

# MedDRA Essentials

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# What is MedDRA?



Med = Medical

D = Dictionary for

R = Regulatory

A = Activities



# 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



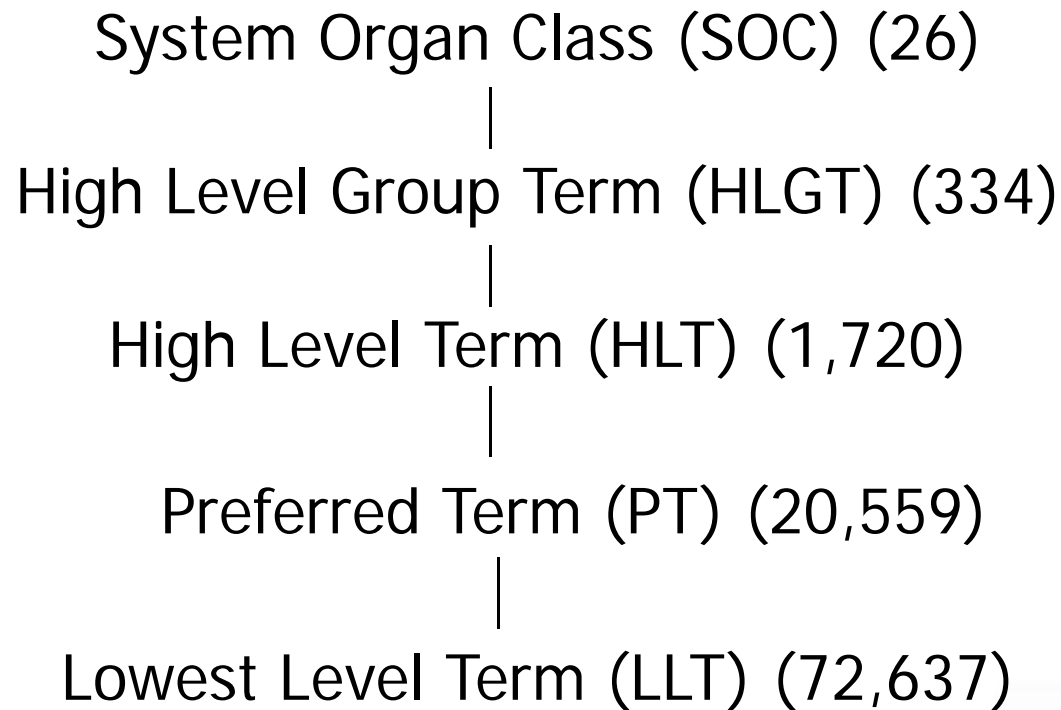
# Regulatory Status



- **US FDA**
  - Used in several databases including FAERS (drugs and biologics), VAERS (vaccines), and CAERS (foods, dietary supplements, cosmetics)
- **Japanese Ministry of Health, Labour and Welfare**
  - Mandatory use in electronic reporting
- **European Union** (EudraVigilance database)
  - Post-authorization Individual Case Safety Reports (ICSRs)
  - Clinical trial SUSARs (Suspected Unexpected Serious Adverse Reactions)



