



MedDRA

# 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.



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

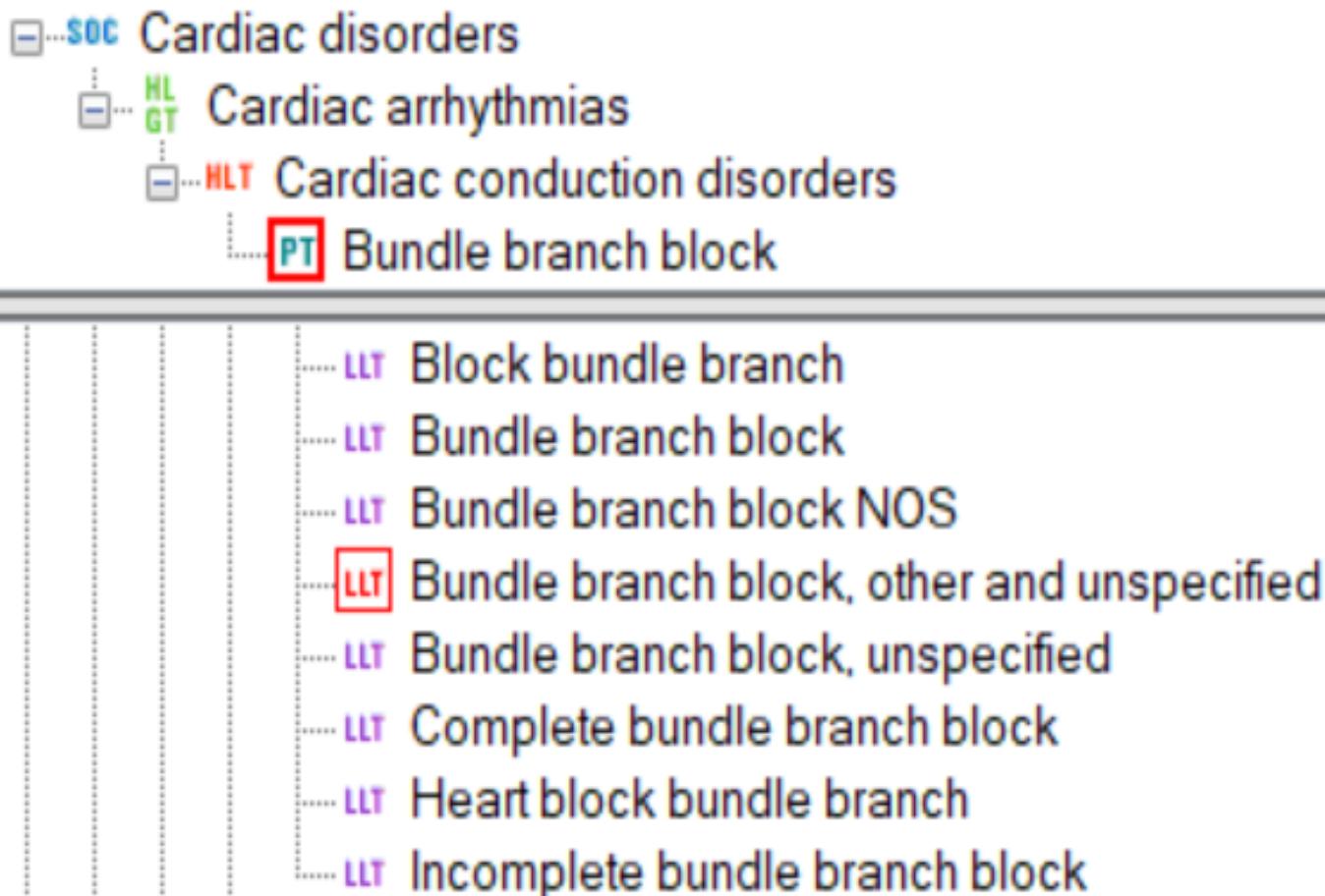


# Scope of MedDRA

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



Frequency qualifiers  
Numerical values for results  
Severity descriptors  
Not an equipment, device, diagnostic product dictionary





# 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





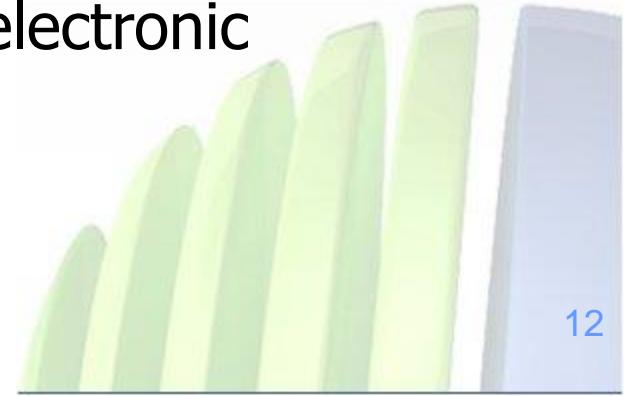
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# MedDRA Codes

