Introduction to MedDRA Coding

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Skill Development Programme-08 March 2022
Indian Pharmacopoeia Commission, Ghaziabad

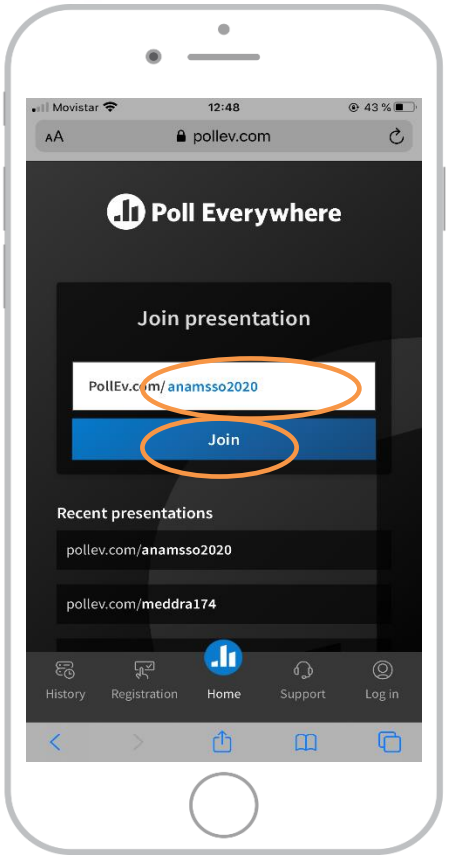


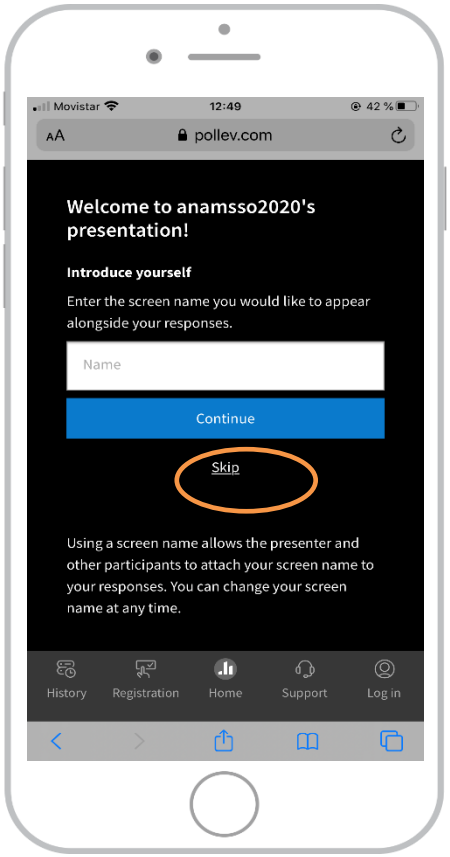
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What is coding?



