



**MedDRA**

# Essentials on MedDRA





MedDRA

# Overview

- MedDRA's structure, scope, and characteristics
- MedDRA maintenance
- Coding conventions: MedDRA Term Selection Points to Consider document
- Hands-on coding exercises



MedDRA

# What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities



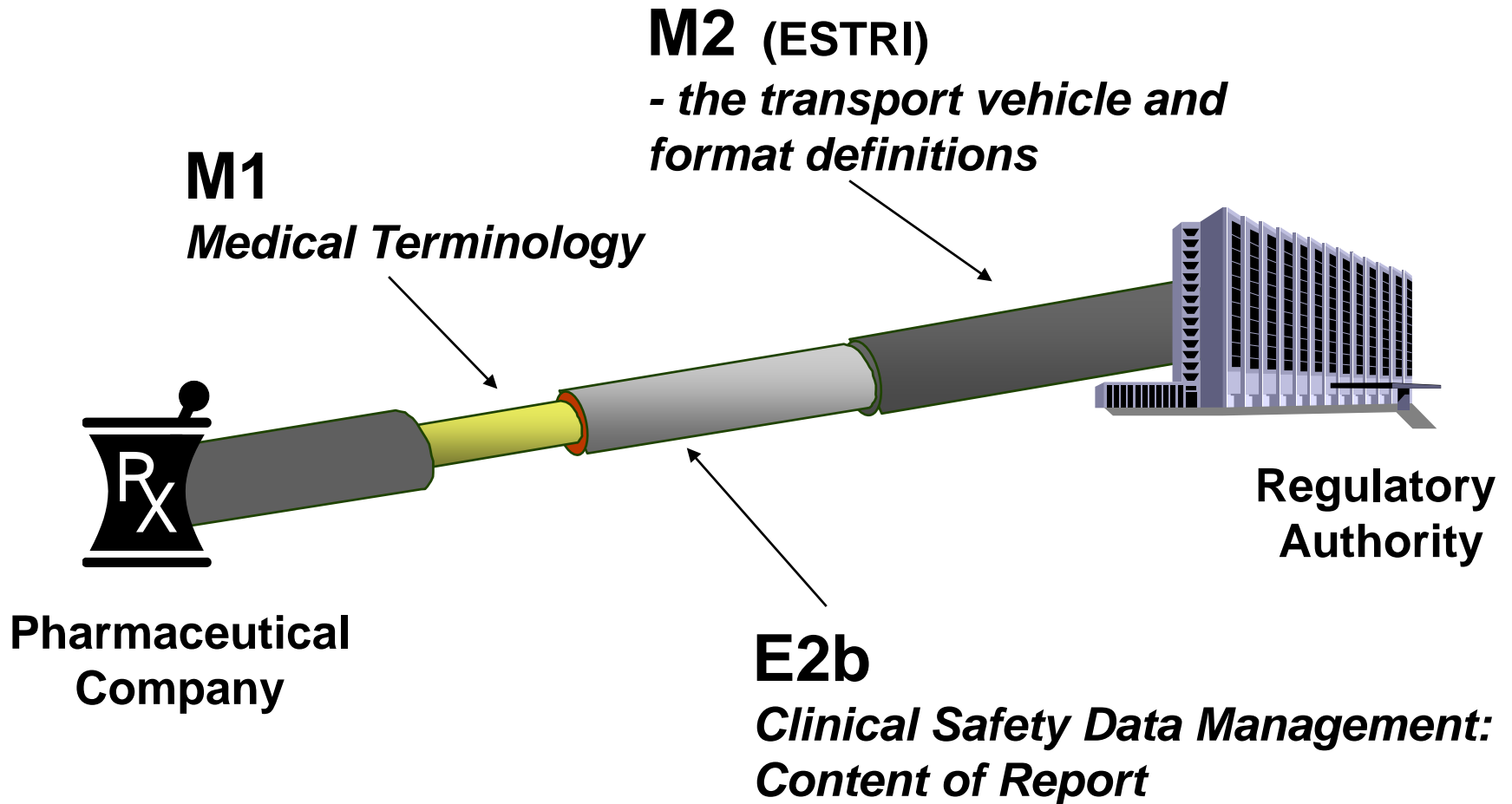


MedDRA

# MedDRA Definition

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.

# ICH EDI Coordination



# I2B(M)

- Information about the safety report itself
  - A.1 Report **identification**
  - A.2 **Primary source** of information
  - A.3.1 Who **sends** the information
  - A.3.2 Who **receives** it
- Case information
  - B.1 **Patient** characteristics
  - B.2 **Adverse reaction/event**
  - B.3 Investigation **test** and procedures
  - B.4 Information about **drugs** (both suspect and concomitant)
  - B.5 **Narrative** case summary and further information



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

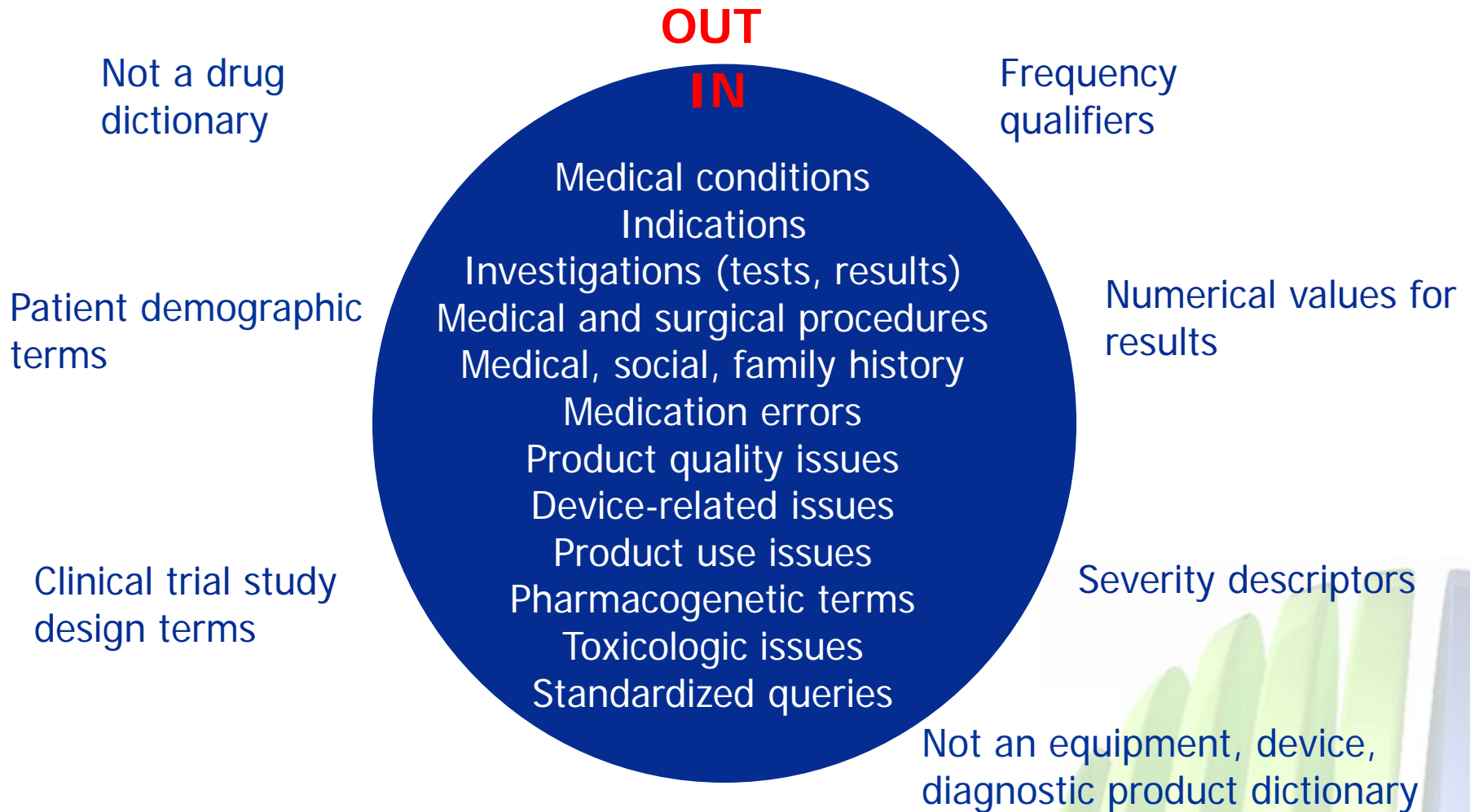
Prescribing Information

Advertising



MedDRA

# Scope of MedDRA







MedDRA

# MedDRA Structure

System Organ Class (SOC) (27)



High Level Group Term (HLGT) (337)



High Level Term (HLT) (1,738)



Preferred Term (PT) (22,499)



Lowest Level Term (LLT) (77,248)



MedDRA

# 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
- Product issues
- 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