## MeDRA Version 17.0



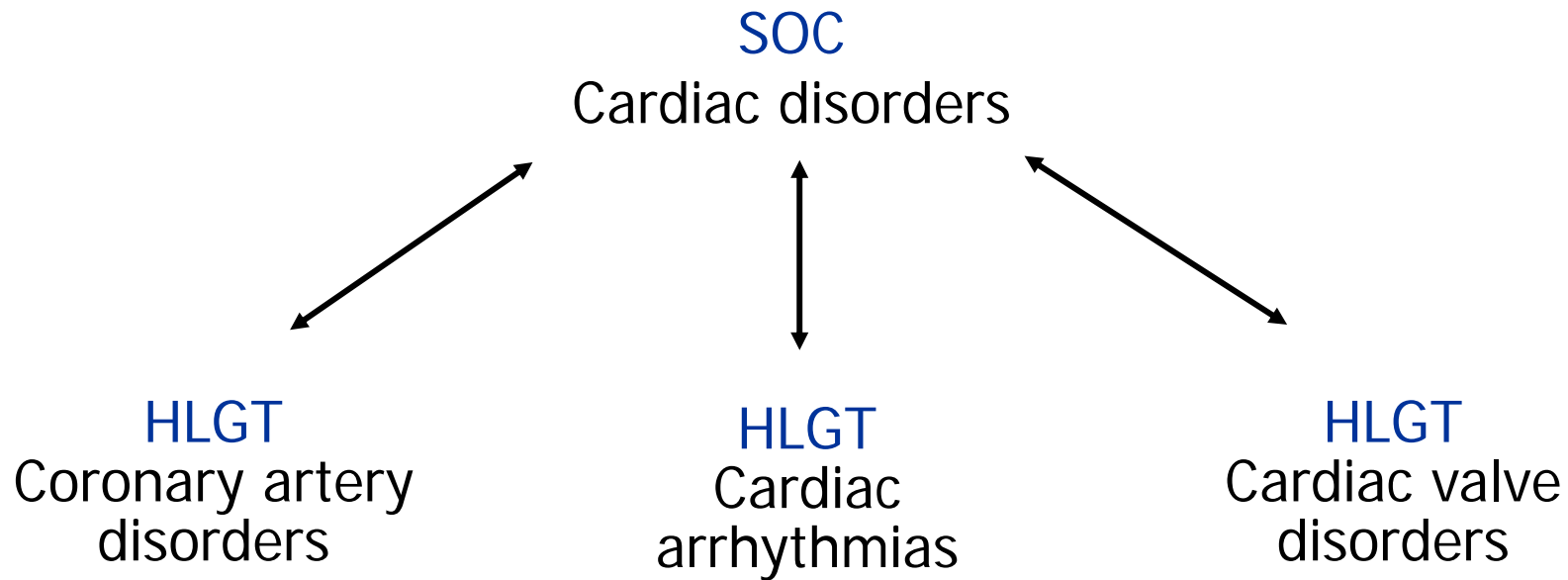
# System Organ Classes

- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders and administration site conditions
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications
- **Investigations**
- Metabolism and nutrition disorders
- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- **Social circumstances**
- **Surgical and medical procedures**
- Vascular disorders

