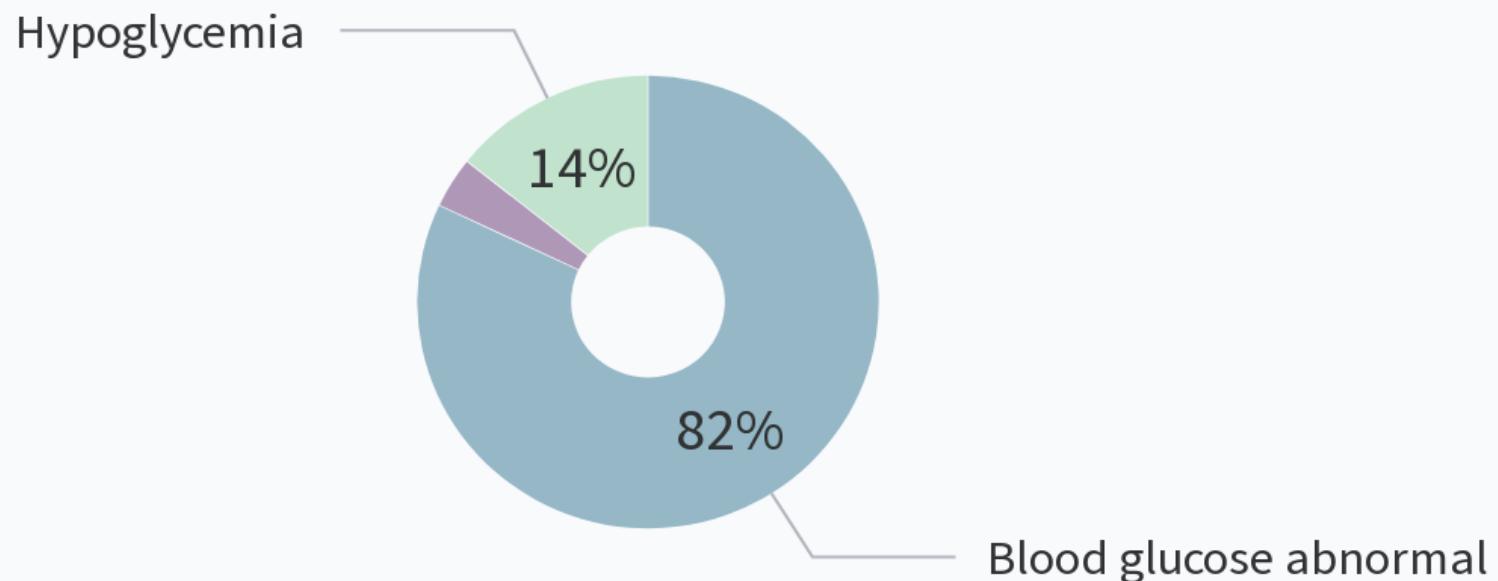
Sudden death Death Cerebral haemorrhage Brain death





Hypoglycemia (blood glucose = 200 mg/dL)