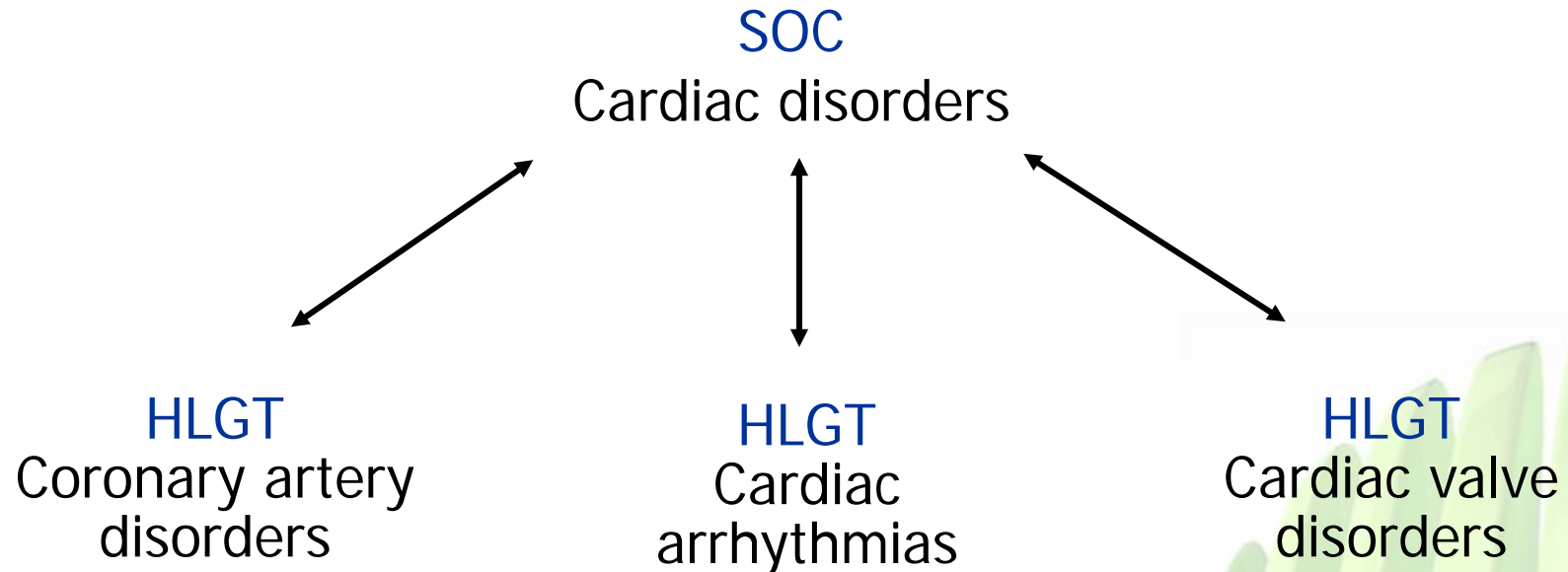
# System Organ Classes

- 
- 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 SOCs and superordinate grouping for one or more HLTs

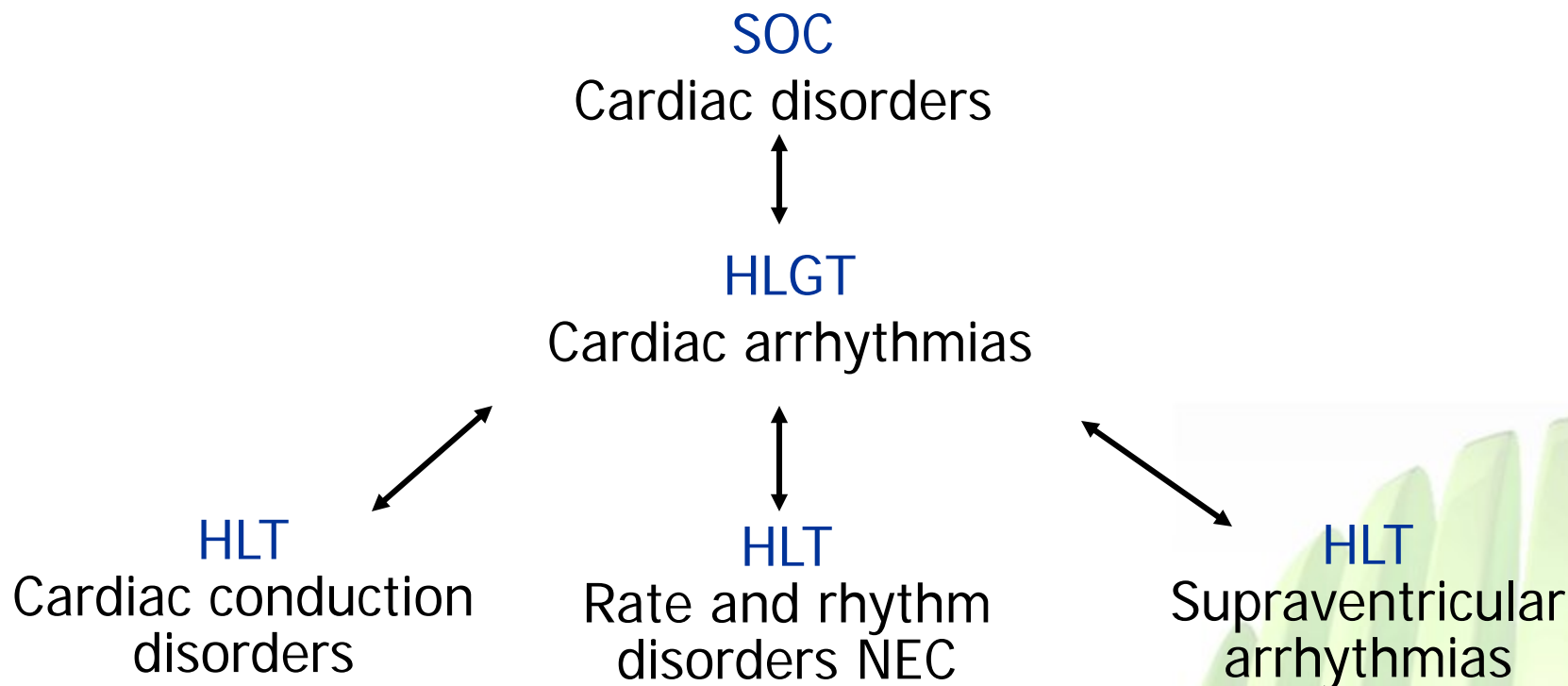


Not all HLTs shown



# High Level Terms

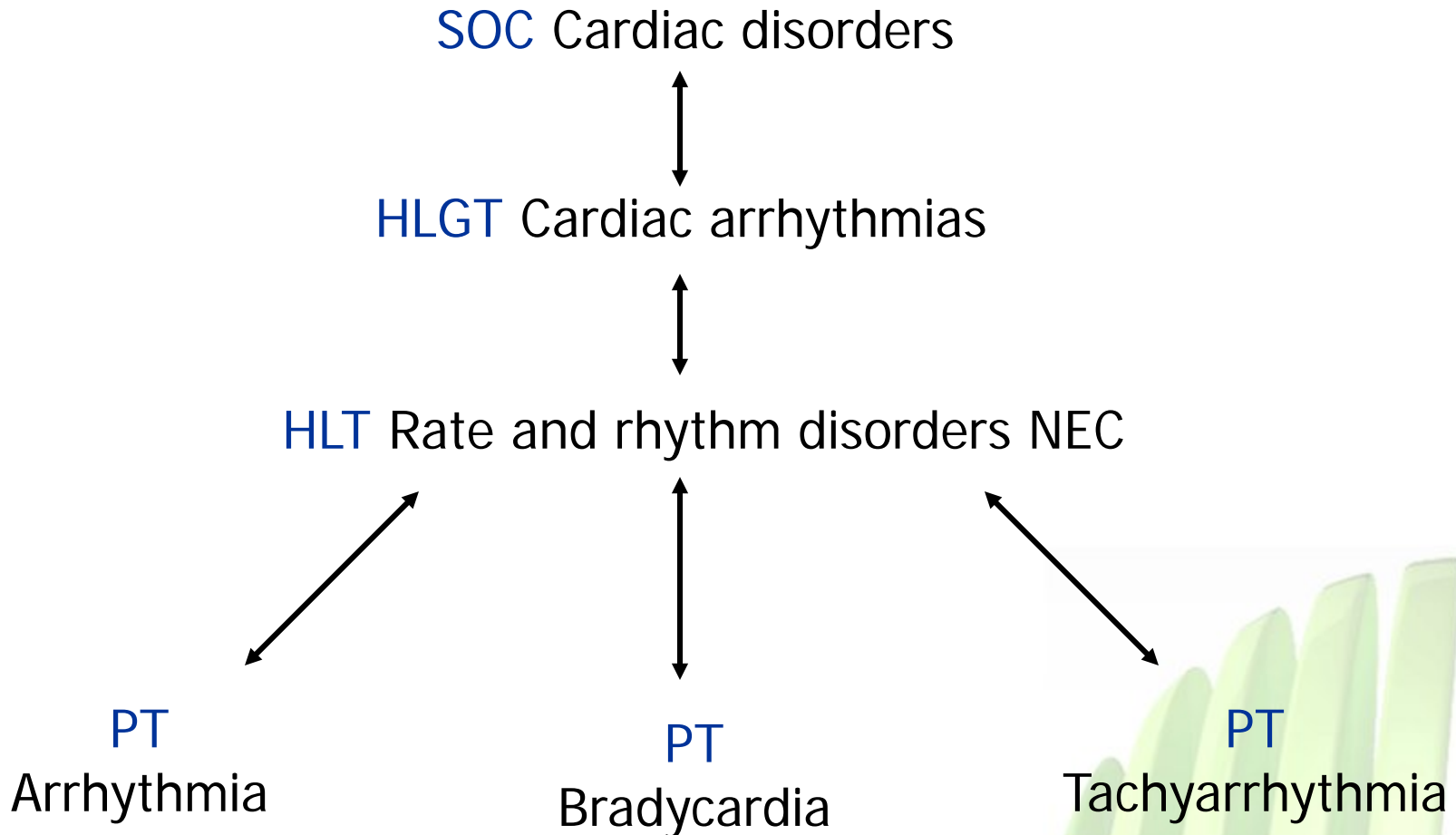
Subordinate to HLGTS and superordinate grouping for the PTs linked to it





