



MedDRA Coding

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Coding in daily life?





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.

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

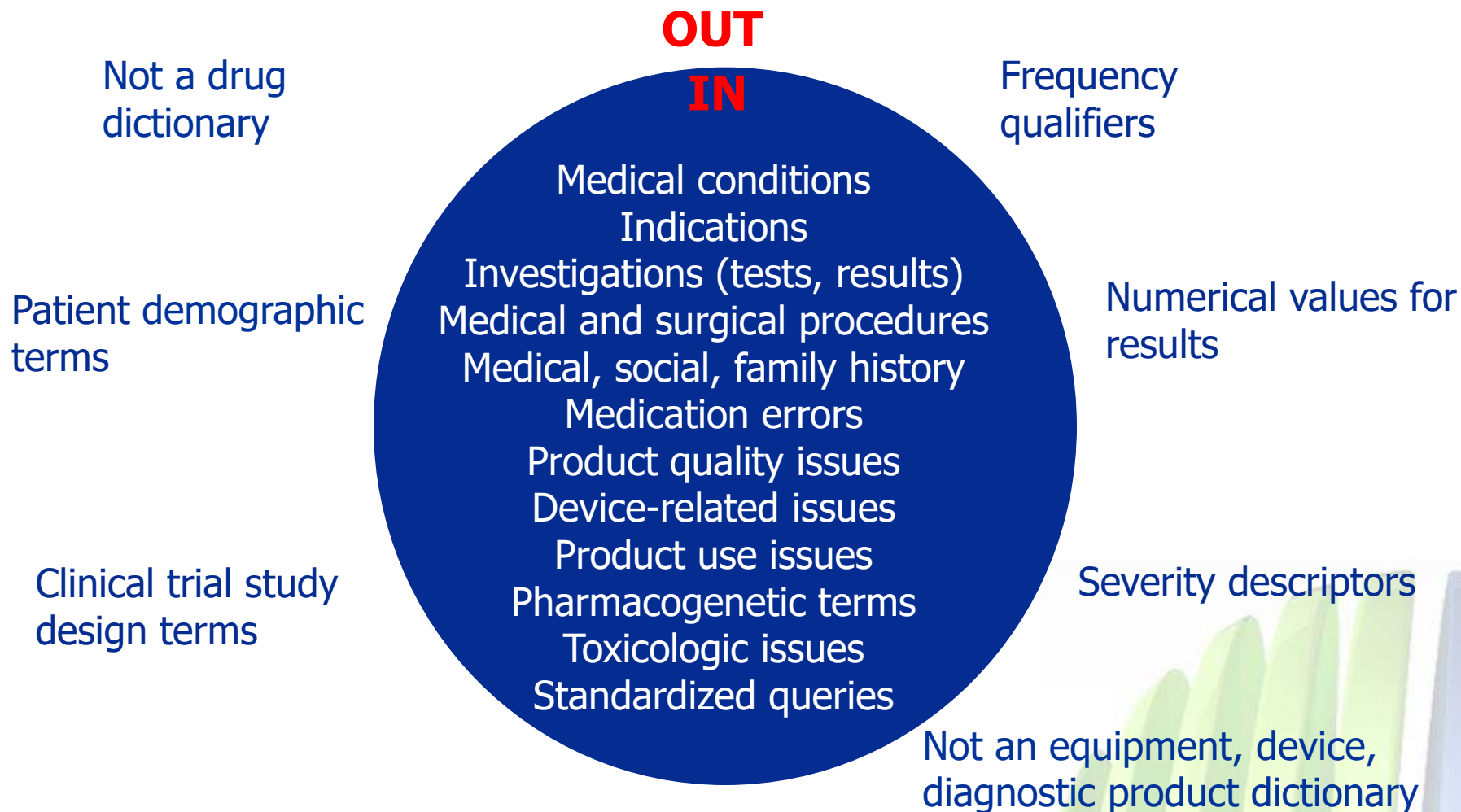
Marketing Applications

Publications

Prescribing Information

Advertising

Scope of MedDRA

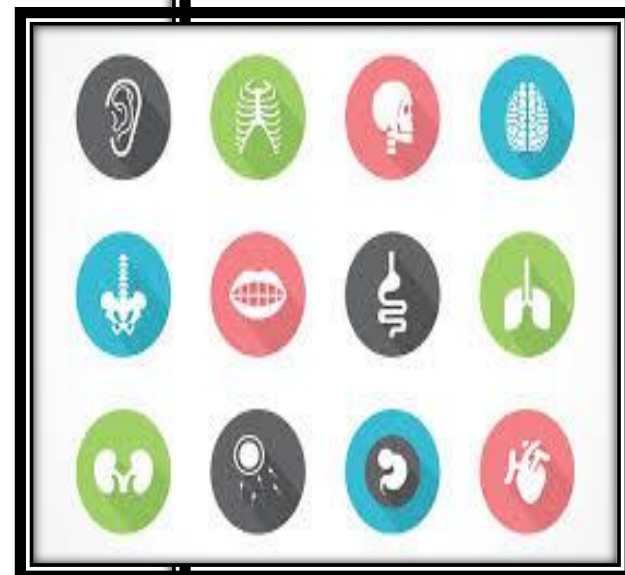


Structure of MedDRA

- [-] SOC Cardiac disorders
 - [-] HL GT Cardiac arrhythmias