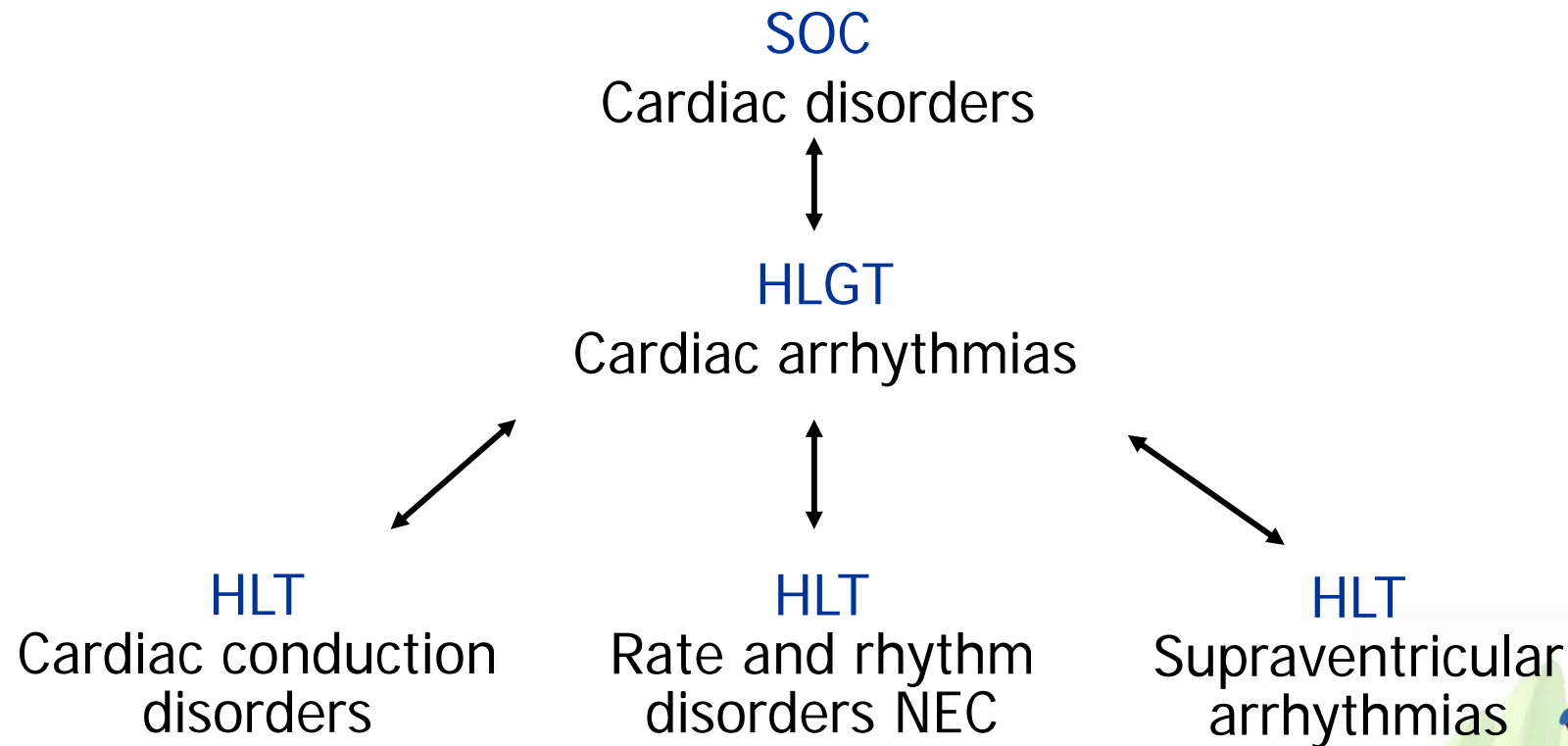
# High Level Group Terms



Subordinate only to SOC and superordinate grouping for one or more HLTs



Subordinate to HLGTS and superordinate grouping for the PTs linked to it

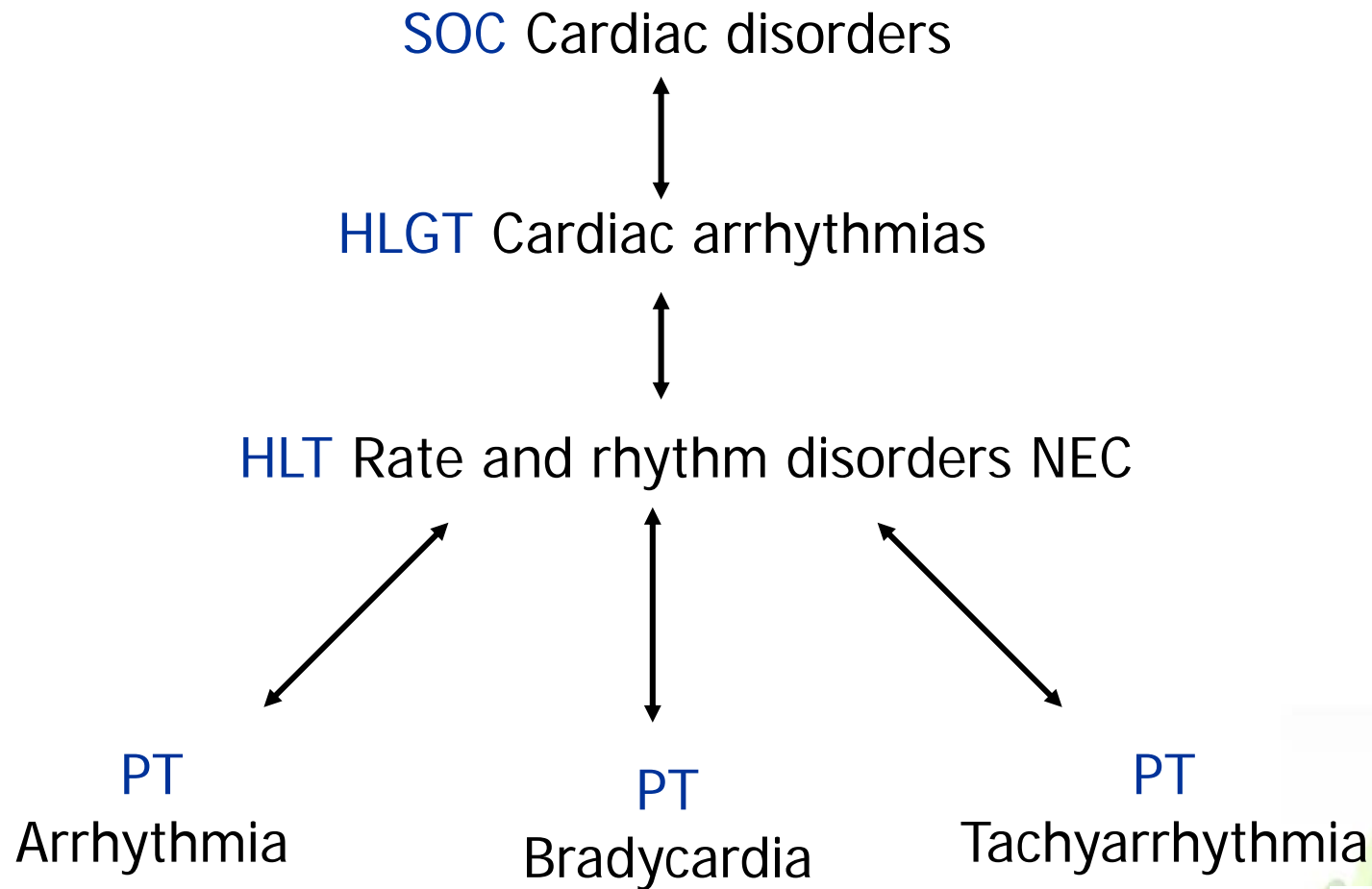




# Preferred Terms

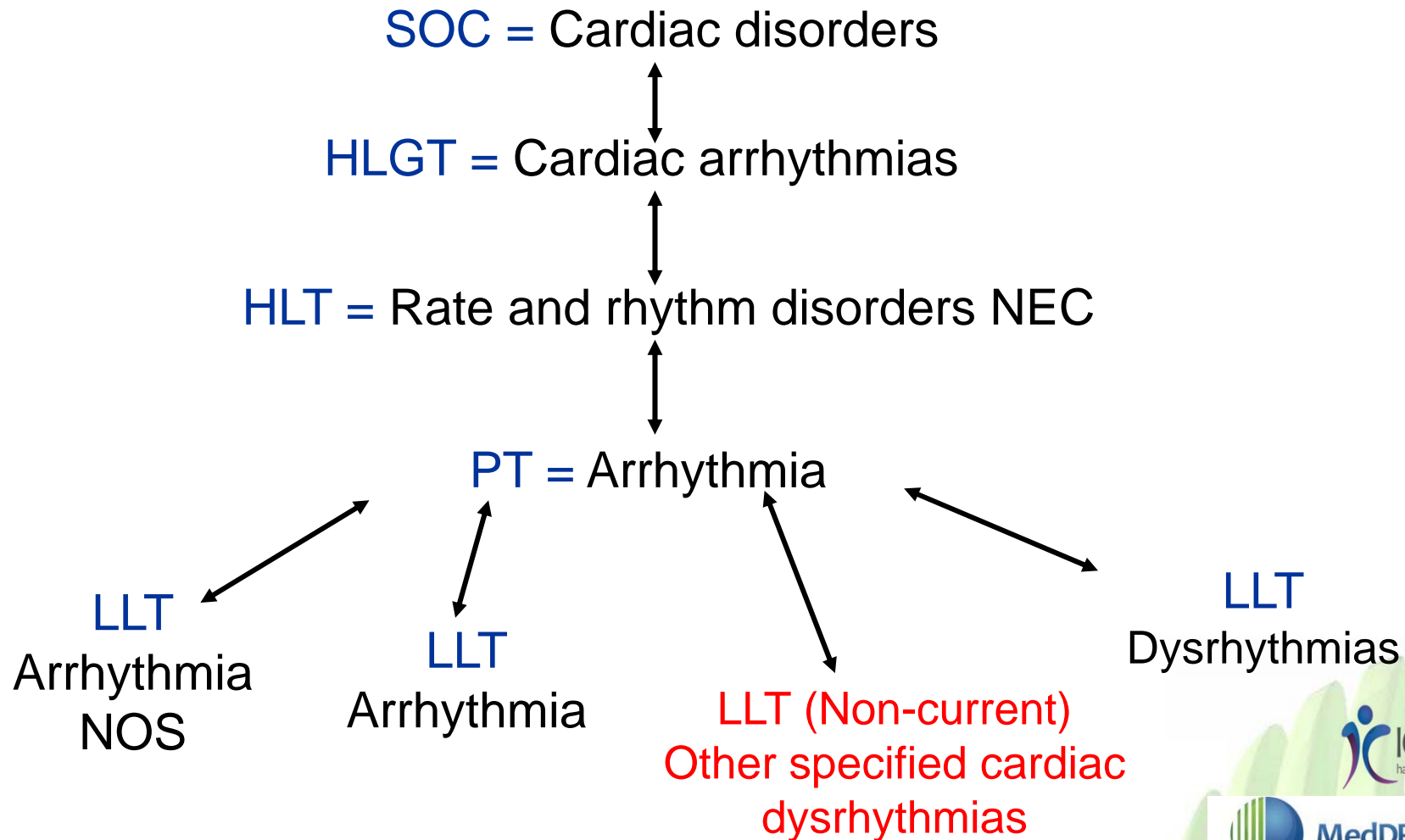


Represents a single medical concept



# Lowest Level Terms

Synonyms, lexical variants, sub-elements



# Codes and Languages



# A Multi-Axial Terminology



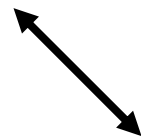
SOC = Respiratory, thoracic and mediastinal disorders



HLGT = Respiratory tract infections



HLT = Viral upper respiratory tract infections



PT = Influenza

SOC = Infections and infestations



HLGT = Viral infectious disorders



HLT = Influenza viral infections



# A Multi-Axial Terminology (cont)



PT	HLT	HLGT	SOC
Congenital HIV infection	Viral infections congenital	Infections and infestations congenital	Congenital, familial and genetic disorders (P)
	Congenital neonatal infections	Neonatal and perinatal conditions	Pregnancy, puerperium and perinatal conditions
	Retroviral infections	Viral infectious disorders	Infections and infestations
	Acquired immunodeficiency syndromes	Immunodeficiency syndromes	Immune system disorders

# Conditions vs. Investigations

PT	HLT	HLGT	SOC
Pregnancy test positive	Reproductive hormone analyses	Endocrine investigations (incl sex hormones)	Investigations
Pregnancy	Normal pregnancy, labour and delivery	Pregnancy, labour, delivery and postpartum conditions	Pregnancy, puerperium and perinatal conditions

Be careful to distinguish between a condition and an investigation or a result of an investigation

- International support and development of terminology
- Foster use of MedDRA through communications and educational offerings
