



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Best practices in VeDDRA coding

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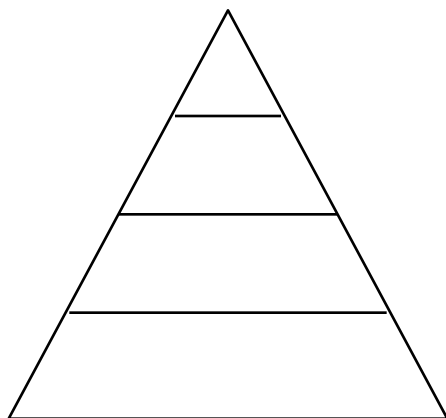
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# Veterinary Dictionary for Drug Related Affairs

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SOC = System Organ Class

HLT = Higher Level Term

PT = Preferred Term

LLT = Lower Level Term

- A terminology used to record clinical signs or other easily detectable clinical information, such as laboratory results or necropsy findings (2013 addition – NT)
- Four level hierarchical structure
- Mono-axial (MedDRA is not)



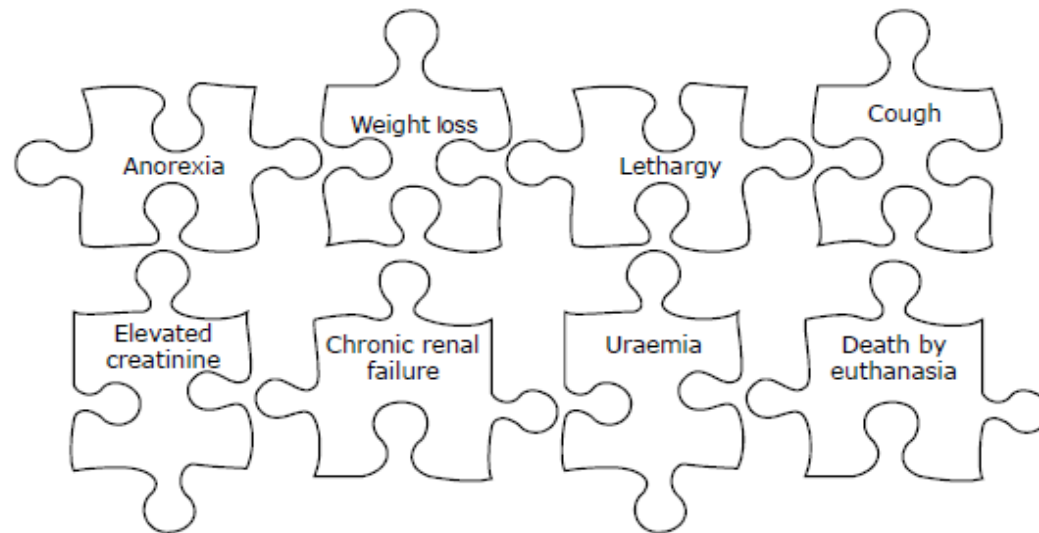
# Terms

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- A specific LLT is only available in one specific SOC
- Each LLT is unique and is linked to a single PT
- An LLT is either a synonym or a sub-classification of a particular PT (each PT is also available as a corresponding LLT).
- A PT represents a single clinical concept
- HLTs are broader terms than the PTs linked to them and provide clinically relevant groupings



## Selection of Terms



- Use LLTs to record the clinical signs as described by the reporter
- Code all the clinical signs without diagnosis or interpretation
- Do not reject the unexpected



# Level of Analysis

SOC	HLT	PT	LLT
Digestive tract disorders	Other digestive tract disorders	Diarrhoea	Diarrhoea
Digestive tract disorders	Intestinal disorders	Enteritis	Enteritis
Digestive tract disorders	Intestinal disorders	Rectal haemorrhage	Rectal bleeding
Digestive tract disorders	Other digestive tract disorders	Digestive tract haemorrhage NOS	Blood in faeces

- Be aware of how the choice of LLT can affect analysis at PT and HLT levels
- Also beware of similar LLTs that belong to different SOC:s:
  - Foaming at the mouth – Digestive tract disorders
  - Foam in the mouth – Respiratory tract disorders



# Pain

SOC	HLT	PT	LLT
Digestive tract disorders	Abdominal cavity disorders	Abdominal pain	Abdominal pain
Systemic disorders	General signs or symptoms	General pain	Pain NOS
Systemic disorders	General signs or symptoms	Localised pain NOS	Localised pain NOS
Neurological disorders	Sensory abnormalities	Hyperaesthesia	Hypersensitivity to pain

- Good information from the reporter is essential
- Is the pain specific, general or localised?
- Is it an exaggerated response?