 - [-] HLT Cardiac conduction disorders
 - [PT] Bundle branch block
 - LLT Block bundle branch
 - LLT Bundle branch block
 - LLT Bundle branch block NOS
 - [LLT] Bundle branch block, other and unspecified
 - LLT Bundle branch block, unspecified
 - LLT Complete bundle branch block
 - LLT Heart block bundle branch
 - LLT Incomplete bundle branch block

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



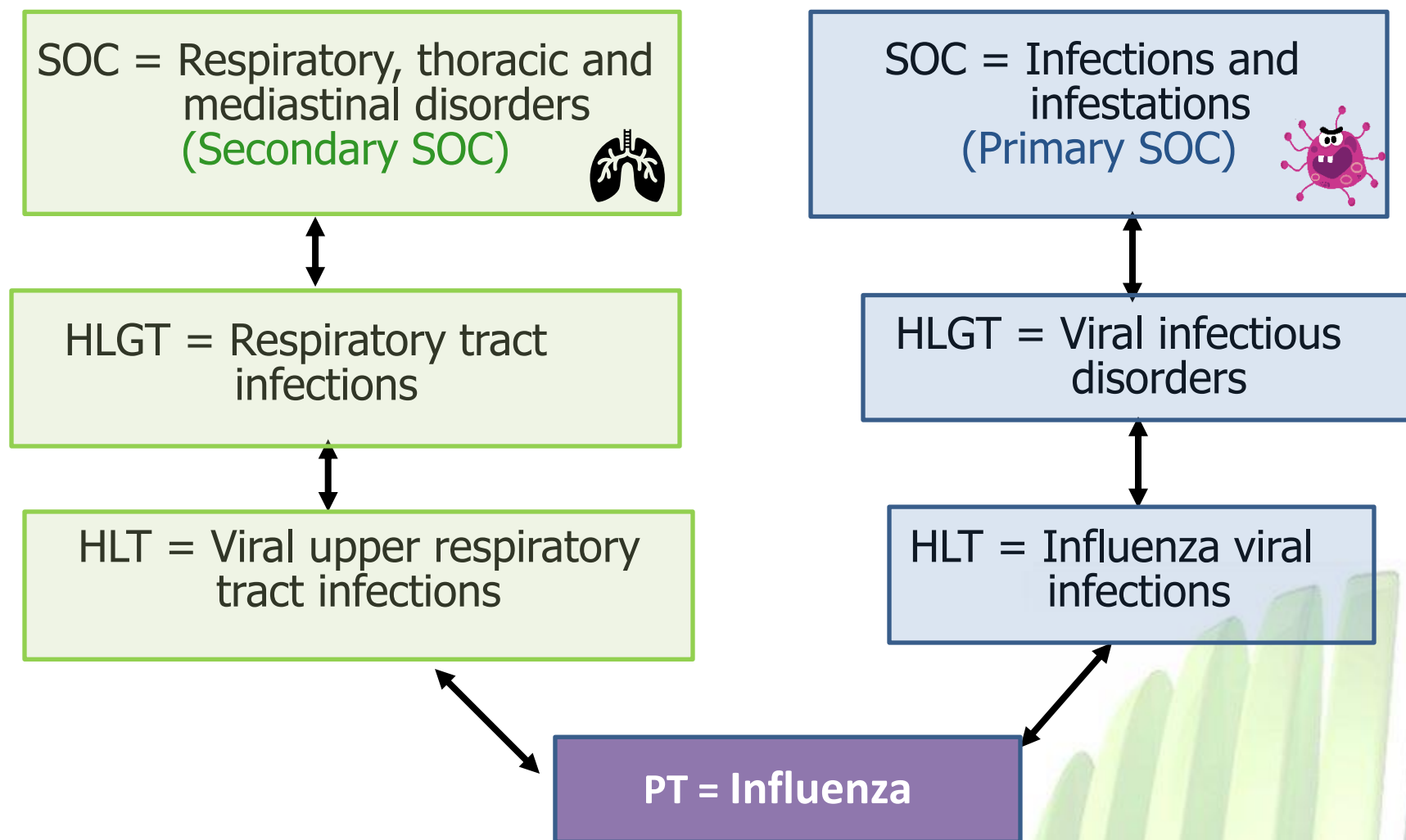
MedDRA Codes

PT Anaemia

[10002034]