# Preferred Terms

Represents a single medical concept





# Lowest Level Term

Synonyms, lexical variants, sub-elements

SOC = Cardiac disorders

HLGT = Cardiac arrhythmias

HLT = Rate and rhythm disorders NEC

PT = Arrhythmia

LLT  
Arrhythmia  
NOS

LLT  
Arrhythmia

LLT (Non-current)  
Other specified cardiac  
dysrhythmias

LLT  
Dysrhythmias



# Non-Current Terms

- Flagged at the LLT level in MedDRA
- Not recommended for continued use
- Retained to preserve historical data for retrieval and analysis
- Terms that are vague, ambiguous, outdated, truncated, or misspelled
- Terms derived from other terminologies that do not fit MedDRA rules





MedDRA

# MedDRA Codes

- Each MedDRA term assigned an 8-digit numeric code starting with "1"
- The code is non-expressive
- Codes can fulfill a data field in various electronic submission types (e.g., E2B)
- New terms are assigned sequentially



MedDRA

# Codes and Languages



Electronic Submission



# A Multi-Axial Terminology

- Multi-axial = the representation of a medical concept in multiple SOC's
  - Allows grouping by different classifications
  - Allows retrieval and presentation via different data sets
- All PTs assigned a primary SOC
  - Determines which SOC will represent a PT during cumulative data outputs
  - Prevents “double counting”
  - Supports standardized data presentation
  - Pre-defined allocations should not be changed by users



MedDRA

# A Multi-Axial Terminology (cont)

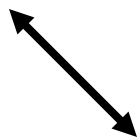
SOC = Respiratory, thoracic and  
mediastinal disorders  
(Secondary SOC)



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



# Rules for Primary SOC Allocation

- PTs represented in **only one SOC** are automatically assigned that SOC as primary
- PTs for diseases, signs and symptoms are assigned to **prime manifestation site** SOC
- **Congenital** and hereditary anomalies terms have SOC *Congenital, familial and genetic disorders* as Primary SOC
- **Neoplasms** terms have SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* as Primary SOC
  - **Exception:** Cysts and polyps have prime manifestation site SOC as Primary SOC
- **Infections** and infestations terms have SOC *Infections and infestations* as Primary SOC



# Primary SOC Priority

If a PT links to more than one of the exceptions, the following priority will be used to determine primary SOC:

- 1<sup>st</sup>: Congenital, familial and genetic disorders*
- 2<sup>nd</sup>: Neoplasms benign, malignant and unspecified (incl cysts and polyps)*
- 3<sup>rd</sup>: Infections and infestations*



# A Multi-Axial Terminology (cont)

PTs in the following SOCs **only** appear in that particular SOC and not in others, i.e., they are not multi-axial

- *Investigations*
- *Surgical and medical procedures*
- *Social circumstances*

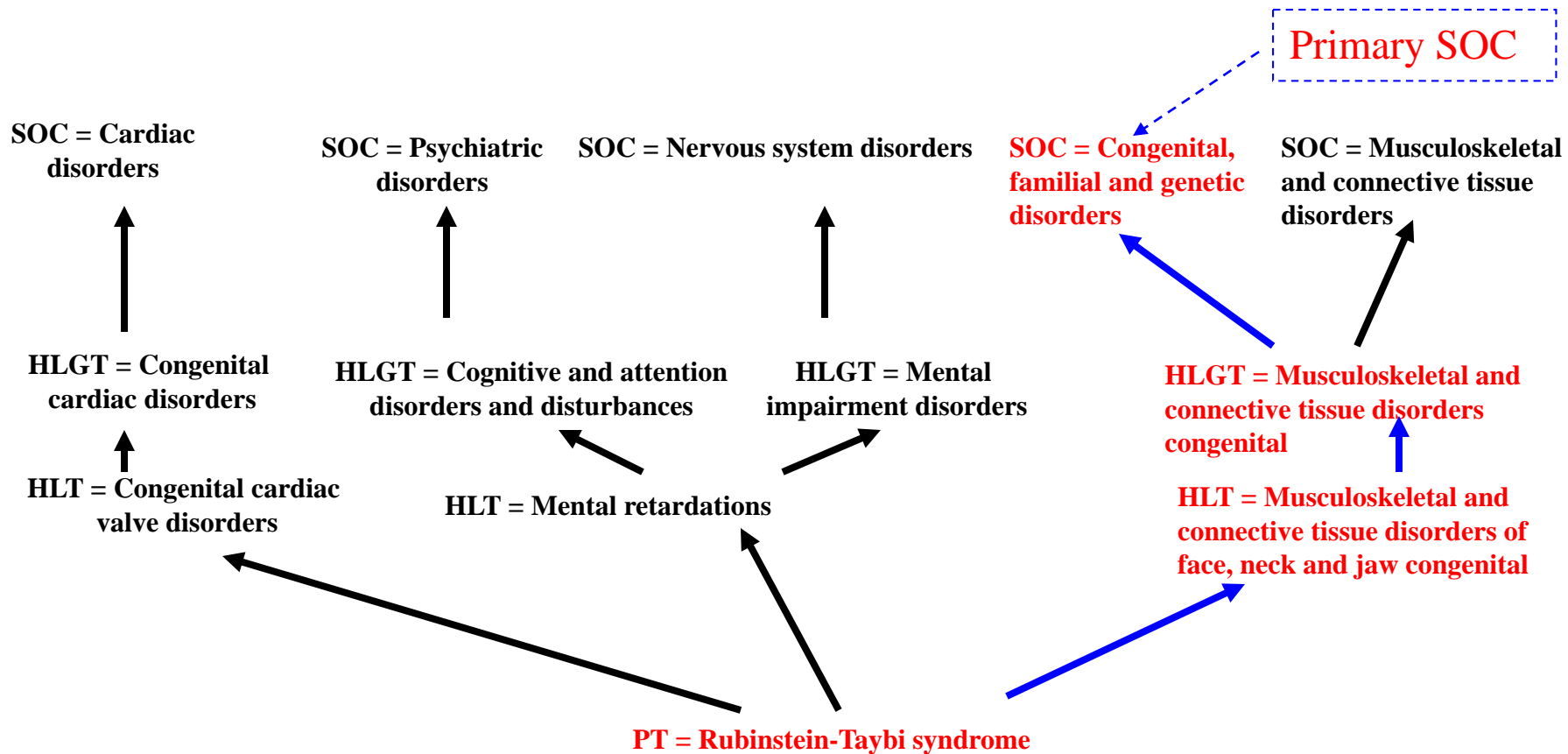


# Can You Select the Primary SOC for This PT?

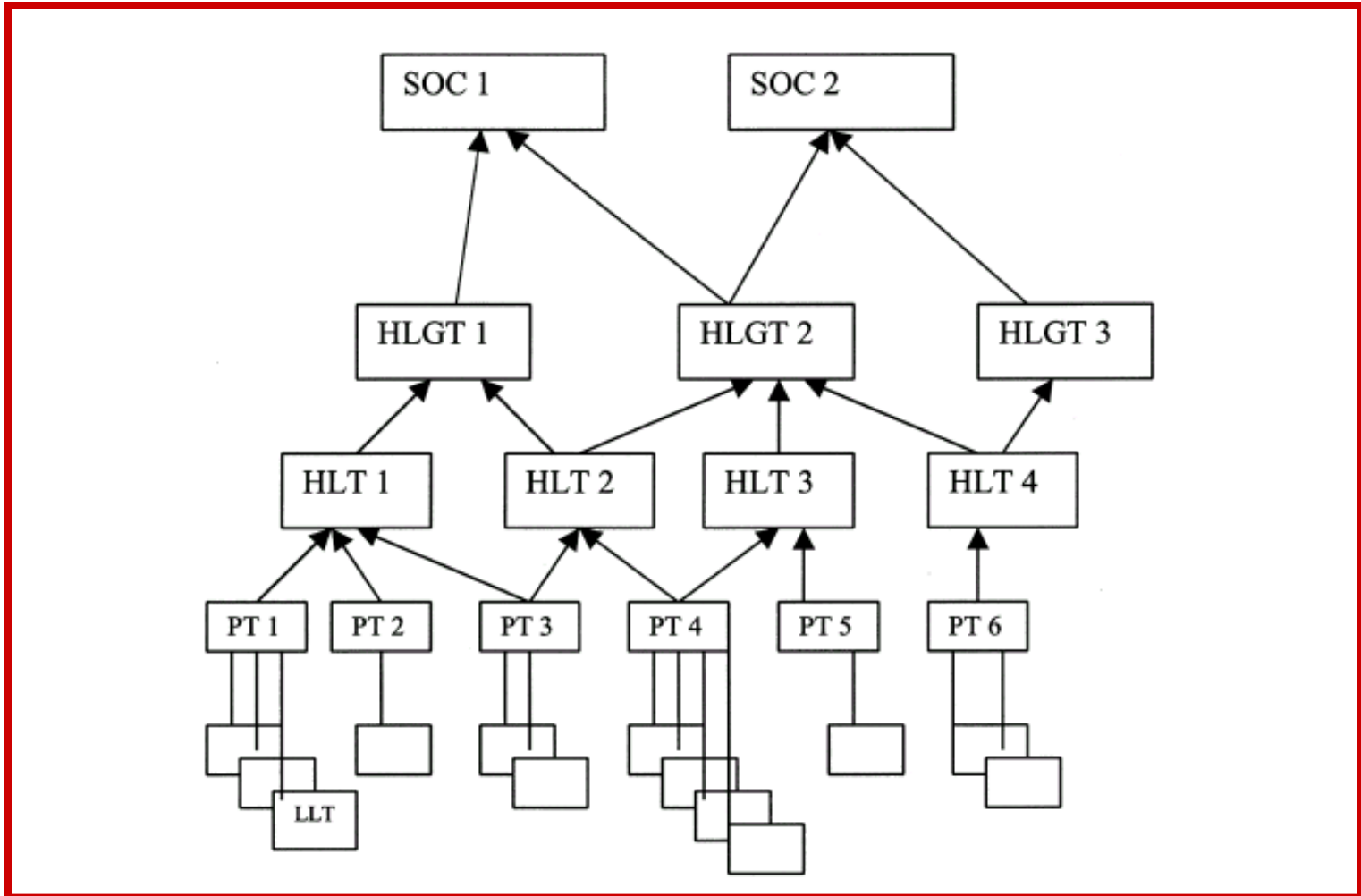
PT	HLT	HLGT	SOC
Congenital HIV infection	Viral infections congenital	Infections and infestations congenital	Congenital, familial and genetic disorders
	Congenital neonatal infections	Neonatal and perinatal conditions	Pregnancy, puerperium and perinatal conditions
	Retroviral infections	Viral infectious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