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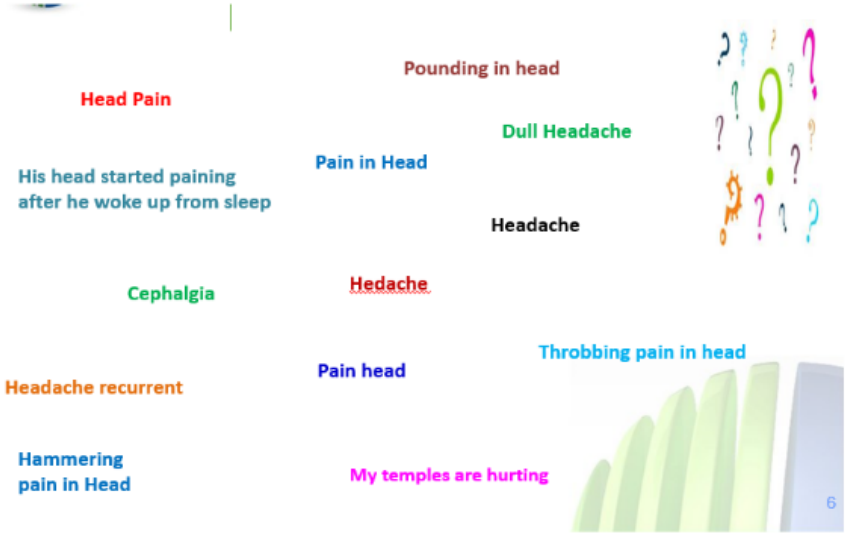
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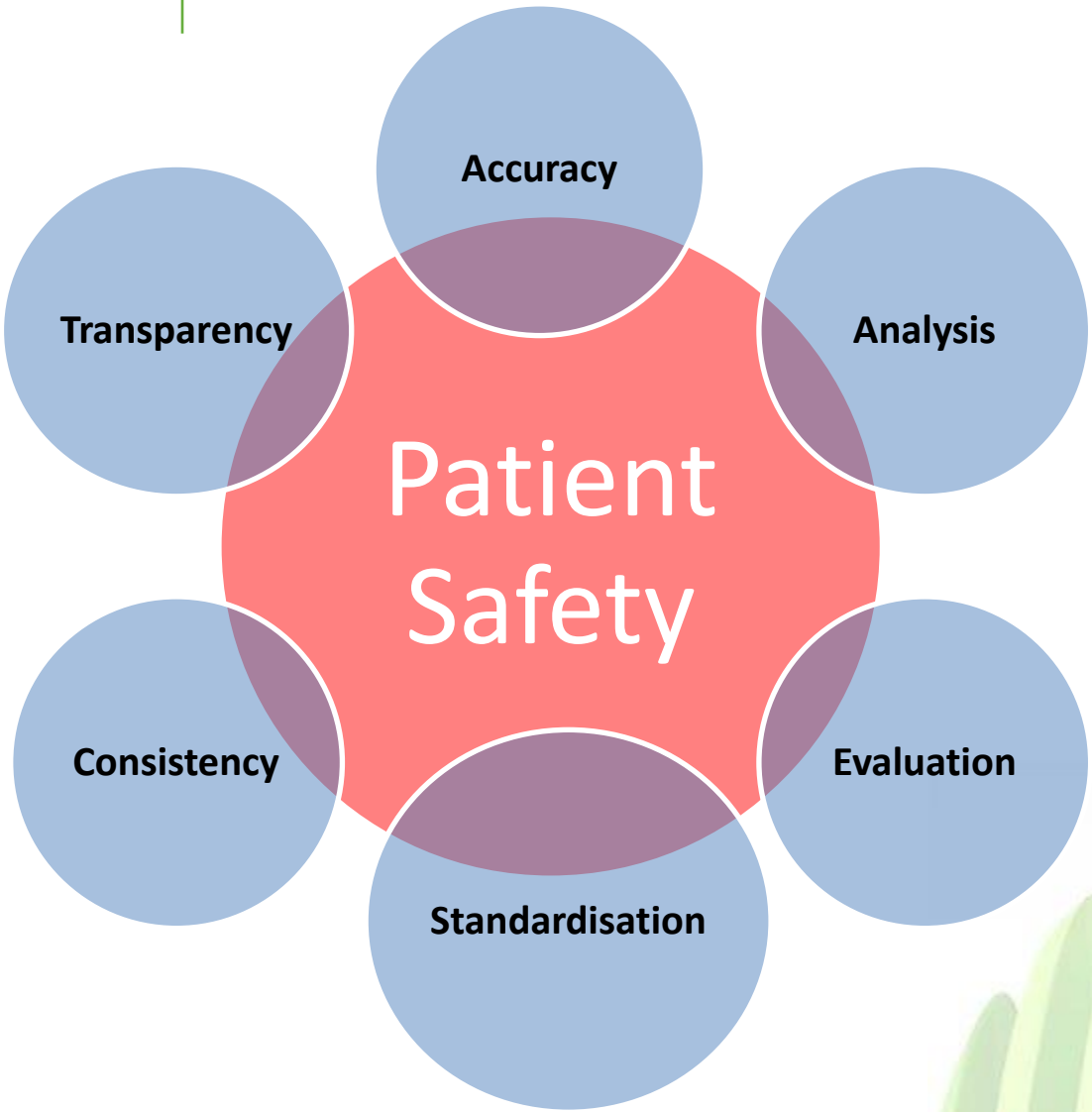


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How many cases of Headache??



Why code?


Accuracy
Transparency
Analysis
Patient Safety
Consistency
Evaluation
Standardisation

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

What is MedDRA?