- Each MedDRA term is assigned an 8-digit numeric code
 - Non-expressive
 - Assigned sequentially
- Codes can fulfill a data field in various electronic submission types (e.g., E2B (R3))

A Multi-Axial Terminology

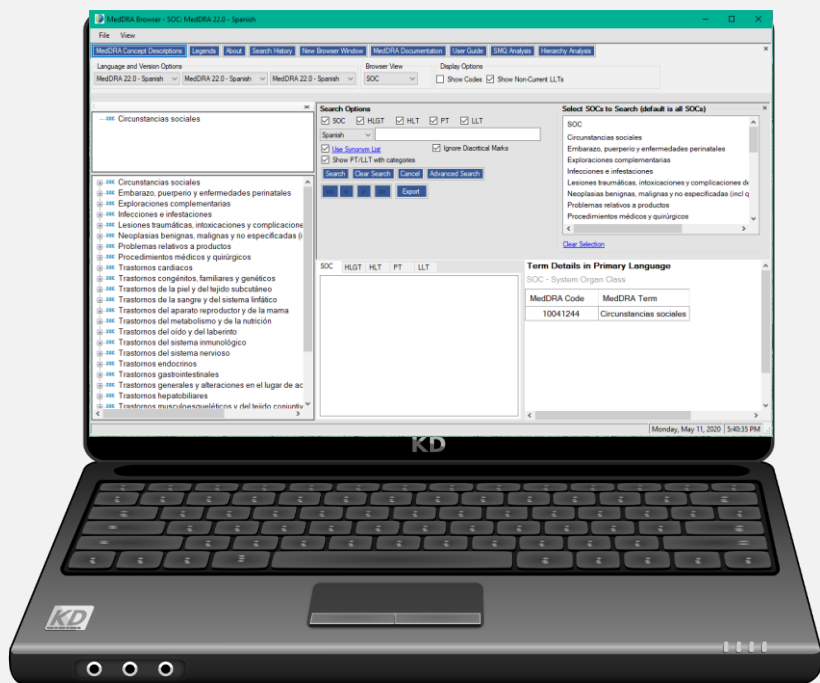


MedDRA Versioning

- Two MedDRA updates/year
 - 1 March X.0 (Complex release)
 - 1 September X.1 (Simple release)
- Resources:
 - “What’s New” document
 - Version report
 - MedDRA Version Analysis Tool (MVAT)
- Version used in data retrieval and presentation should be documented
- Terms used for queries should be in same version as data being queried



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 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 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
- 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 consistent with diagnosis
 - 3.14.3 Investigation results not consistent with diagnosis
 - 3.14.4 Grouped 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

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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



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

General term selection principles



Select Terms for All Reported Information



Do Not Add 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 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	

Important Coding Errors

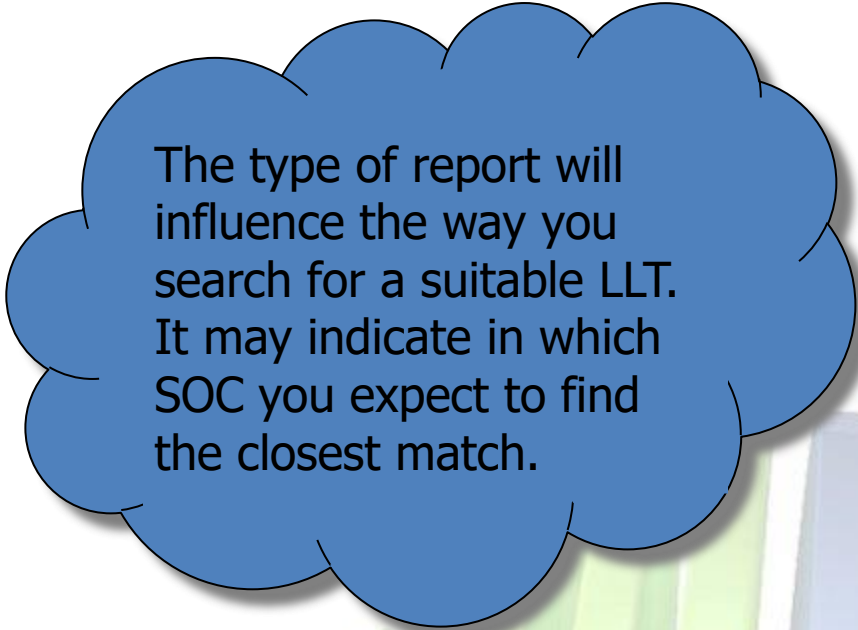
- Missed Concepts
 - All medical concepts described after the product is taken should be coded
 - Example: “*The patient took drug X and developed alopecia, increased LFTs and pancreatitis*”. Manufacturer only codes alopecia and increased LFTs (missed concept of pancreatitis)
- “Soft Coding”
 - Selecting a term which is both less specific and less severe than another MedDRA term is “soft coding”
 - Example: “*Liver failure*” coded as hepatotoxicity or increased LFTs