# A Multi-Axial Terminology (cont)



# A Multi-Axial Terminology (cont)





MedDRA

# MedDRA Maintenance





MedDRA

# MedDRA and the MSSO

- 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

# MedDRA Maintenance

- MedDRA is a user-responsive terminology
- Users may submit change requests (CRs) to the MSSO for consideration
  - Each organization: up to 100 CRs per month
  - For simple changes (PT and LLT levels), notification of final disposition within 7-10 working days
  - Complex changes above PT level received all year round. Posted for users' comments mid-year.
- Twice yearly official updates
  - 1 March X.0 release (Complex and simple changes)
  - 1 September X.1 release (Simple changes only)



MedDRA


# WebCR

- Web-based tool for Change Requests (CR)
  - URL: <https://mssotools.com/webcr/>
  - Via the Change Request Information page
- Ability to submit CRs online
- Immediate confirmation
- Review unsubmitted CRs online
- Ability to query CR history back to v5.1



MedDRA

# Submitting Changes



## WebCR

MedDRA Change Request

Freeze Date for MedDRA v20.1  
1 June 2017 5:00 PM U.S. EST

---

Login to WebCR

MedDRA ID:

Password:

Welcome to the MedDRA User Change Request Data Entry Web site.  
You may submit your MedDRA Change Request to the MSSO here.  
If you have problems logging in, please contact the MSSO Help Desk at:  
[MSSOHelp@meddra.org](mailto:MSSOHelp@meddra.org) or 1-877-258-8280

---

Copyright © 2012 All Rights Reserved

- Online change request submission tool
- Guides the user to enter all needed information



# Submitting Changes (cont)

**Add a New PT**

**Proposed PT (Required)**

Second degree chemical burns of skin

**Primary HLT (Optional)**

Chemical injuries

**Primary SOC (Optional)**

Injury, poisoning and procedural complications

**Secondary HLT (Optional)**

Dermatitis ascribed to specific agent

**Secondary SOC (Optional)**

Skin and subcutaneous tissue disorders

---

**Justification statement is required**

**Justification**

Please consider including the gradation of chemical burns similar to the gradation of thermal burns under HLT Thermal burns to assist with coding and analysis.

---

**Attach supporting document (Optional)**

Attachment

000024 C:\Users\s804733\Desktop\SupportingInforma Browse...

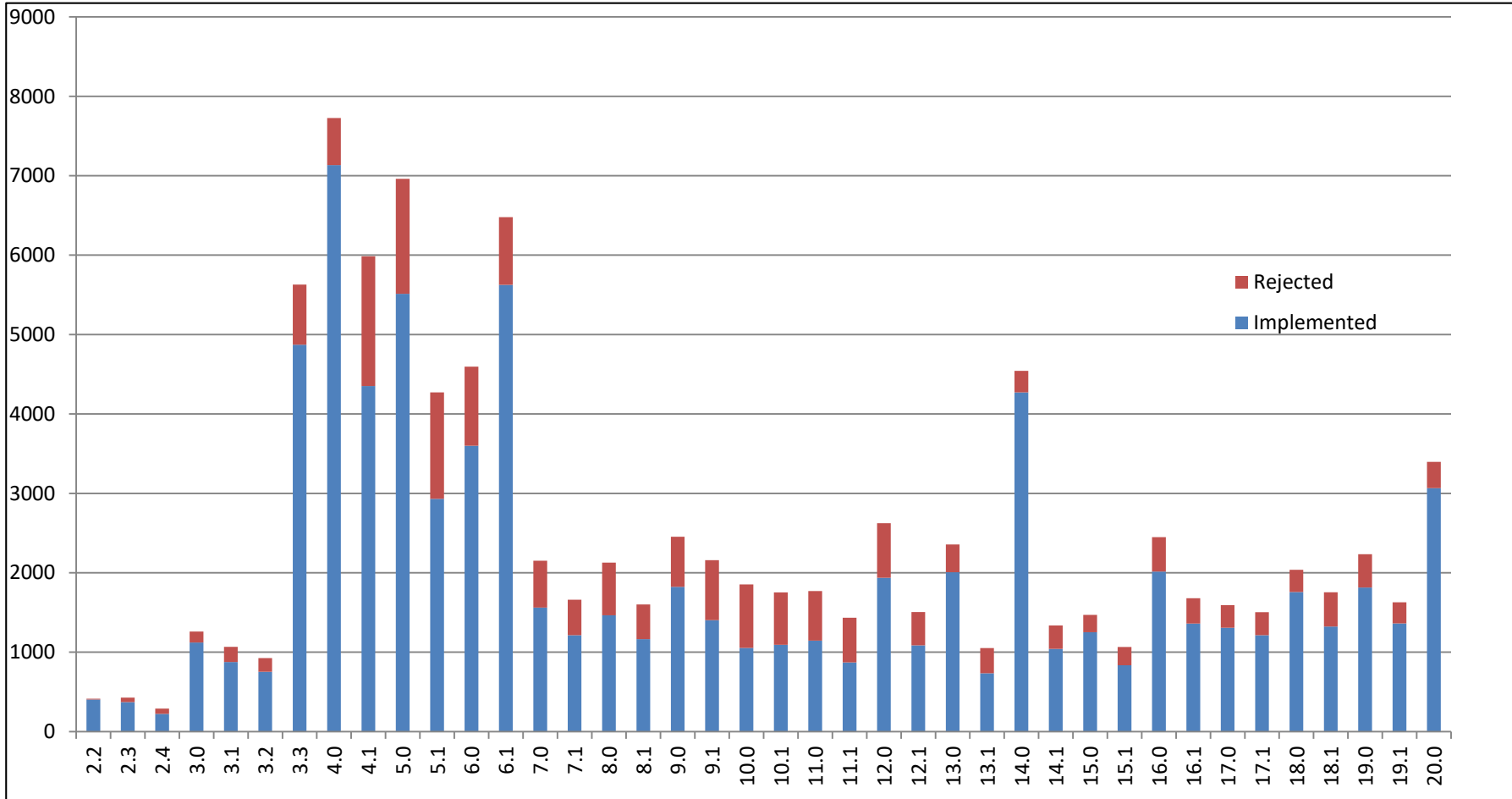
- Sample entry for a new PT in WebCR
- Justification and supporting documentation is important to help MSSO understand the need





MedDRA

# Implemented Changes in MedDRA



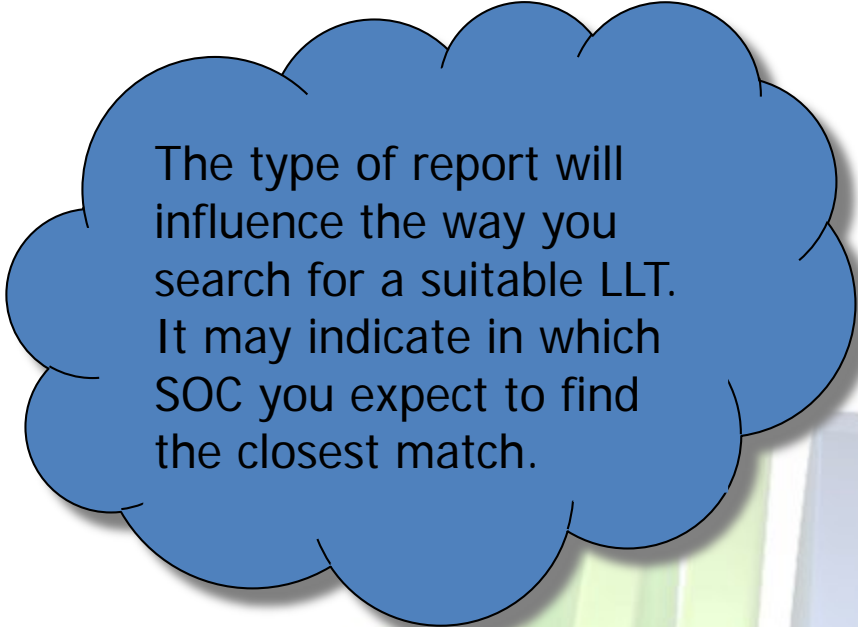


MedDRA

# Coding with MedDRA

# 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.



## Verbatim term

Disconnected feeling

Unspecified neurological condition

Echoing in ears

After the patient's drug was substituted with a generic drug, his response to therapy was different

Severe bronchospasm on induction of anesthesia

Elderly woman complained her arm was tender where she had received her seasonal flu vaccine

PANDAS

Influenza with body aches, fever, cough

72 year old man with aphasia and right hemiplegia. Stroke in middle cerebral artery territory is suspected.