Med = Medical

D = Dictionary for

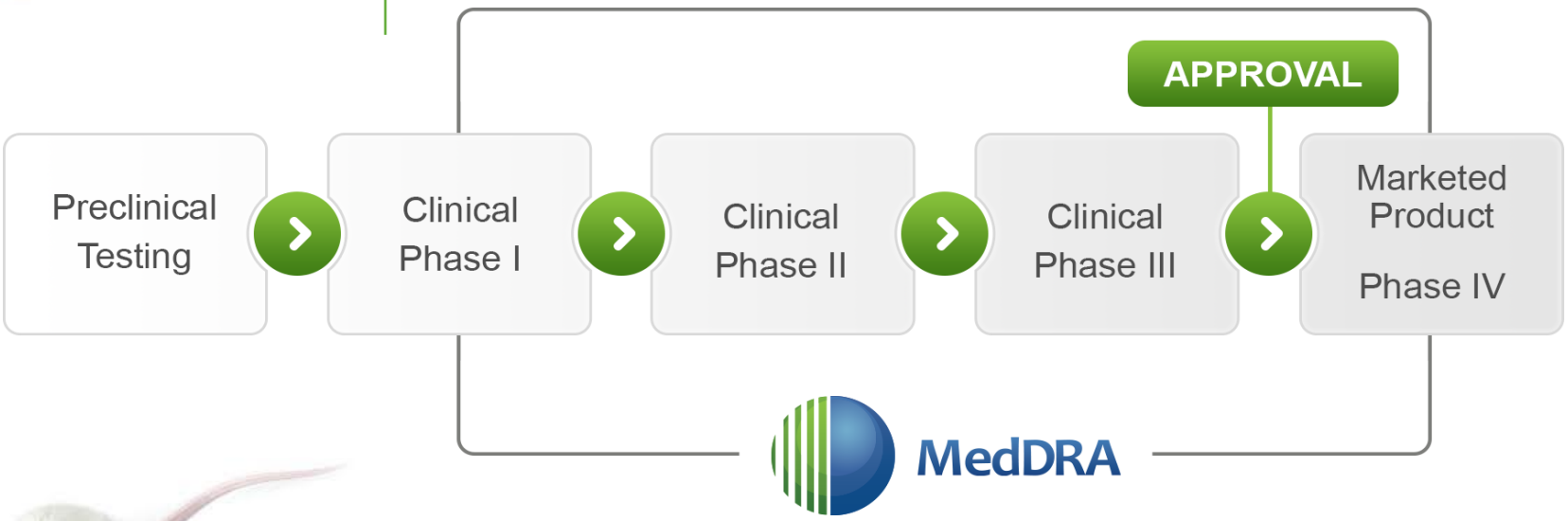
R = Regulatory

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.

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

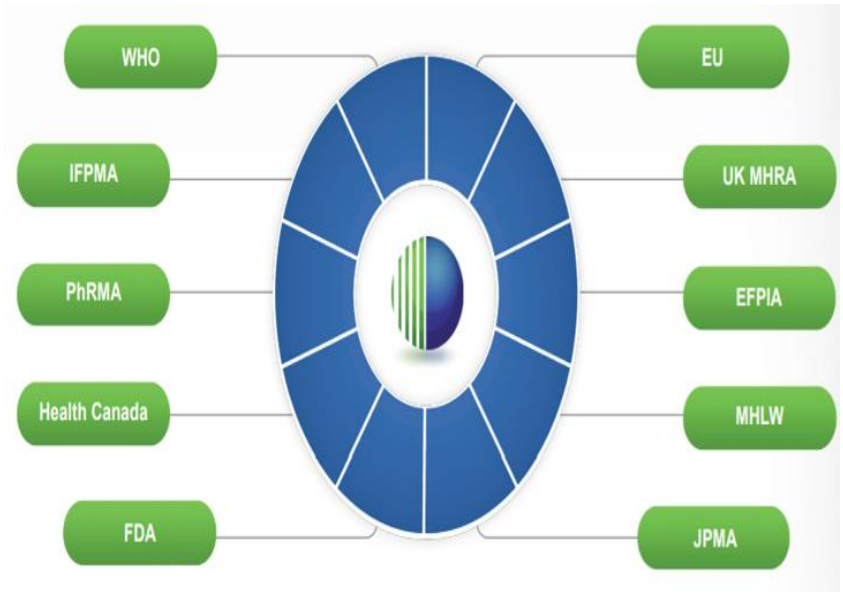
Advertising

MedDRA Governance & the MSSO

Governed by a Management comittee

International support & development terminology

"Custodians" of the terminology



Foster use of MedDRA

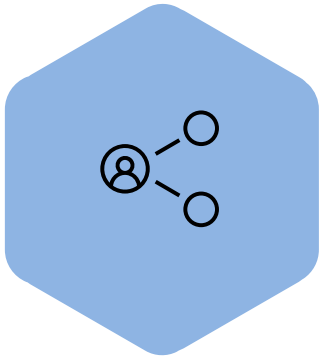
JMO for MedDRA Japanese

MedDRA Data Sharing



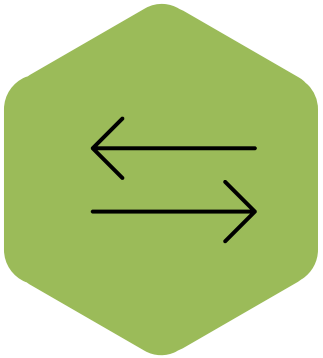
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Last Name: *