- “Custodians”, not owners, of the terminology
- JMO (partner organization for Japanese-language MedDRA)
- Governed by a Management Board (industry, regulators, multi-national, other interested parties)



# MedDRA Term Selection: Points to Consider (MTS:PTC)



## **MedDRA<sup>®</sup> TERM SELECTION: POINTS TO CONSIDER**

**ICH-Endorsed Guide for MedDRA Users**

*Release 4.7*  
*Based on MedDRA Version 17.0*

**1 March 2014**

- Provides term selection advice for industry and regulatory purposes
- Objective is to 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





# Analysis with MedDRA



# Analysis & Multi-Axiality



SOC	HLGT	HLT	PT
Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Hepatocellular damage and hepatitis NEC	<a href="#">Autoimmune hepatitis</a>
Blood and lymphatic system disorders	Haemolyses and related conditions	Anaemias haemolytic immune	<a href="#">Coombs positive haemolytic anaemia</a>
Renal and urinary disorders	Nephropathies	Glomerulonephritis and nephrotic syndrome	<a href="#">Nephritis allergic</a>
Skin and subcutaneous tissue disorders	Epidermal and dermal conditions	Bullous conditions	<a href="#">Stevens-Johnson syndrome</a>



# Analysis & Multi-Axiality (cont.)



SOC	HLGT	HLT	PT
Immune system disorders	Autoimmune disorders	Hepatic autoimmune disorders	Autoimmune hepatitis
		Blood autoimmune disorders	Coombs positive haemolytic anaemia
	Allergic conditions	Allergic conditions NEC	Nephritis allergic
			Stevens-Johnson syndrome



# Standardised MedDRA Queries (SMQs)



# Example – Cardiac Arrhythmias



- Obvious starting point – HLGTT *Cardiac arrhythmias* (“Top-down” search)
- Also use “Arrhythmia” terms as starting point of “Bottom-up” search
- What about non-multi-axial SOCs?