Patient said she received flu vaccine 3 months before she became pregnant



# Disconnected feeling

- + SOC Gastrointestinal disorders
- SOC General disorders and administration site conditions
  - + HLT Administration site reactions
  - + HLT Body temperature conditions
  - + HLT Complications associated with device
  - + HLT Fatal outcomes
  - HLT General system disorders NEC
  - + HLT Acquired gene mutations and other alterations
  - + HLT Adverse effect absent
  - + HLT Asthenic conditions
  - HLT Feelings and sensations NEC
    - + PT Alcoholic hangover
    - + PT Burning sensation
    - + PT Chills
    - + PT Decreased appetite
    - + PT Early satiety
    - PT Feeling abnormal
      - LLT Cotton wool in head
      - LLT Feeling abnormal
      - LLT Feeling bad
      - LLT Feeling dazed
      - LLT Feeling floating
      - LLT Feeling lifeless
      - LLT Feeling miserable
      - LLT Feeling stoned
      - LLT Feeling strange
      - LLT Feeling weightless
      - LLT Feels awful
      - LLT Feels bad
      - LLT Feels poorly
      - LLT Felt like a zombie
      - LLT Floating feeling

- SOC Psychiatric disorders
  - + HLT Adjustment disorders (incl subtypes)
  - + HLT Anxiety disorders and symptoms
  - + HLT Changes in physical activity
  - + HLT Cognitive and attention disorders and disturbances
  - + HLT Communication disorders and disturbances
  - + HLT Deliria (incl confusion)
  - + HLT Dementia and amnesic conditions
  - + HLT Depressed mood disorders and disturbances
  - + HLT Developmental disorders NEC
  - HLT Dissociative disorders
    - HLT Dissociative states
      - + PT Depersonalisation/derealisation disorder
      - PT Dissociation
        - LLT Corporal disassociation
        - LLT Corporeal detachment
        - LLT Corporeal dissociation
        - LLT Detached thought processes
        - LLT Detachment
        - LLT Detachment corporeal
        - LLT Detachment psychological
        - LLT Disassociation/association
        - LLT Dissociation
        - LLT Dissociation corporeal
        - LLT Feeling detached
        - LLT Feeling remote
    - + PT Dissociative amnesia
    - + PT Dissociative disorder
    - + PT Dissociative identity disorder
  - + HLT Disturbances in thinking and perception
  - + HLT Eating disorders and disturbances
  - + HLT Impulse control disorders NEC



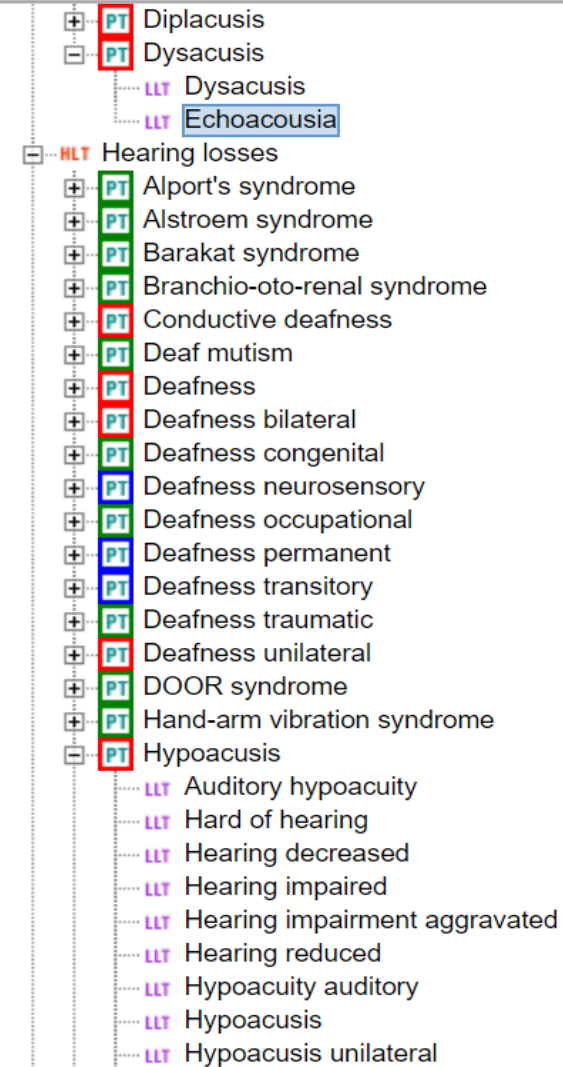
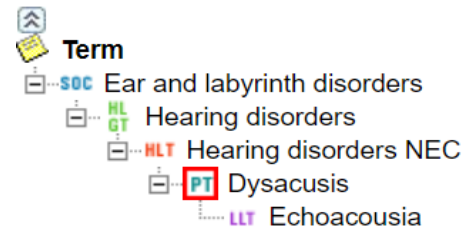
MedDRA

# Unspecified neurological condition

- [-] SOC Nervous system disorders
  - [+] HLT Central nervous system infections and inflammations
  - [+] HLT Central nervous system vascular disorders
  - [+] HLT Congenital and peripartum neurological conditions
  - [+] HLT Cranial nerve disorders (excl neoplasms)
  - [+] HLT Demyelinating disorders
  - [+] HLT Encephalopathies
  - [+] HLT Headaches
  - [+] HLT Increased intracranial pressure and hydrocephalus
  - [+] HLT Mental impairment disorders
  - [+] HLT Movement disorders (incl parkinsonism)
  - [+] HLT Nervous system neoplasms benign
  - [+] HLT Nervous system neoplasms malignant and unspecified NEC
  - [-] HLT Neurological disorders NEC
    - [+] HLT Abnormal reflexes
    - [+] HLT Coma states
    - [+] HLT Coordination and balance disturbances
    - [+] HLT Cortical dysfunction NEC
    - [+] HLT Disturbances in consciousness NEC
    - [-] HLT Nervous system disorders NEC
      - [+] PT Anaesthetic complication neurological
      - [+] PT Atypical haemolytic uraemic syndrome
      - [+] PT Bing-Neel syndrome
      - [+] PT Bloch-Sulzberger syndrome
      - [+] PT Brain satellitosis
      - [+] PT Brain stem syndrome
      - [+] PT Central bradycardia
      - [+] PT Central nervous system injury
      - [+] PT Central nervous system lesion
      - [+] PT Central nervous system leukaemia
      - [+] PT Central nervous system lupus

- [+] PT Nerve degeneration
- [+] PT Nerve injury
- [-] PT Nervous system disorder
  - LLT Central nervous system disorder
  - LLT Central nervous system disorder NOS
  - LLT Cerebellar disorder NOS
  - LLT Cerebellar hemisphere disorder
  - LLT Cerebral dysfunction
  - LLT CNS disorder (NOS)
  - LLT Disorder central nervous system
  - LLT Disorder nervous system
  - LLT Nervous system disorder
  - LLT Nervous system disorder NOS
  - LLT Nervous system disorder, central
  - LLT Neurologic complication
  - LLT Neurologic disorder NOS
  - LLT Neurological complication
  - LLT Neurological disorder NOS
  - LLT Neurological impairment
  - LLT Other and unspecified cerebral irritability in newborn
  - LLT Other and unspecified disorders of the nervous system
  - LLT Other conditions of brain
  - LLT Other specified conditions of brain
  - LLT Other specified disorder of nervous system
  - LLT Other specified disorders of nervous system
  - LLT Unspecified condition of brain
  - LLT Unspecified disorders of nervous system
- [+] PT Nervous system injury
- [+] PT Neuroacanthocytosis
- [+] PT Neurodegenerative disorder
- [+] PT Neurogenic shock

# Echoing in ears



# ... response to therapy was different

**MedDRA Browser**

**Term**

- SOC General disorders and administration site conditions
  - HL GT Therapeutic and nontherapeutic effects (excl toxicity)
    - HLT Therapeutic and nontherapeutic responses
      - PT Therapeutic response changed
        - LLT Generic substitution altered therapeutic response

**Search Results**

- LLT
  - Exact Match - 0
  - Lexical Match - 0
  - Synonym Search - 0
  - Contains Search - 1
  - Echo - 0

**Term Details in Primary Language**

LLT - Lowest Level Term

MedDRA Code	MedDRA Term	Currency
10063752	Generic substitution altered therapeutic response	Y

SMQ Code	SMQ Name	Scope	Status	Category	Weight	Addition Version	Last Modified Version
20000032	Lack of efficacy/effect (SMQ)	Narrow	Active	A	0	17.1	17.1

**LLT Occurrences in MedDRA**

- LLT **Generic substitution altered therapeutic response**
  - PT Therapeutic response changed
    - HLT Therapeutic and nontherapeutic responses
      - HL GT Therapeutic and nontherapeutic effects (excl toxicity)
        - SOC General disorders and administration site conditions

**LLT Occurrences in SMQ**

- LLT Generic substitution altered therapeutic response
  - PT Therapeutic response changed
    - SMQ Lack of efficacy/effect (SMQ)