Street, No: *

City: *

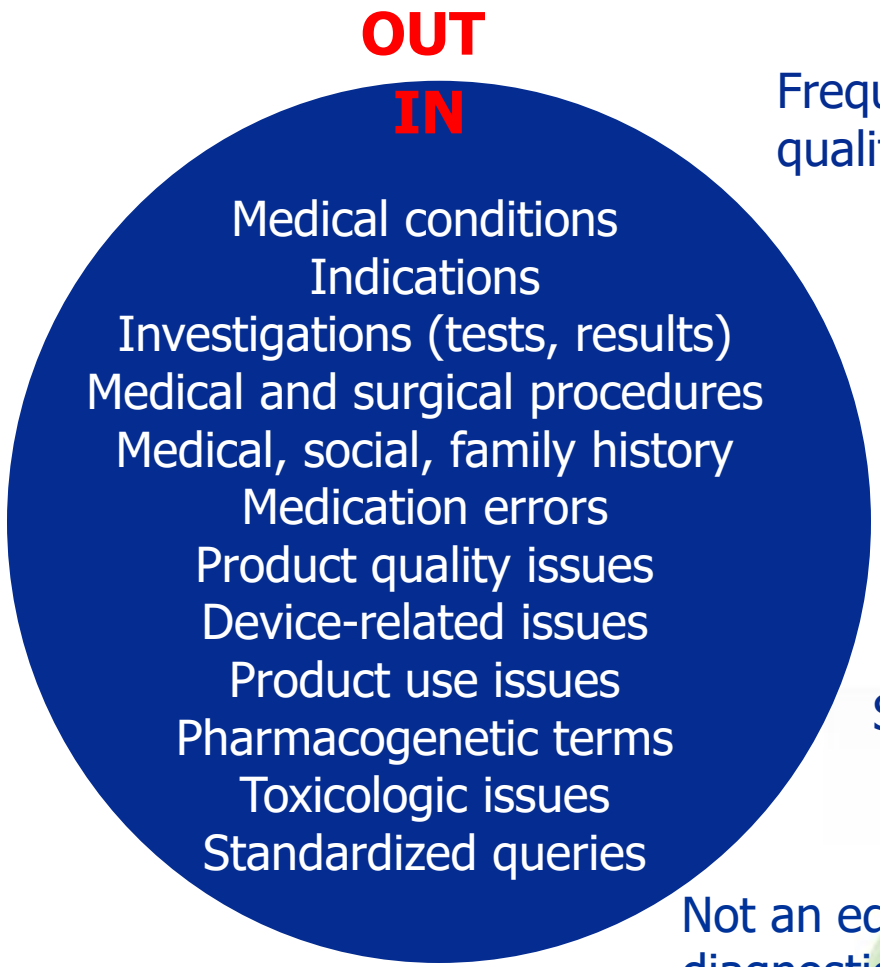
Province/State: *

Postal/Zip Code:

Country: *

Phone: *

Scope of MedDRA



Not a drug dictionary

Frequency qualifiers

Patient demographic terms

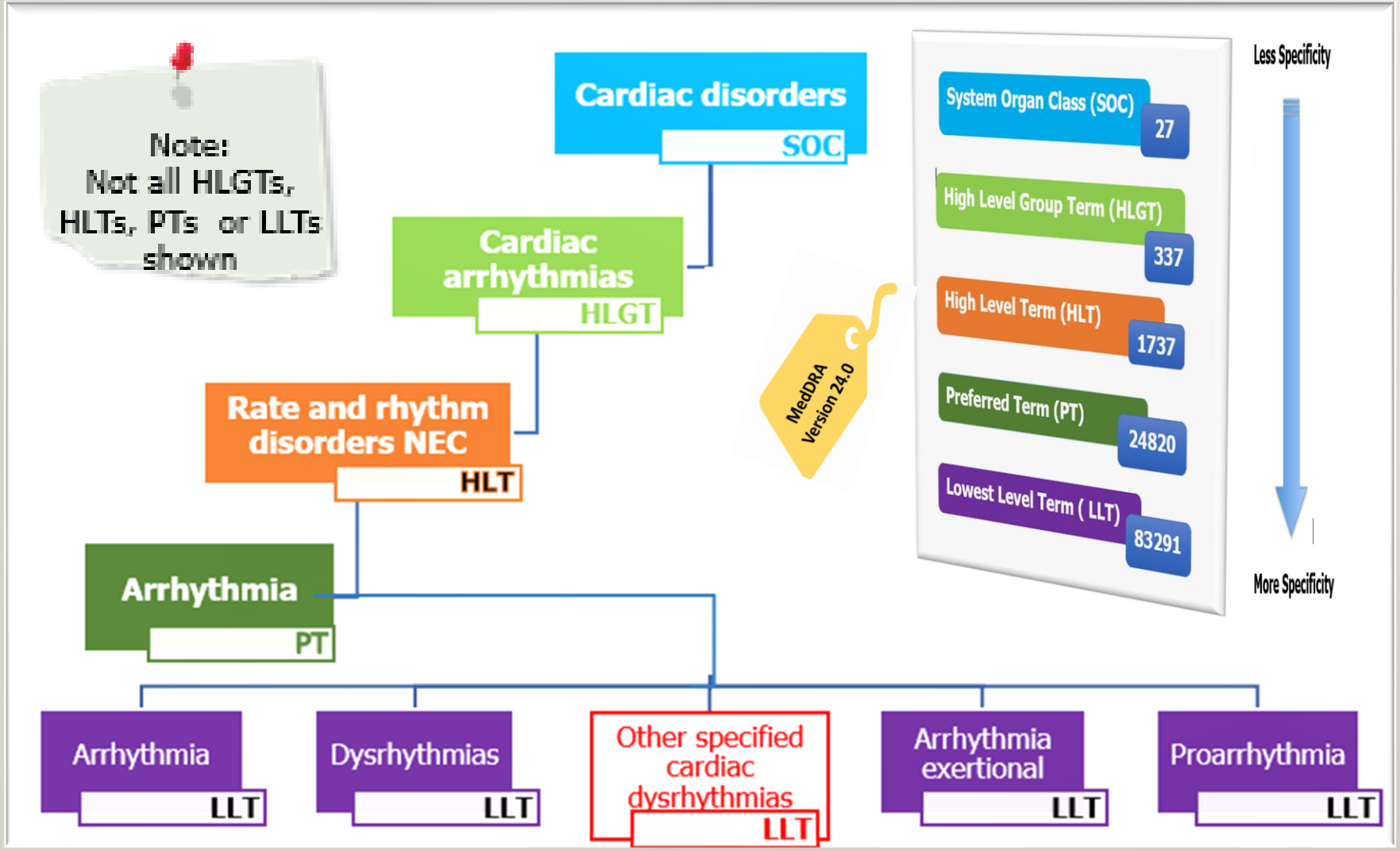
Numerical values for results

Clinical trial study design terms

Severity descriptors

Not an equipment, device, diagnostic product dictionary

MedDRA Structure



System Organ 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 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

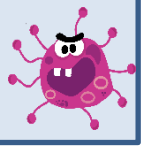
SOC = Respiratory, thoracic and mediastinal disorders (Secondary SOC)



HLGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

SOC = Infections and infestations (Primary SOC)

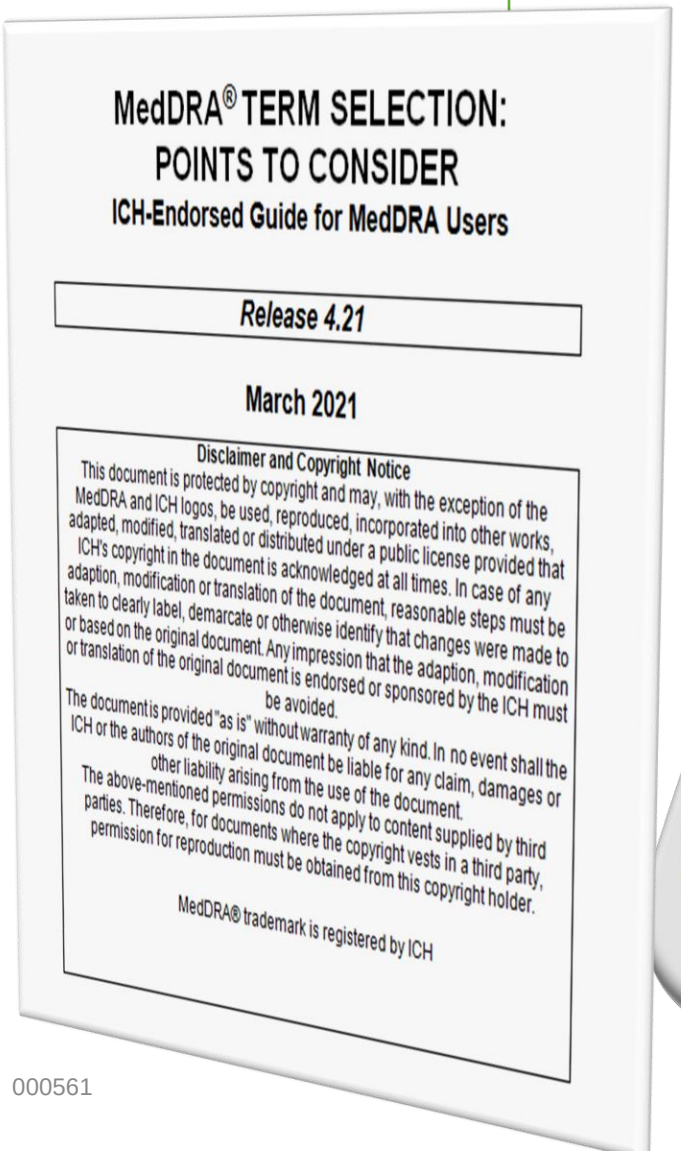


HLGT = Viral infectious disorders

HLT = Influenza viral infections

PT = Influenza

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 Diagnosis 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 19
3.9 Modification of Pre-existing Conditions
3.10 Exposures during Pregnancy and Breast Feeding
3.10.1 Events in the mother
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 with diagnosis
3.14.3 Investigations not consistent with diagnosis
3.14.4 Investigation result terms
Investigation terms without qualifiers
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
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