# Example – Cardiac Arrhythmias (cont)



- *SOC Investigations*
  - PTs subordinate to HLT *ECG investigations* and HLT *Heart rate and pulse investigations* should be reviewed
    - Example: PT *Heart rate irregular*



# Example – Cardiac Arrhythmias (cont)



- SOC *Surgical and medical procedures*  
Important to review:
  - PTs subordinate to HLT *Cardiac device therapeutic procedures*\*
    - Example: PT *Implantable defibrillator insertion*
  - PTs subordinate to HLT *Cardiac therapeutic procedures NEC*\*
    - Example: PT *Cardioversion*

\*Note: Pacemaker and other cardiac therapeutic procedure terms were not included in SMQ *Cardiac arrhythmias*

# Example – Cardiac Arrhythmias (cont)



- Because arrhythmias may produce various signs and symptoms, you may wish to review PTs subordinate to the following HLTs:
  - HLT *Disturbances in consciousness NEC*
  - HLT *Neurological signs and symptoms NEC*
  - HLT *Cardiac disorders NEC*
  - HLT *Cardiac signs and symptoms NEC*
  - HLT *Dyspnoeas*





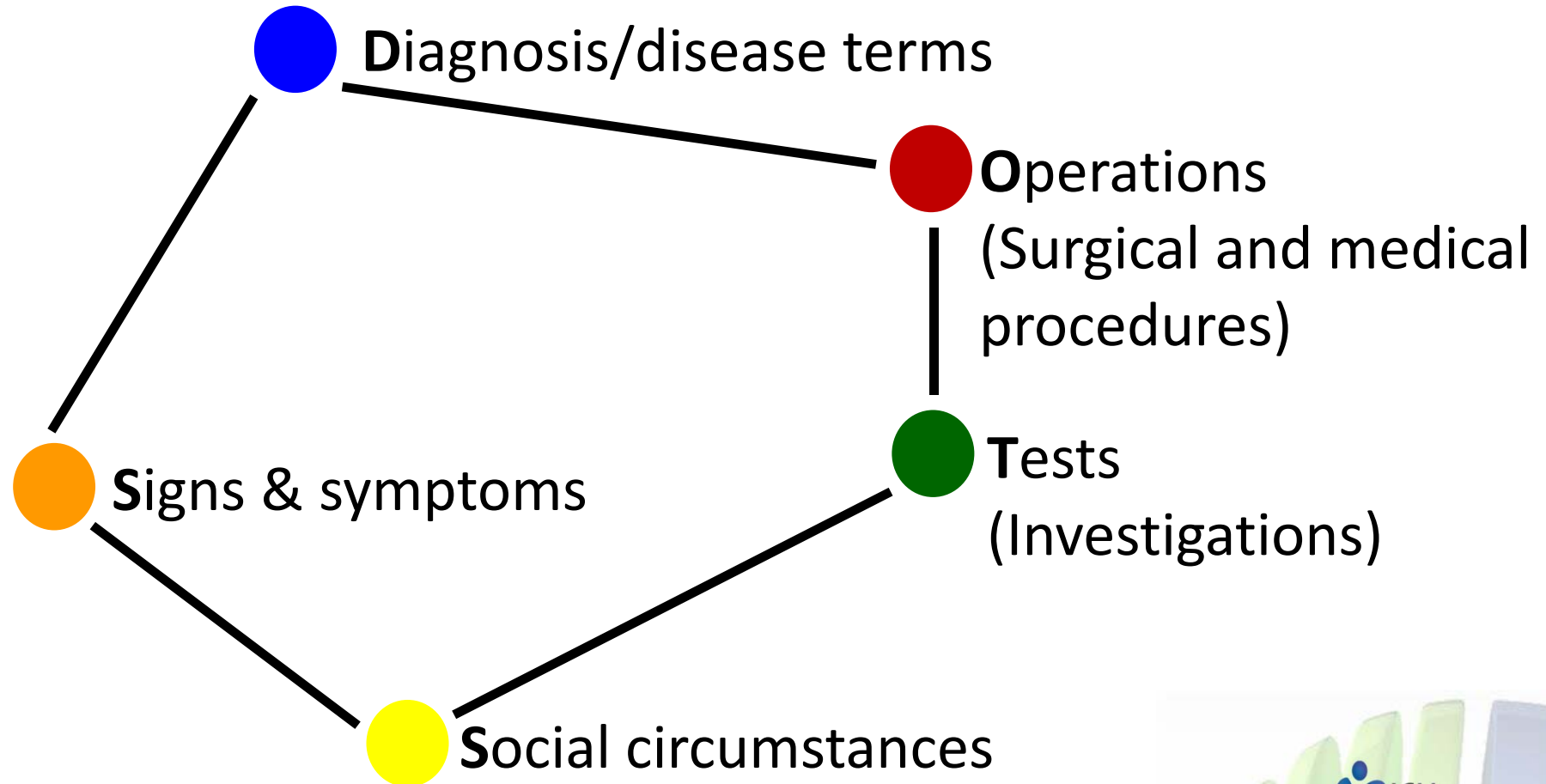
# Example – Cardiac Arrhythmias (cont)