- PT Paradoxical drug reaction
- PT Positive cardiac inotropic effect
- PT Procedural failure
- PT Product intolerance
- PT Reactogenicity event
- PT Remission not achieved
- PT Renin-angiotensin system inhibition
- PT Similar reaction on previous exposure to drug
- PT Subcutaneous drug absorption impaired
- PT Surgical failure
- PT Sympathomimetic effect
- PT Tachyphylaxis
- PT Therapeutic product effective for unapproved indication
- PT Therapeutic product ineffective
- PT Therapeutic product ineffective for unapproved indication
- PT Therapeutic reaction time decreased
- PT Therapeutic response changed
  - LLT Biosimilar substitution altered therapeutic response
  - LLT **Generic substitution altered therapeutic response**
  - LLT Good effect
  - LLT Inappropriate drug response
  - LLT Therapeutic response changed
- PT Therapeutic response decreased
- PT Therapeutic response delayed
- PT Therapeutic response increased
- PT Therapeutic response prolonged
- PT Therapeutic response shortened
- PT Therapeutic response unexpected
- PT Therapy naive
- PT Therapy non-responder
- PT Therapy partial responder
- PT Therapy responder

After the patient's drug was substituted with a generic drug, his response to therapy was different



# Severe bronchospasm on induction of anesthesia

MedDRA Browser

Term

- Respiratory, thoracic and mediastinal disorders
  - Respiratory, thoracic and mediastinal disorders
    - Bronchial disorders (excl neoplasms)
      - Bronchial conditions NEC
        - Bronchospasm and obstruction
          - Acute post asthmatic amyotrophy
          - Airway remodelling
          - Aspirin-exacerbated respiratory disease
          - Asthma
          - Asthma exercise induced
          - Asthma late onset
          - Asthma-chronic obstructive pulmonary disease overlap syndrome
          - Asthmatic crisis
          - Bronchial hyperreactivity
          - Bronchial obstruction
          - Bronchial oedema
          - Bronchitis chronic
          - Bronchospasm
            - Allergic bronchospasm
            - Bronchial spasm
            - Bronchoconstriction
            - Bronchospasm
            - Bronchospasm aggravated
            - Bronchospasm NOS
            - Exercise-induced bronchospasm
            - Spasm bronchial
          - Bronchospasm paradoxical
          - Bronchostenosis
          - Childhood asthma
          - Chronic obstructive pulmonary disease
          - Cystic fibrosis
          - Cystic fibrosis lung
          - Infective exacerbation of chronic obstructive airways disease
          - Infective pulmonary exacerbation of cystic fibrosis
          - Obliterative bronchiolitis

LLT

- Exact Match - 1
  - Bronchospasm
- Lexical Variant - 0
- Synonym Search Results - 0
- Contains Search Results - 9
  - Allergic bronchospasm
  - Bronchospasm aggravated
  - Bronchospasm NOS
  - Bronchospasm on induction
  - Bronchospasm paradoxical
  - Exercise-induced bronchospasm
  - Paradoxical bronchospasm
  - Prophylaxis against bronchospasm
  - Unilateral bronchospasm

## Term Details in Primary Language

LLT - Lowest Level Term

MedDRA Code	MedDRA Term	Currency
10006482	Bronchospasm	Y

SMQ Code	SMQ Name	Scope	Status	Category	Weight	Addition Version	Last Modified Version
20000021	Anaphylactic reaction (SMQ)	Broad	Active	B	0	8.1	8.1
20000025	Asthma/bronchospasm (SMQ)	Narrow	Active	A	0	8.1	8.1
20000157	Eosinophilic pneumonia (SMQ)	Broad	Active	C	0	12.0	12.0
20000214	Hypersensitivity (SMQ)	Narrow	Active	A	0	16.0	16.0

## LLT Occurrences in MedDRA

- LLT Bronchospasm
  - PT Bronchospasm
    - HLT Bronchospasm and obstruction
      - HL GT Bronchial disorders (excl neoplasms)
        - SOC Respiratory, thoracic and mediastinal disorders
- LLT Bronchospasm
  - PT Bronchospasm
    - HLT Allergic conditions NEC
      - HL GT Allergic conditions
        - SOC Immune system disorders

## LLT Occurrences in SMQ

- LLT Bronchospasm
  - PT Bronchospasm
    - SMQ Anaphylactic reaction (SMQ)
  - PT Bronchospasm
    - SMQ Asthma/bronchospasm (SMQ)
  - PT Bronchospasm
    - SMQ Eosinophilic pneumonia (SMQ)
  - PT Bronchospasm
    - SMQ Hypersensitivity (SMQ)



# Severe bronchospasm on induction of anesthesia (cont)

**MedDRA Browser**

**Term**

- SOC Injury, poisoning and procedural complications
  - HLGT Procedural related injuries and complications NEC
    - HLT Anaesthetic and allied procedural complications
      - PT Airway complication of anaesthesia
        - LLT Bronchospasm on induction

**Search Options**

SOC  
  HLGT  
  HLT  
  PT  
  LLT

English  
 bronchospasm on induction

Use Synonym List  
 Ignore Diacritical Marks  
 Show PT/LLT with categories

[Search](#)  
 [Clear Search](#)  
 [Cancel](#)  
 [Advanced Search](#)

[<](#)  
 [<<](#)  
 [>>](#)  
 [>](#)  
 [Export](#)

**Total Search Results: 1**

**Select SOCs to Search (default is all SOCs)**

- 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

[Clear Selection](#)

**Search Results**

LLT

- LLT
  - Exact Match - 1
    - LLT Bronchospasm on induction
  - Lexical Variant - 0
  - Synonym Search Results - 0
  - Contains Search Results - 0

**Term Details in Primary Language**

LLT - Lowest Level Term

MedDRA Code	MedDRA Term	Currency
10050636	Bronchospasm on induction	Y

**LLT Occurrences in MedDRA**

- LLT **Bronchospasm on induction**
  - PT Airway complication of anaesthesia
    - HLT Anaesthetic and allied procedural complications
      - HLGT Procedural related injuries and complications NEC
        - SOC Injury, poisoning and procedural complications
- LLT **Bronchospasm on induction**
  - PT Airway complication of anaesthesia
    - HLT Respiratory tract disorders NEC
      - HLGT Respiratory disorders NEC
        - SOC Respiratory, thoracic and mediastinal disorders

# Severe bronchospasm on induction of anesthesia (cont)

MedDRA Browser

**Term**

- SOC Respiratory, thoracic and mediastinal disorders
  - HLT Respiratory disorders NEC
    - HLT Respiratory tract disorders NEC
      - PT** Airway complication of anaesthesia

---

- SOC Reproductive system and breast disorders
- SOC Respiratory, thoracic and mediastinal disorders
  - HLT Bronchial disorders (excl neoplasms)
    - HLT Bronchial conditions NEC
    - HLT Bronchospasm and obstruction
  - HLT Congenital respiratory tract disorders
  - HLT Lower respiratory tract disorders (excl obstruction and infection)
  - HLT Neonatal respiratory disorders
  - HLT Pleural disorders
  - HLT Pulmonary vascular disorders
  - HLT Respiratory disorders NEC
    - HLT Breathing abnormalities
    - HLT Conditions associated with abnormal gas exchange
    - HLT Coughing and associated symptoms
    - HLT Respiratory failures (excl neonatal)
    - HLT Respiratory tract disorders NEC
      - PT Airway burns
      - PT** Airway complication of anaesthesia
        - LLT Airway complication of anaesthesia
        - LLT Airway complication of anesthesia
        - LLT Airway complications of anaesthesia
        - LLT Airway obstruction on anaesthetic emergence
        - LLT Airway obstruction on anaesthetic induction
        - LLT Airway obstruction on anesthetic emergence
        - LLT Airway obstruction on anesthetic induction
        - LLT Bronchospasm on induction
        - LLT Bucking
        - LLT Bucking, anaesthesia related
        - LLT Bucking, anesthesia related
        - LLT Coughing on induction
        - LLT Laryngospasm on emergence
        - LLT Laryngospasm on induction

**Search Results**

- LLT
- LLT Exact Match
- LLT Bronchospasm on induction
- LLT Lexical Variants
- LLT Synonyms
- LLT Contains

**Term Details in Primary Language**

PT - Preferred Term

MedDRA Code	MedDRA Term
10049979	Airway complication of anaesthesia

SOC Code	SOC Name	Primary SOC
10022117	Injury, poisoning and procedural complications	Y
10038738	Respiratory, thoracic and mediastinal disorders	N

**PT Occurrences in MedDRA**

- PT Airway complication of anaesthesia
  - HLT Anaesthetic and allied procedural complications
    - HLT Procedural related injuries and complications NEC
      - SOC Injury, poisoning and procedural complications
- PT Airway complication of anaesthesia
  - HLT Respiratory tract disorders NEC
    - HLT Respiratory disorders NEC
      - SOC Respiratory, thoracic and mediastinal disorders

# Elderly woman complained her arm was tender where she had received her seasonal flu vaccine

**MedDRA Browser**

Hepatobiliary disorders  
Immune system disorders

Total Search Results: 1

**Term**

- SOC General disorders and administration site conditions
  - HLT Administration site reactions
    - HLT Vaccination site reactions
      - PT Vaccination site pain
        - LLT Vaccination site tenderness