# Dullness and Depression

SOC	HLT	PT	LLT
Neurological disorders	Impaired consciousness	Impaired consciousness	Dullness
Systemic disorders	General signs or symptoms	Lethargy	Depression
Systemic disorders	General signs or symptoms	Malaise	Off colour

- Good information from the reporter is essential
- Code all the clinical signs
- Take care not to exaggerate seriousness when coding systemic signs



## Reluctance to Move

SOC	HLT	PT	LLT
Systemic disorders	General signs or symptoms	Lethargy	Reluctant to move
Musculoskeletal disorders	Musculoskeletal disorders	Musculoskeletal disorder NOS	Limb weakness
Neurological disorders	Coordination and balance signs	Ataxia	Walking difficulty

- Good information from the reporter is essential
- Code all the clinical signs
- Select LLTs in more than one SOC when the reaction is non-specific



# Death

SOC	HLT	PT	LLT
Systemic disorders	Death	Death	Death
Systemic disorders	Death	Death	Death by euthanasia
Systemic disorders	Death	Death	Sudden death
Systemic disorders	Death	Death	Found dead
Systemic disorders	Death	Death	Unexplained death
Systemic disorders	Death	Death	Unrelated death

- Death should always be coded
- Remember to add it when death is reported in a follow up report
- Selection of more than one LLT may be necessary for events involving multiple animals but could influence the analysis



# Anaphylaxis

SOC	HLT	PT	LLT
Immune system disorders	Allergic conditions	Anaphylaxis	Anaphylaxis

- Code all the clinical signs
- Code as anaphylaxis if reported as such
- Add anaphylaxis if reaction occurred within 1 hour with signs of circulatory and respiratory disturbance

SOC	HLT	PT	LLT
Cardio-vascular system disorders	Circulatory disorders	Circulatory shock	Circulatory collapse
Cardio-vascular system disorders	Circulatory disorders	Circulatory shock	Shock



# Glucose Metabolism Disorders

SOC	HLT	PT	LLT
Endocrine system disorders	Pancreas endocrine disorders	Diabetes mellitus	Diabetes mellitus

- Code all the clinical signs
- Code as diabetes mellitus if reported as such
- Add diabetes mellitus if other characteristic signs are reported

SOC	HLT	PT	LLT
Renal and urinary disorders	Urinary tract disorders	Urine abnormalities	Glucosuria
Metabolism and nutrition disorders	Other metabolic disorders	Hyperglycaemia	Hyperglycaemia



# Injection Site Sarcoma

SOC	HLT	PT	LLT
Application site disorders	Injection site reactions	Injection site sarcoma	Injection site sarcoma
Application site disorders	Application site reactions	Application site sarcoma	Application site sarcoma
Skin and appendages disorders	Skin and appendages neoplasms	Skin and/or appendage neoplasm NOS	Skin sarcoma NOS
Skin and appendages disorders	Skin and appendages neoplasms	Skin fibrosarcoma	Skin fibrosarcoma

- Take care to select the specific term



# Balance Problems

SOC	HLT	PT	LLT
Ear and labyrinth disorders	Internal ear disorders	Internal ear disorder	Head tilt
Neurological disorders	Coordination and balance signs	Ataxia	Balance problem

- Head tilt is associated with internal ear disorders in VeDDRA
- Head tilt may be reported in adverse events not involving administration of a product into the ear
- Add a neurological term if appropriate



## Lack of Expected Efficacy

SOC	HLT	PT	LLT
Systemic disorders	Lack of efficacy	Lack of efficacy	Lack of efficacy
Systemic disorders	Lack of efficacy	Lack of efficacy	Partial lack of efficacy

- Lack of efficacy should always be coded
- Consider the product indications before coding as 'Partial lack of efficacy'
- Code all the clinical signs if there may be both safety and lack of efficacy issues



# Infections

SOC	HLT	PT	LLT
Respiratory tract disorders	Respiratory tract disorders	Respiratory tract infection NOS	Respiratory tract infection NOS
Renal and urinary disorders	Urinary tract disorders	Urine abnormalities	Urinary tract infection
Skin and appendages disorders	Skin and tissue infections	Bacterial skin infection	Bacterial skin infection NOS
Immune system disorders	Other immune system disorders	Other immune system disorder NOS	Persistent infection

- Limited choice of terms to describe infection
- No common group higher than LLT for analysis
- Add 'Persistent infection' if immunosuppression is suspected



# Any Questions?

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