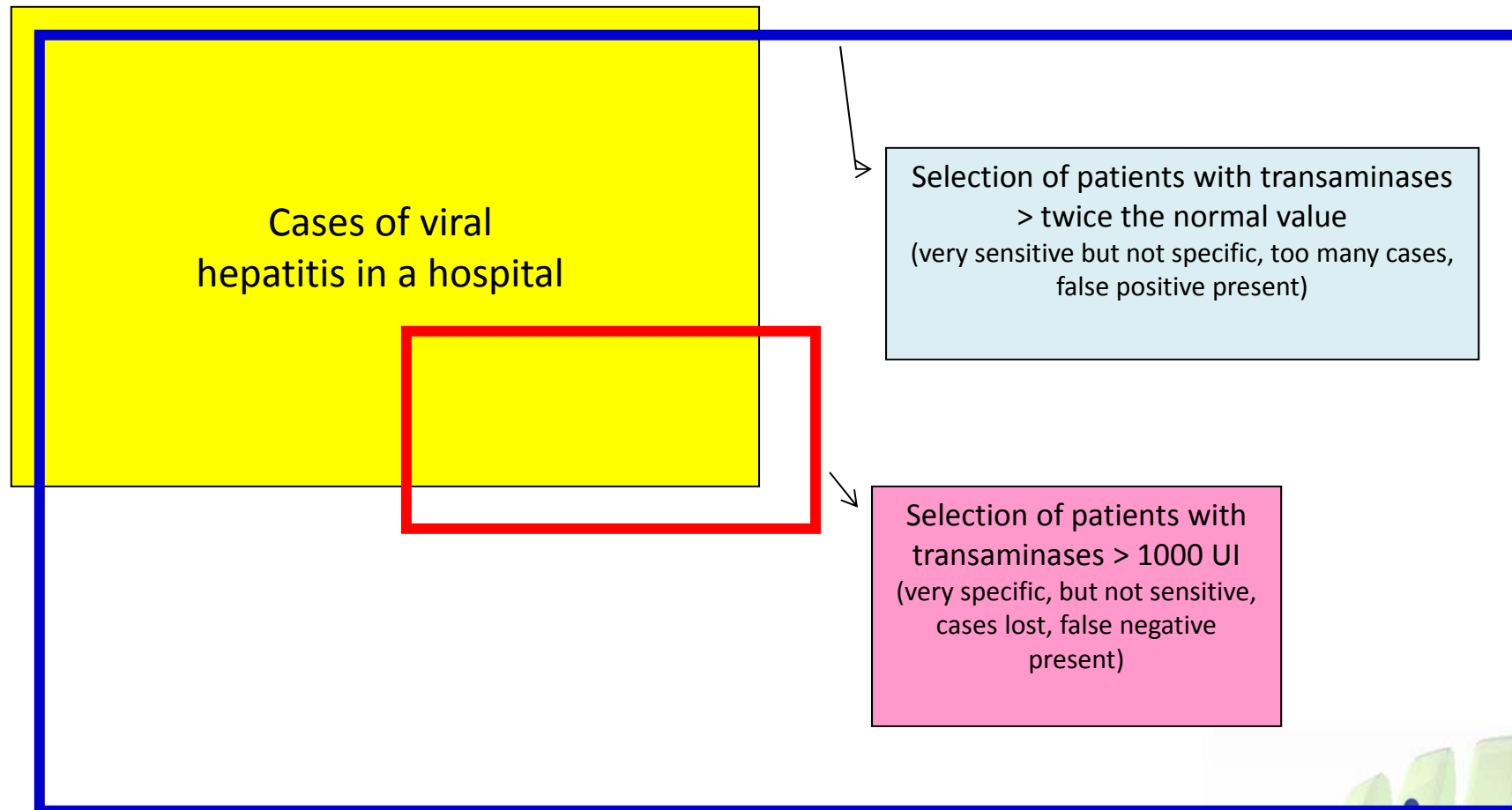
- Lastly...
  - PTs subordinate to HLT *Death and sudden death* (under SOC *General disorders and administration site conditions*) should be reviewed
    - Example: PT *Cardiac death*



# Connect the DOTSS!



# SENSITIVITY / SPECIFICITY



# SMQs in Production - Examples



Groupings of terms from more than one SOC related to defined medical condition or area of interest

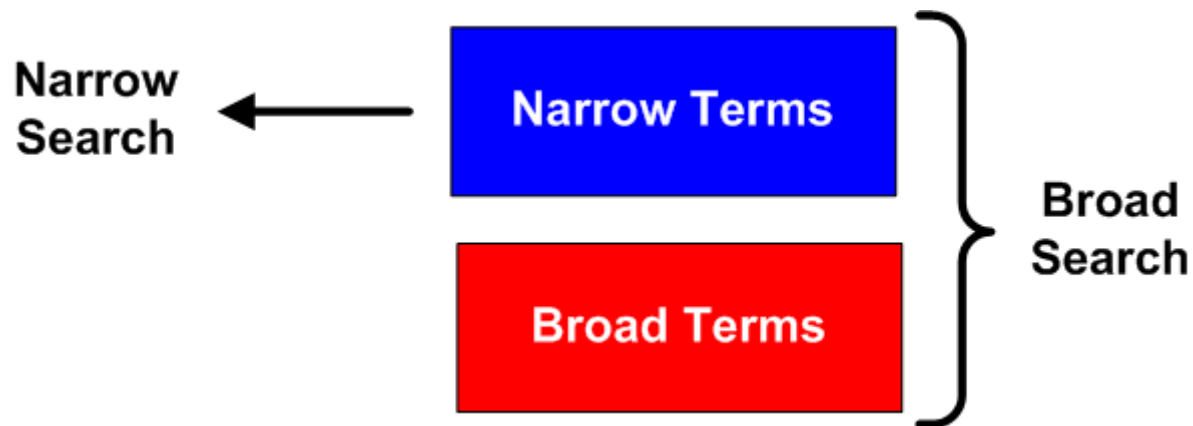
94 SMQ topics available in MedDRA v17.0

- Agranulocytosis
- Anaphylactic reaction
- Cerebrovascular disorders
- Convulsions
- Depression and suicide/self-injury
- Hepatic disorders
- Hypersensitivity
- Ischaemic heart disease
- Lack of efficacy/effect
- Osteonecrosis
- Peripheral neuropathy
- Pregnancy and neonatal topics
- Pseudomembranous colitis
- Rhabdomyolysis/myopathy
- Severe cutaneous adverse reactions
- Systemic lupus erythematosus