**Search Results**

LLT

- LLT
  - Exact Match
  - Lexical
  - Synonym Results
  - Contains Results

**Term Details in Primary Language**

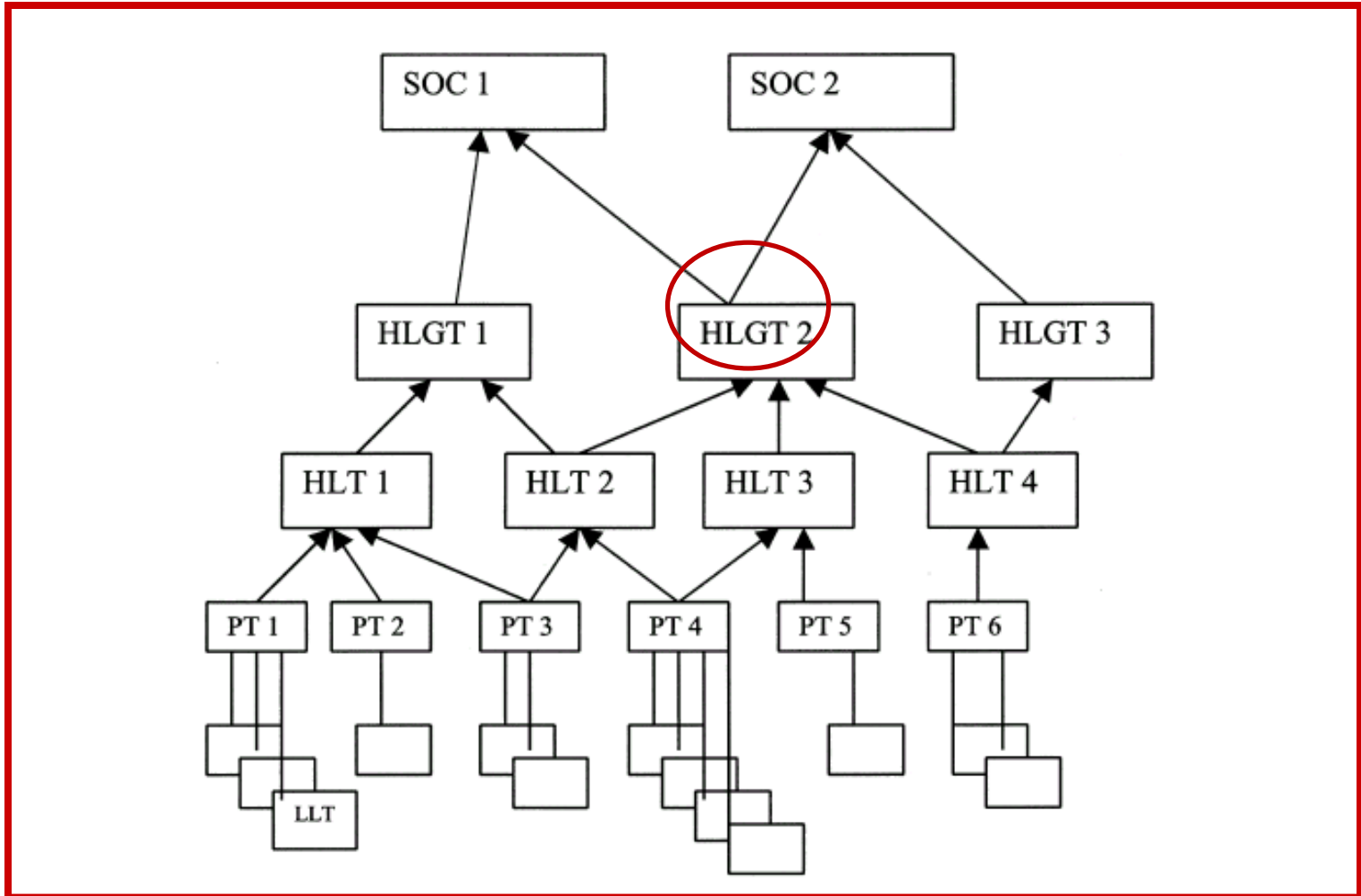
LLT - Lowest Level Term

MedDRA Code	MedDRA Term	Currency
10069631	Vaccination site tenderness	Y

**LLT Occurrences in MedDRA**

- LLT Vaccination site tenderness
  - PT Vaccination site pain
    - HLT Vaccination site reactions
      - HLT Administration site reactions
        - SOC General disorders and administration site conditions
- LLT Vaccination site tenderness
  - PT Vaccination site pain
    - HLT Vaccination site reactions
      - HLT Administration site reactions
        - SOC Injury, poisoning and procedural complications

# A Multi-Axial Terminology (cont)





**Term**

- SOC Psychiatric disorders
  - HLT Anxiety disorders and symptoms
    - HLT Obsessive-compulsive disorders and symptoms
      - PT Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
        - LLT PANDAS

- PT Compulsive cheek biting
- PT Compulsive handwashing
- PT Compulsive hoarding
- PT Compulsive lip biting
- PT Compulsive shopping
- PT Dermatillomania
- PT Dermatophagia
- PT Nail picking
- PT Obsessive need for symmetry
- PT Obsessive rumination
- PT Obsessive thoughts
- PT Obsessive-compulsive disorder
- PT Obsessive-compulsive symptom
- PT Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
  - LLT Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
    - LLT PANDAS
    - LLT Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
- PT Trichotemnomania
- PT Trichotillomania
- HLT Panic attacks and disorders
- HLT Stress disorders
- HLT Changes in physical activity
- HLT Cognitive and attention disorders and disturbances
- HLT Communication disorders and disturbances
- HLT Deliria (incl confusion)
- HLT Dementia and amnesic conditions
- HLT Depressed mood disorders and disturbances
- HLT Developmental disorders NEC
- HLT Dissociative disorders
- HLT Disturbances in thinking and perception

**Search Results**

- LLT
  - Exact Match - 1
    - LLT PANDAS
  - Lexical Variant - 0
  - Synonym Search Results - 0
  - Contains Search Results - 0

### Term Details in Primary Language

LLT - Lowest Level Term

MedDRA Code	MedDRA Term	Currency
10071582	PANDAS	Y

### LLT Occurrences in MedDRA

- LLT PANDAS
  - PT Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
    - HLT Obsessive-compulsive disorders and symptoms
      - HLT Anxiety disorders and symptoms
        - SOC Psychiatric disorders
- LLT PANDAS
  - PT Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
    - HLT Nervous system autoimmune disorders
      - HLT Autoimmune disorders
        - SOC Immune system disorders
- LLT PANDAS
  - PT Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
    - HLT Inflammatory disorders following infection
      - HLT Ancillary infectious topics
        - SOC Infections and infestations
- LLT PANDAS
  - PT Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
    - HLT Neurological signs and symptoms NEC
      - HLT Neurological disorders NEC
        - SOC Nervous system disorders

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) is a hypothesis that there exists a subset of children with rapid onset of obsessive-compulsive disorder (OCD) or tic disorders and these symptoms are caused by group A beta-hemolytic streptococcal (GABHS) infections

# Influenza with body aches, fever, cough

- HL GT Fungal infectious disorders
- HL GT Helminthic disorders
- HL GT Infections - pathogen unspecified
- HL GT Mycobacterial infectious disorders
- HL GT Mycoplasmal infectious disorders
- HL GT Protozoal infectious disorders
- HL GT Rickettsial infectious disorders
- HL GT Viral infectious disorders
  - HLT Adenoviral infections
  - HLT Alphaviral infections
  - HLT Arboviral infections NEC
  - HLT Arenaviral infections
  - HLT Astroviral infections
  - HLT Caliciviral infections
  - HLT Coxsackie viral infections
  - HLT Cytomegaloviral infections
  - HLT Echo viral infections
  - HLT Enteroviral infections NEC
  - HLT Epstein-Barr viral infections
  - HLT Filovirus viral infections
  - HLT Flaviviral infections
  - HLT Hanta viral infections
  - HLT Hepatitis viral infections
  - HLT Herpes viral infections
  - HLT Influenza viral infections
    - PT Avian influenza
    - PT Encephalitis influenzal
    - PT H1N1 influenza
    - PT H2N2 influenza
    - PT H3N2 influenza
    - PT Influenza
    - PT Pneumonia influenzal

Select MedDRA Term: 21.1 - English ...

https://mssoweb.meddra.org/wbb30beta/mu...

The selected MedDRA term is multi-axial. Double-click to select a MedDI term and return to the main Browser window.

- SOC Infections and infestations
  - HL GT Viral infectious disorders
    - HLT Influenza viral infections
      - PT Influenza
        - LLT Influenza
- SOC Respiratory, thoracic and mediastinal disorders
  - HL GT Respiratory tract infections
    - HLT Viral upper respiratory tract infections
      - PT Influenza
        - LLT Influenza

- LLT Cough
    - PT Cough
      - HLT Coughing and associated symptoms
        - HL GT Respiratory disorders NEC
          - SOC Respiratory, thoracic and mediastinal disorders
- LLT Fever
  - PT Pyrexia
    - HLT Febrile disorders
      - HL GT Body temperature conditions
        - SOC General disorders and administration site conditions





# 72 year old man with aphasia and right hemiplegia. Stroke in middle cerebral artery territory is suspected

**Term**

- Central nervous system disorders
  - Central nervous system vascular disorders
    - Central nervous system haemorrhages and cerebrovascular accidents
      - Haemorrhagic stroke

**Search Options**

SOC  HLT  HLT

English    stroke

Use Synonym List  
 Ignore Diacritical Marks  
 Show PT/LLT with category

Select MedDRA Term: 21.1 - Engl...

<https://mssoweb.meddra.org/wbb30beta/...>

The selected MedDRA term is multi-axial. Double-click to select a MedDRA term and return to the main Browser window.