Detailed coding instructions



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

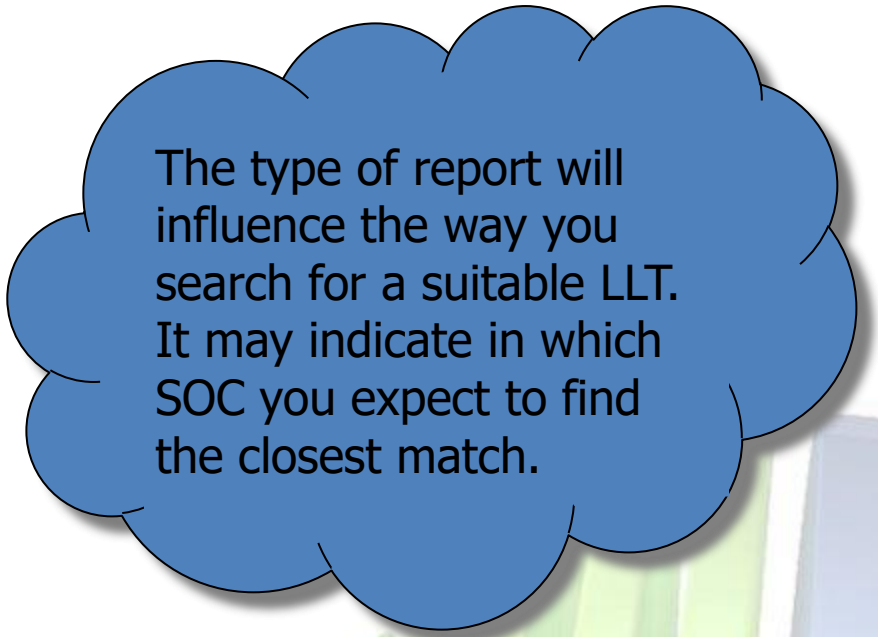
General term selection principles

- 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

Assessing the Reported Information

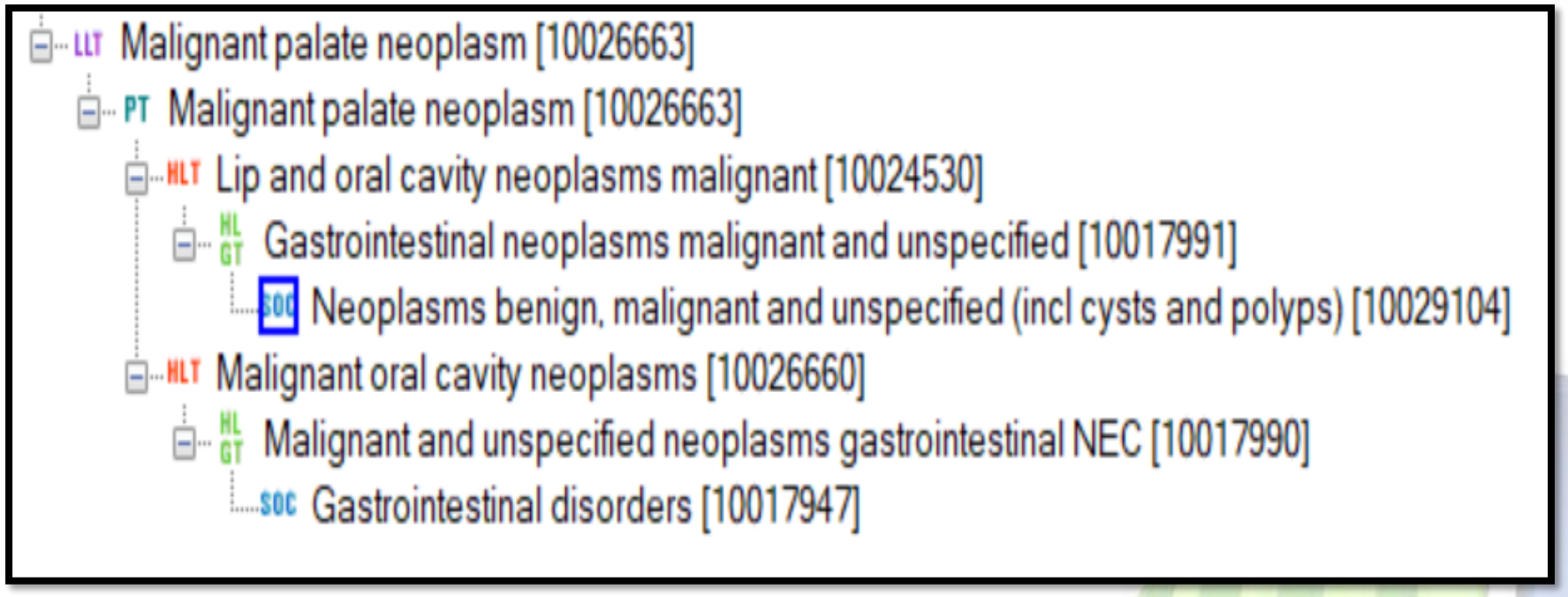
- Consider what is being reported. Is it a:
  - Clinical condition - Diagnosis, sign or symptom?
  - Indication?
  - Test result?
  - Injury?
  - Procedure?
  - Medication error?
  - Product use issue?
  - Product quality issue?
  - Social circumstance?
  - Device issue?
  - Procedural complication?