*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))





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# A Multi-Axial Terminology

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

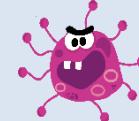


HLGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

PT = Influenza

SOC = Infections and infestations  
(Primary SOC)



HLGT = Viral infectious disorders

HLT = Influenza viral infections

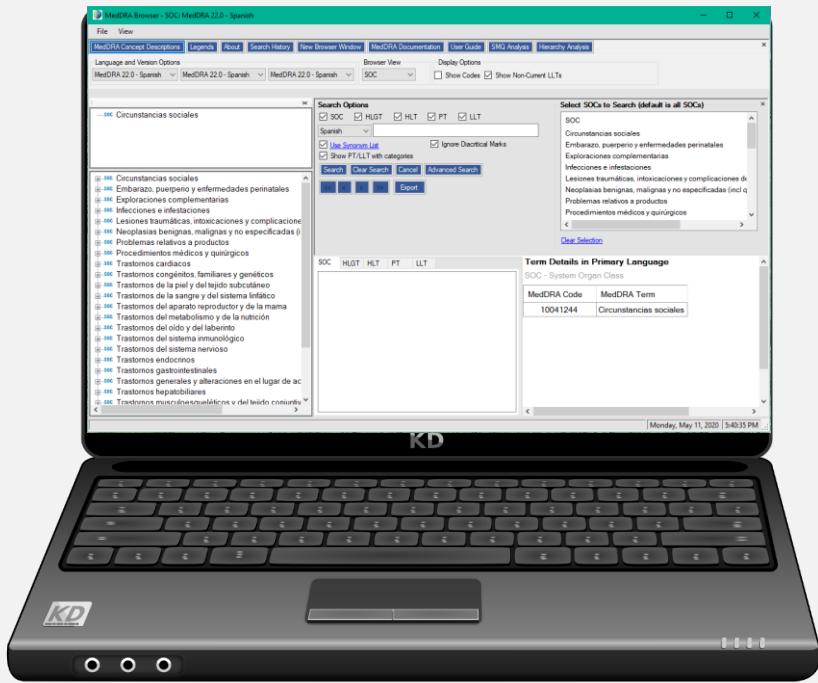


- Two MedDRA updates/year
  - 1 March X.0 (Complex release)
  - 1 September X.1 (Simple release)
- Resources:
  - “What’s New” document
  - Version report
  - MedDRA Version Analysis Tool (MVAT)
- Version used in data retrieval and presentation should be documented
- Terms used for queries should be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



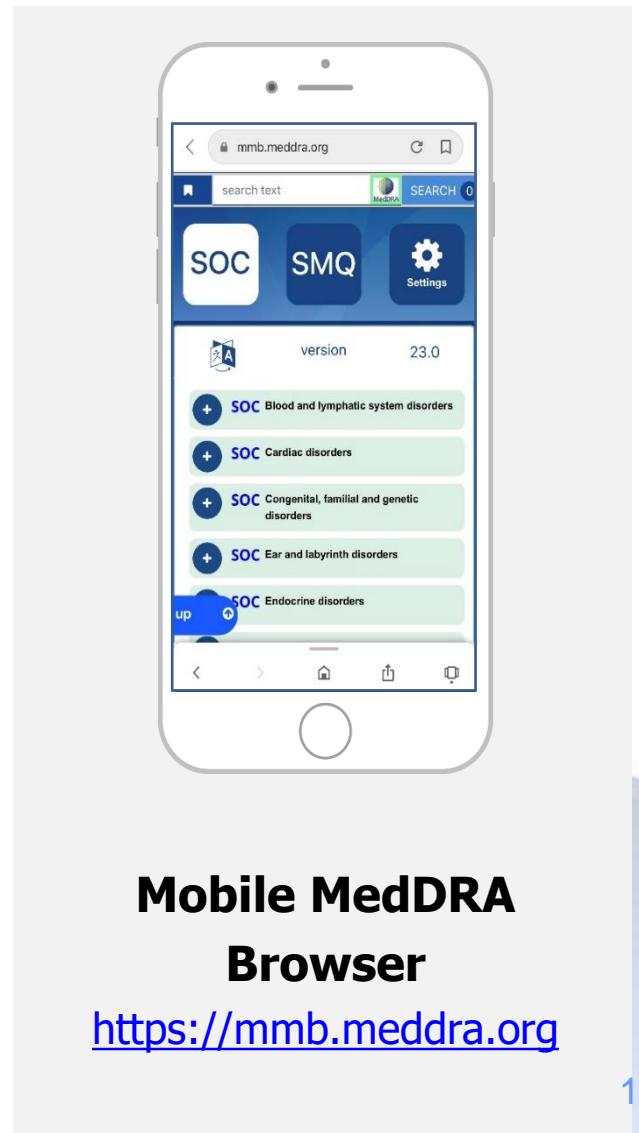


# MSSO's MedDRA Browsers



**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



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# 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