Blood glucose abnormal Blood glucose increased Hypoglycemia



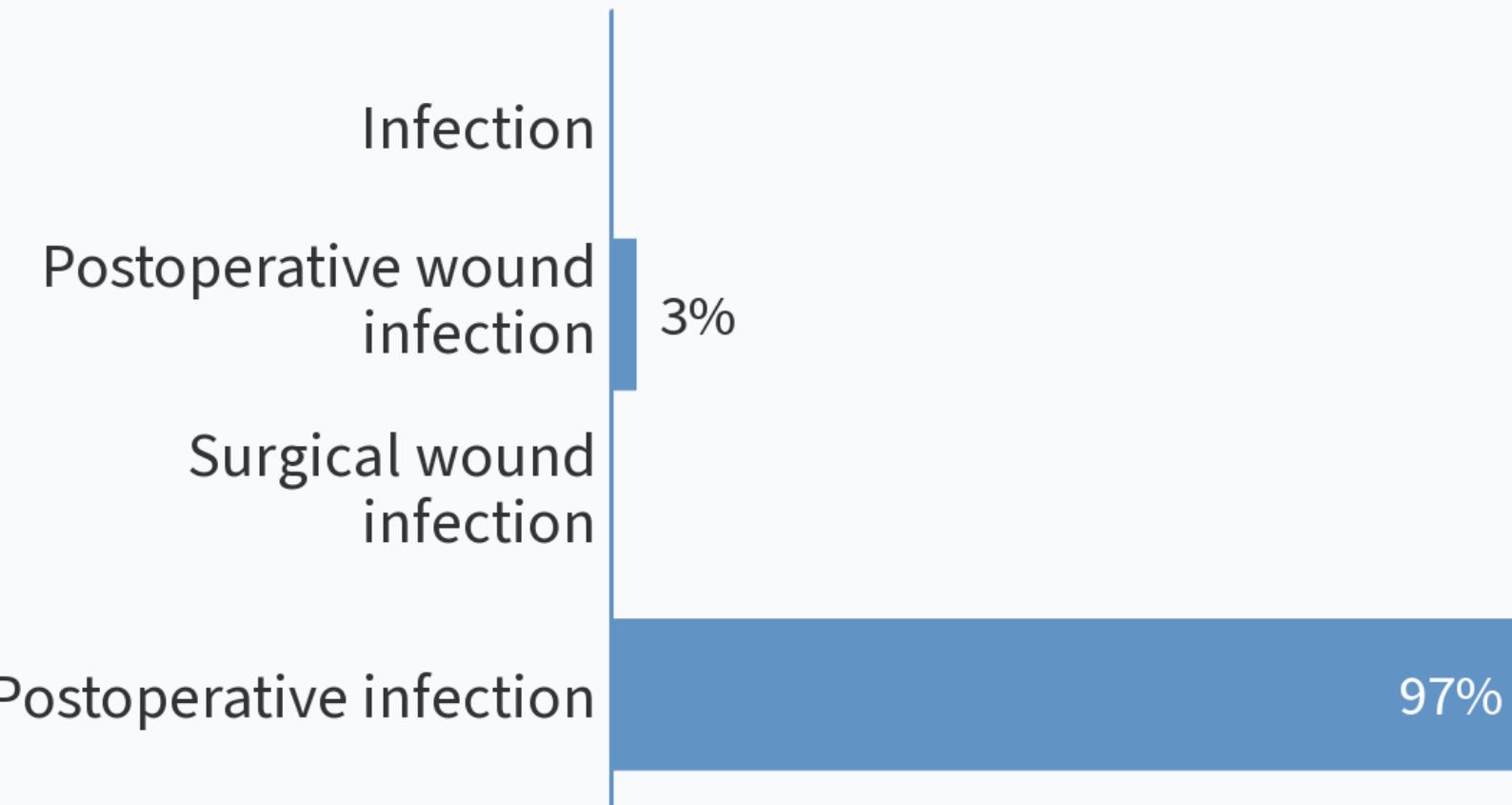


Took intramuscular drug by mouth

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



"Infection after surgery"





"Spray it in the nose as much as you want and the Septum is gone!!!"



Which of these reported "Animal Pharma events" is your favourite?

Deer ria

Pees like a camel

Hippo tension

Red wine tastes like fox urine

Menstrual clams

Seeing stars and chicken farting



MedDRA

How is MedDRA Used for Analysis?

MedDRA can be used to summarise large volumes of data

- *Standard approach*
List data at PT and SOC levels for overview



Focused searches can be made using features of MedDRA

- *Selecting specific PTs*
- *Summarising at HLT or HLGT levels*
- *Using multiaxial links*
- *Using Standardised MedDRA Queries*
- *Customized search*
- *Modified MedDRA Queries*



MedDRA

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

MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users on Data Output

Release 3.21

March 2021

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



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

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MedDRA

Medical Dictionary
for Regulatory Activities

Thank You!!

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