  - **Is it a combination of these?**



How to code? Example:

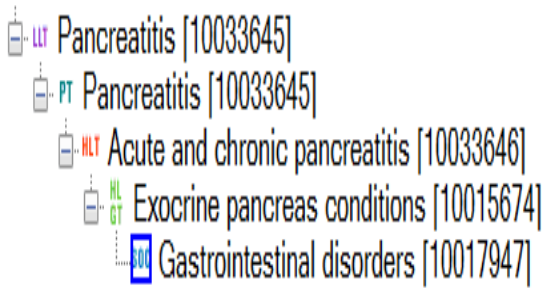
- Verbatim: Malignant neoplasm of palate
  - Coded to LLT : Malignant palate neoplasm



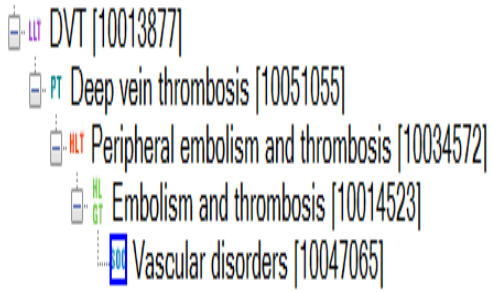
How to code with MedDRA? Example:

- 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



How to code?

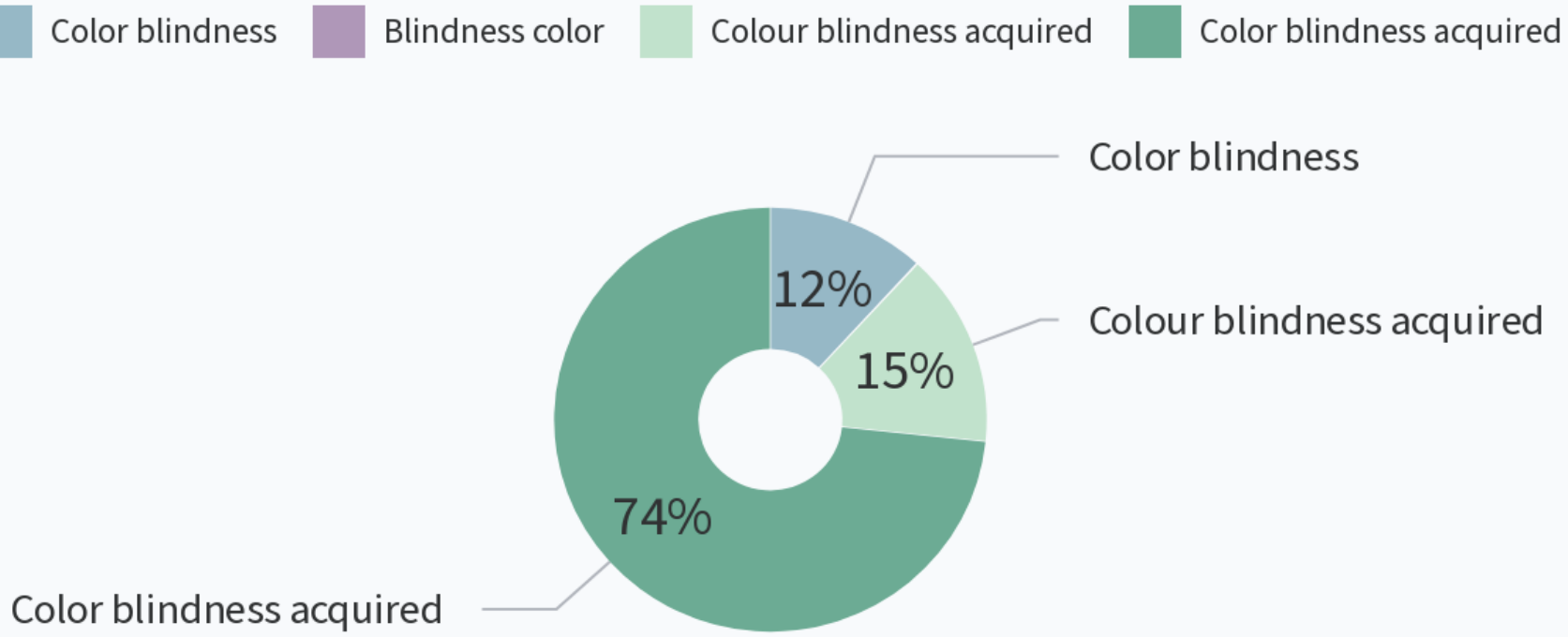
- Gastric Boating





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"Became color blind in adolescence"