Problems With Coding Data

- Appropriate coding requires clear initial data
- Code only reported verbatim term; cannot interpret or draw information from other sources
- Ambiguous information
 - Example: Congestion (nasal, liver, sinus, pulmonary?)
 - Example: Decreased BS (breath sounds, bowel sounds or blood sugar?)
- Combination terms, should be split, Example: Nausea & vomiting
- Death, hospitalization, and disability are outcomes, underlying event needs to be coded
 - Example: Hospitalization due to congestive heart failure”
(Coded as Congestive heart failure, hospitalization captured as the outcome)

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

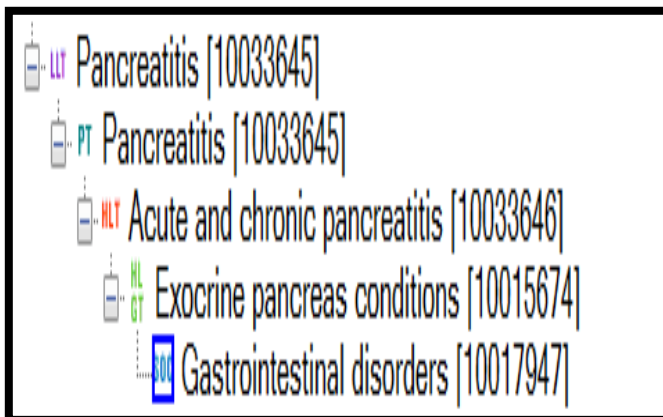


How to code? Example:

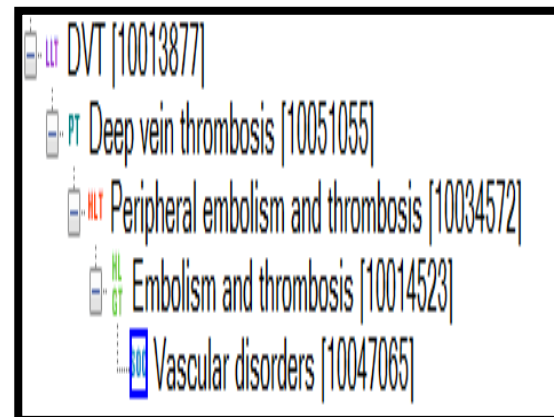
Verbatim: Patient was hospitalized with severe upper abdominal burning pain radiating to the back, nausea, and vomiting that worsened with eating. Upon further investigation her serum amylase levels were found to be elevated and was diagnosed with Pancreatitis. During the hospitalization she was also 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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Reported term: 'Abuse'

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**"Man with decreased
fertility."**

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**"Deliberately took an
overdose".**

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"Death from cerebral haemorrhage"

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**"Hypoglycemia (blood
glucose = 200 mg/dL)"**

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**"Took intramuscular
drug by mouth".**

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Infection after surgery

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www.meddra.org



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Regulatory Activities

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Direct: +1 703.556.2950

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via the MedDRA Self-Service Application

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Social Media Channels

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to join the MedDRA group on WhatsApp or WeChat.



WhatsApp

English/Spanish:
MedDRA Group



French:

MedDRA - French speakers



Russian:

MedDRA RU Users Support



WeChat

Chinese:



MedDRA MSSO

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Telephone:

E-mail: Confirm E-mail:

Organization:

Comment:

☒ Add me to the MSSO email list

☐ I'm not a robot

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Support Documentation / How to Use /



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 /

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

General / Basics		
> Topic	Presentation	Training Type
Coding		
> Topic	Presentation	Training Type
Retrieval / Analysis (SMQs)		
> Topic	Presentation	Training Type
MedDRA Versioning		
> Topic	Presentation	Training Type
Tools		
> Topic	Presentation	Training Type
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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MedDRA

Thank You!

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