# Narrow and Broad Searches

- “Narrow” scope – specificity (cases highly likely to be condition of interest)
- “Broad” scope – sensitivity (all possible cases)
- “Broad search” = All broad + all narrow terms



# Narrow vs. Broad Example



## SMQ *Lactic acidosis*

### Definition

Lactic acidosis is a form of high anion gap metabolic acidosis - Intrinsic cardiac contractility may be depressed, but inotropic function can be normal because of catecholamine release- Peripheral arterial vasodilatation and central vasoconstriction can be present - Central nervous system function is depressed, with headache, lethargy, stupor, and, in some cases, even coma - Glucose intolerance may occur - Characterized by an increase in plasma L-lactate - Acidosis is seldom significant unless blood lactate exceeds 5 mmol/l - Clinical presentation in type B lactic acidosis: o Symptoms: hyperventilation or dyspnea, stupor or coma, vomiting, drowsiness, and abdominal pain o Onset of symptoms and signs is usually rapid accompanied by deterioration in the level of consciousness.

### Source

1. Braunwald E, Fauci A, Kasper D. Harrison's Principles of Internal Medicine. 15th Edition, 2001 pp 285-9
2. Weatherall D, Ledingham J and Warrell D. Oxford Textbook of Medicine. Third edition, 1996; volume 2 pp 1541-44

### Note

Testing in two regulatory databases confirmed that the term list is adequate; in one regulatory database, the term "acidosis" identified cases, but this may be a phenomenon of the database characteristics (coding of verbatims to terms of an older terminology or other coding conventions).