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Clinical complication of IUD

LLT IUD complication

LLT Intra-uterine death

LLT Unevaluable event

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MedDRA

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

Serum sodium abnormal

Hypernatraemia

Hyponatraemia

Serum sodium decreased

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Died as a result of a suicide attempt

A. Suicide gesture

B. Attempted suicide

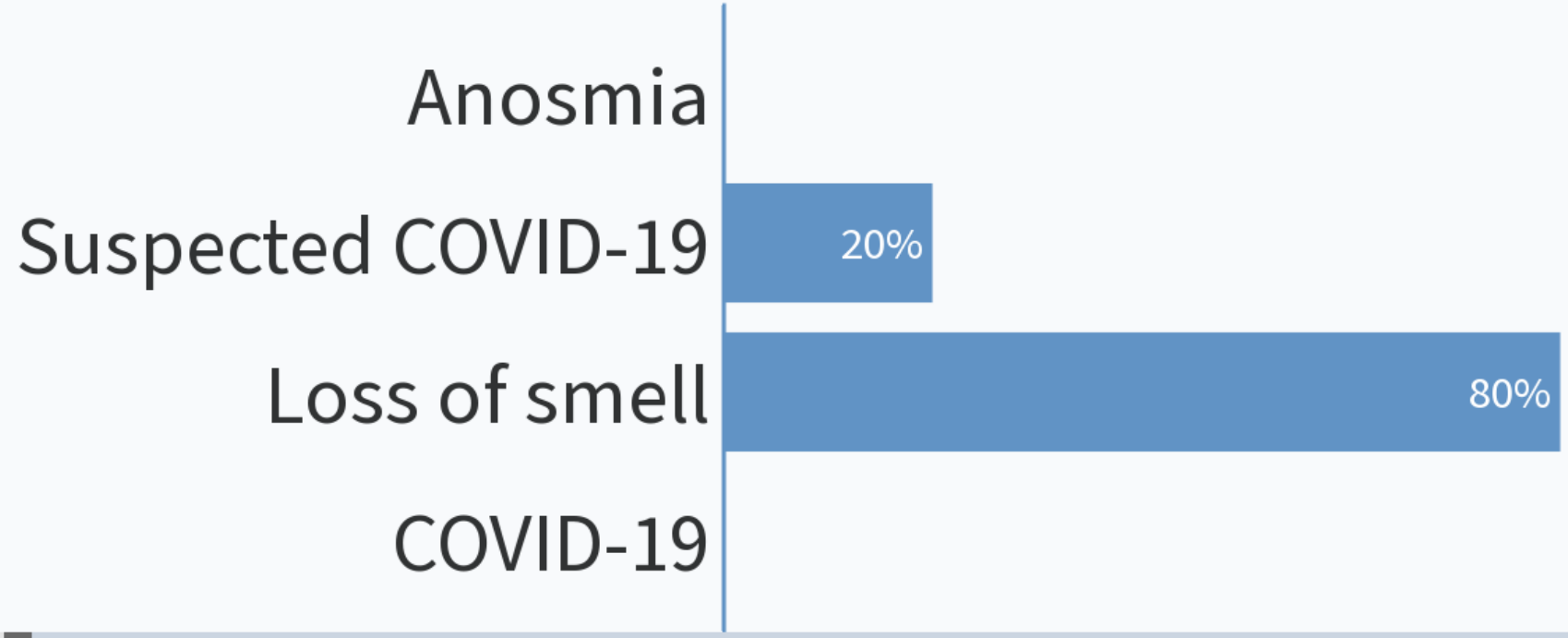
C. Completed suicide

D. Death

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"The patient reported a loss of smell and thought that he might have a COVID-19 infection"



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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

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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

Who uses MedDRA?



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USA

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Direct: +1 703.556.2950

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Russian: MedDRA RU Users Support

WeChat Chinese:

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

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General / Basics		
Topic	Presentation	Training Type

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Topic	Presentation	Training Type

Retrieval / Analysis (SMQs)		
Topic	Presentation	Training Type

MedDRA Versioning		
Topic	Presentation	Training Type

Tools		
Topic	Presentation	Training Type

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Thank You!!

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