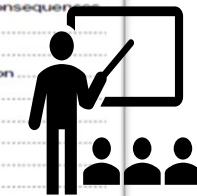
- 3.1 Definitive and Provisional Diagnoses with or without Signs and Symptoms
- 3.2 Death and Other Patient Outcomes
  - 3.2.1 Death with ARs/AEs
  - 3.2.2 Death as the only reported information
  - 3.2.3 Death terms that add important clinical information
  - 3.2.4 Other patient outcomes (non-fatal)
- 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

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 consistent with diagnosis
  - 3.14.3 Investigation results not consistent with diagnosis
  - 3.14.4 Grouped in with other result terms
  - 3.14.5 Investigations 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





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# General term selection principles



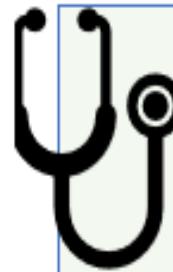
Lowest Level Term that most accurately reflects the reported verbatim information should be selected



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



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# 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	





- 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





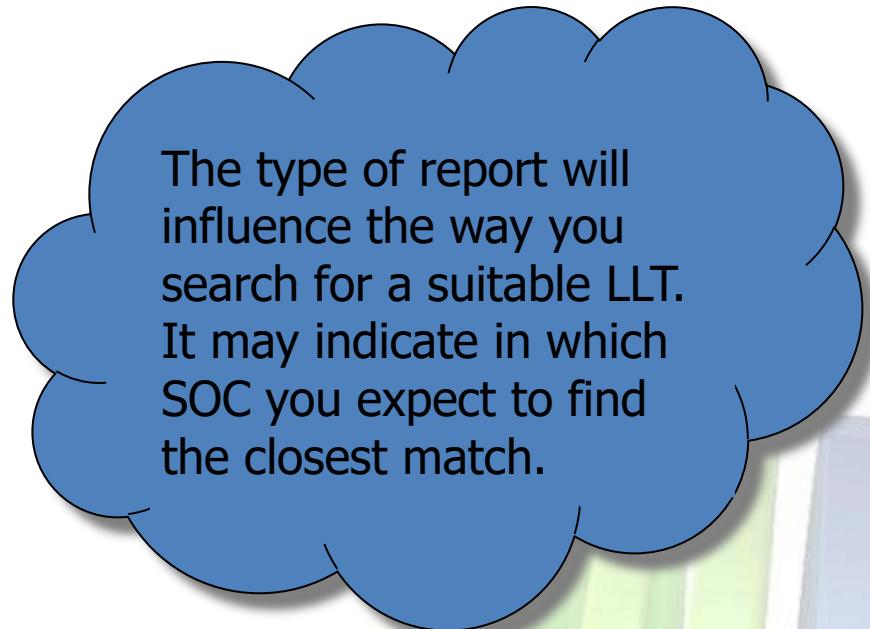
# Problems With Coding Data

- 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



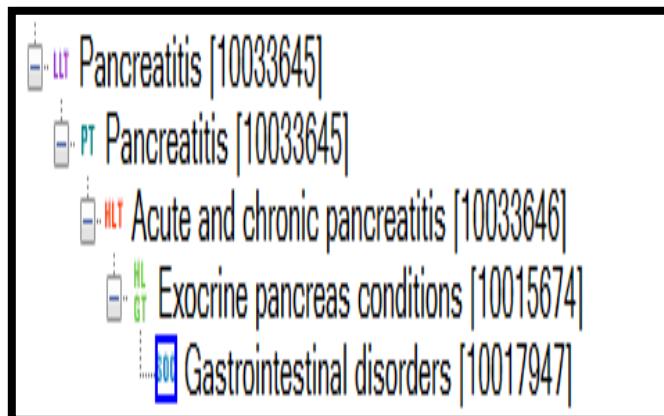


# How to code? Example:

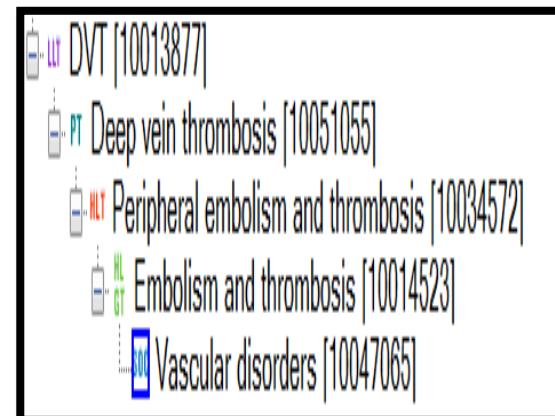
Verbatim: Patient was hospitalized with severe upper abdominal burning pain radiating to the back, nausea, and vomiting that worsened with eating. Upon further investigation her serum amylase levels were found to be elevated and was diagnosed with Pancreatitis. During the hospitalization she was also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

— Coded to

1. LLT : Pancreatitis



2. LLT : DVT





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# 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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Medical Dictionary for Regulatory Activities

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**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

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