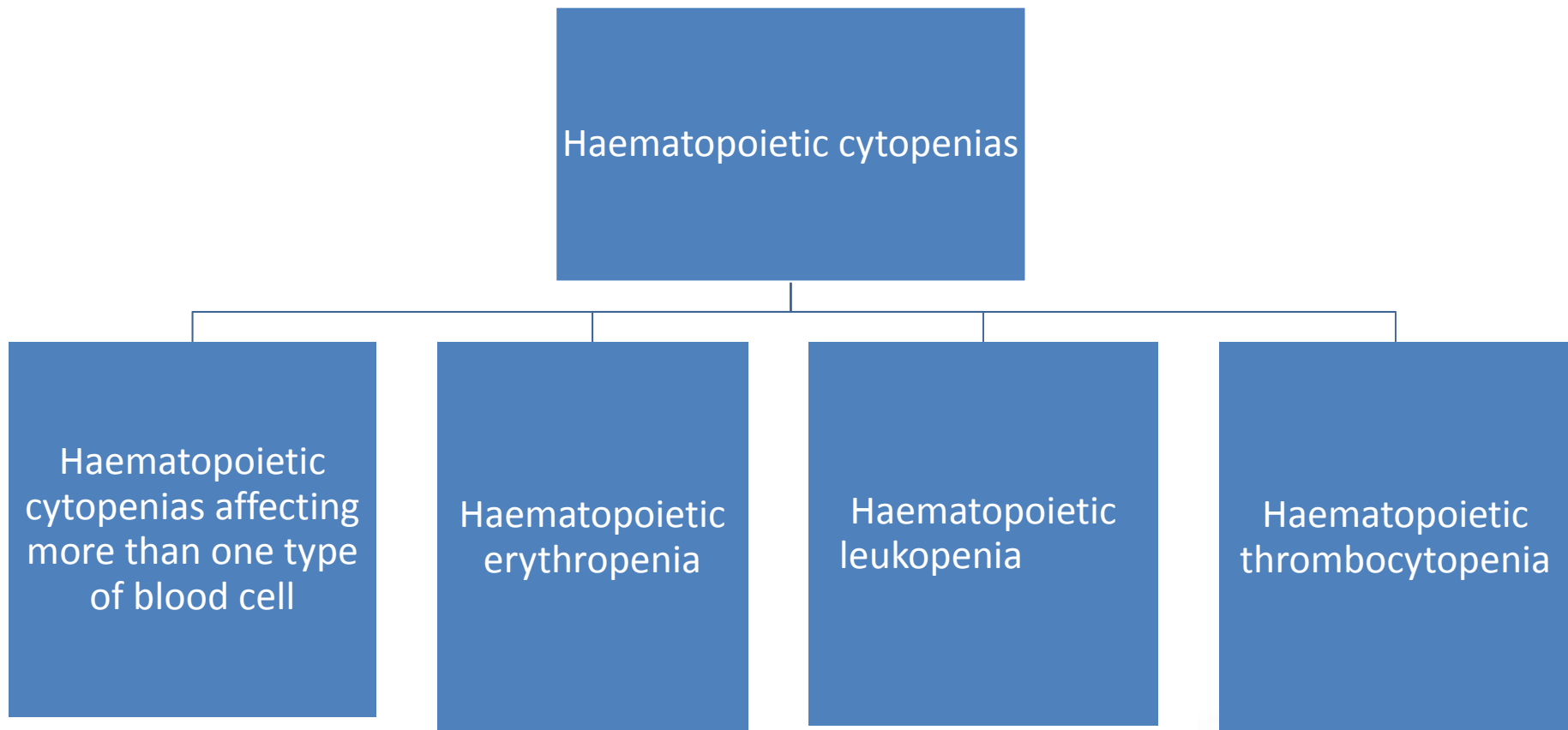
### Narrow Terms

Blood lactic acid increased
Hyperlactacidaemia
Lactic acidosis

### Broad Terms

Acid base balance abnormal
Acidosis
Anion gap abnormal
Anion gap increased
Blood bicarbonate abnormal
Blood bicarbonate decreased
Blood gases abnormal
Blood lactic acid abnormal
Blood pH abnormal
Blood pH decreased
Coma acidotic
Kussmaul respiration
Metabolic acidosis
PCO2 abnormal
PCO2 decreased
Urine lactic acid increased

# Hierarchical SMQ Example



- Clinical trials
  - Where safety profile is not fully established, use multiple SMQs on routine basis as screening tool
  - Selected SMQs to evaluate previously identified issue (pre-clinical data or class effect)
- Post-marketing
  - Selected SMQs to retrieve cases for suspected or known safety issue
  - Signal detection (multiple SMQs employed)
  - Single case alerts
  - Periodic reporting (aggregate cases for safety and other issues, e.g., lack of efficacy)



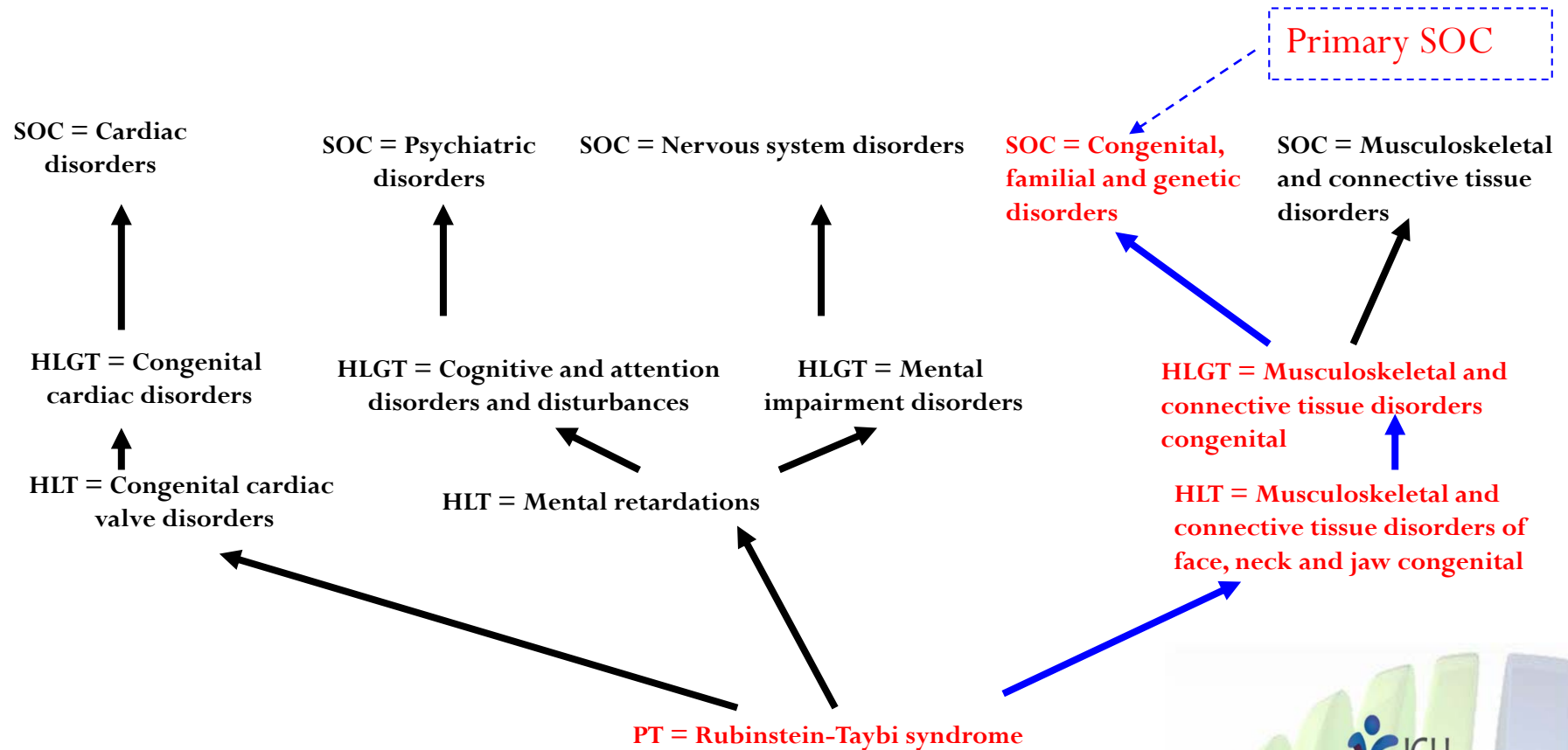
*¡Muchas gracias!*

*muito dúvidas e questões?*

*¿Preguntas!?*



# A Multi-Axial Terminology (cont)



# A Multi-Axial Terminology (cont)