- Central nervous system disorders
  - Central nervous system vascular disorders
    - Central nervous system haemorrhages and cerebrovascular accidents
      - Cerebrovascular accident
        - Stroke
- Vascular disorders
  - Vascular disorders NEC
    - Cerebrovascular and spinal vascular disorders NEC
      - Cerebrovascular accident
        - Stroke

- Coordination and balance disturbances
- Cortical dysfunction NEC
  - Acalculia
  - Agnosia
  - Agraphia
  - Alexia
  - Altered pitch perception
  - Amimia
  - Amusia
  - Anosognosia
  - Aphasia
    - Amnesic aphasia
    - Amnesic aphasia
    - Anomia
    - Aphasia
    - Aphasia motor
    - Aphasia nominal
    - Aphasia sensory
    - Broca's aphasia

- Movement disorders (incl parkinsonism)
- Choreiform movements
- Dyskinesias and movement disorders NEC
- Dystonias
- Paralysis and paresis (excl cranial nerve)
  - Acute post asthmatic amyotrophy
  - Alternating hemiplegia of childhood
  - Cervical spinal cord paralysis
  - Congenital flaccid paralysis
  - Congenital hemiparesis
  - Diaphragmatic paralysis
  - Diplegia
  - Gait spastic
  - Hemiparesis
  - Hemiplegia
  - Locked-in syndrome
  - Lumbar spinal cord paralysis
  - Man-in-the-barrel syndrome

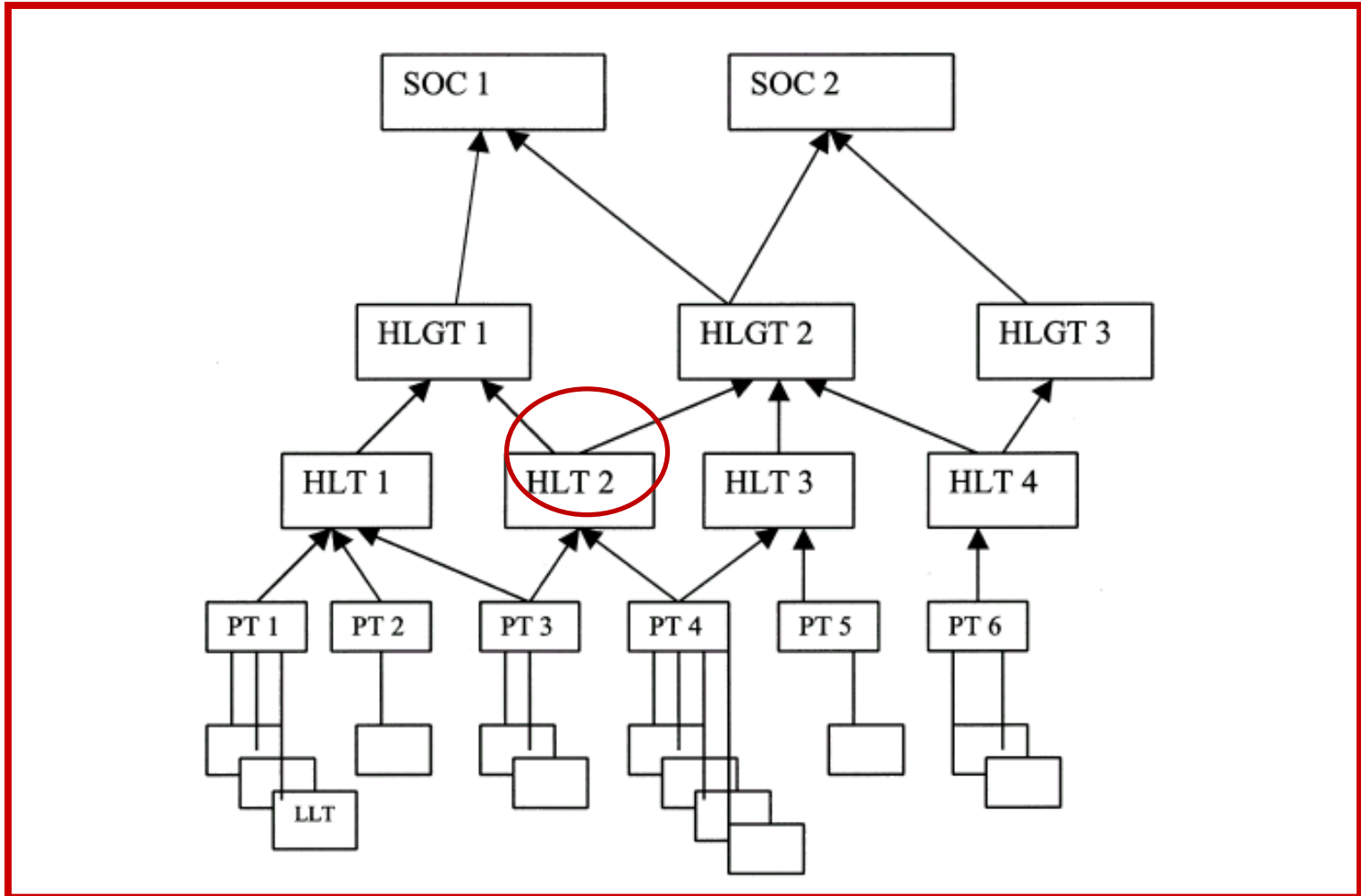


# Patient said she received flu vaccine 3 months before she became pregnant

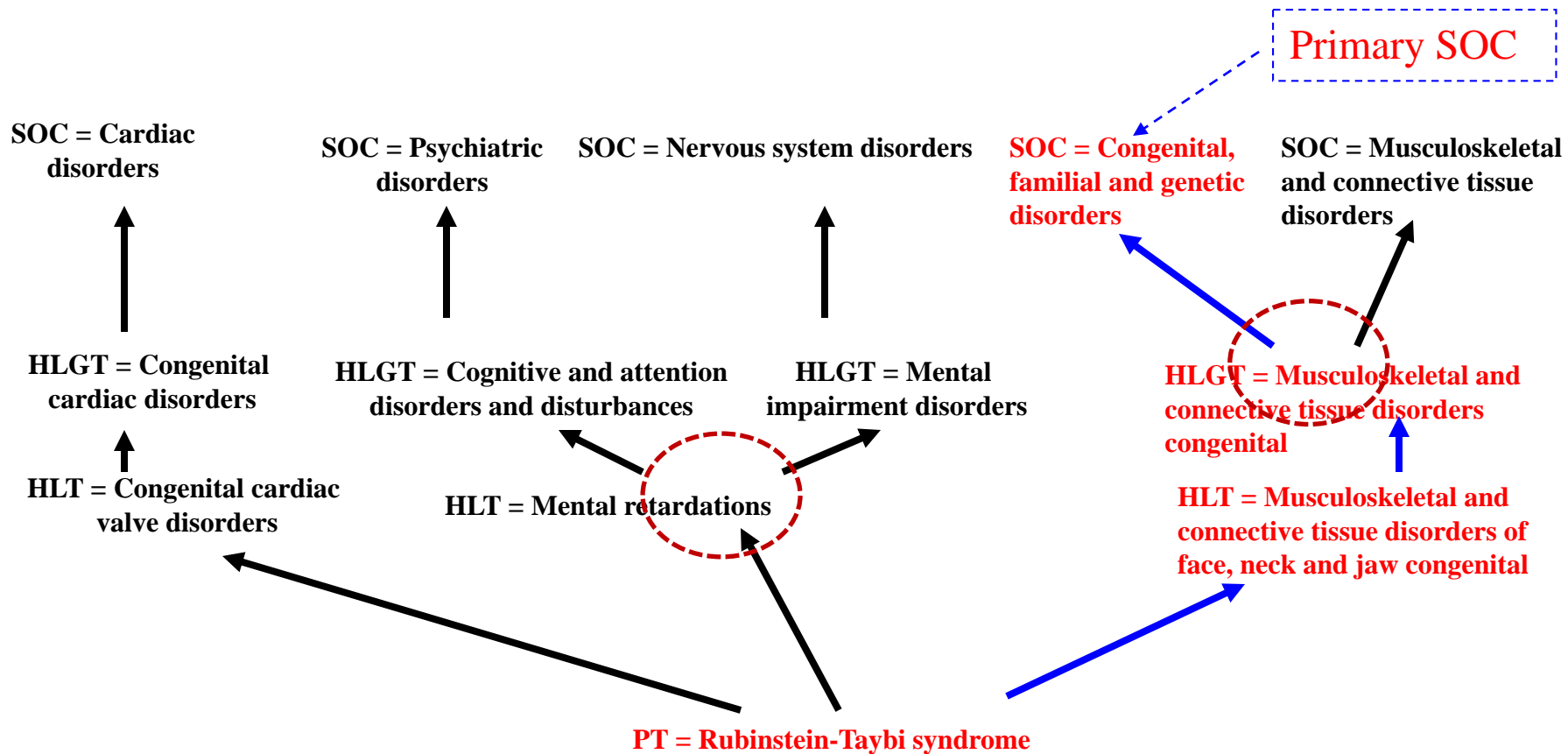
- [-] SOC Injury, poisoning and procedural complications
  - [+] HLT Administration site reactions
  - [+] HLT Bone and joint injuries
  - [+] HLT Exposures, chemical injuries and poisoning ↖
  - [+] HLT Chemical injuries ↘
  - [-] HLT Exposures associated with pregnancy, delivery and lactation
    - [+] PT Exposure during pregnancy
    - [+] PT Exposure via breast milk
    - [+] PT Exposure via father
    - [+] PT Foetal exposure during delivery
    - [+] PT Foetal exposure during pregnancy
    - [+] PT Foetal exposure timing unspecified
    - [-] PT Maternal exposure before pregnancy
      - ... LLT Drug exposure before pregnancy
      - ... LLT Maternal exposure before pregnancy
      - ... LLT Vaccine exposure before pregnancy
    - [+] PT Maternal exposure during breast feeding
    - [+] PT Maternal exposure during delivery
    - [+] PT Maternal exposure during pregnancy
    - [+] PT Maternal exposure timing unspecified
    - [+] PT Paternal exposure before pregnancy
    - [+] PT Paternal exposure during pregnancy
    - [+] PT Paternal exposure timing unspecified
  - [+] HLT Exposures to agents or circumstances NEC
  - [+] HLT Foetal and neonatal conditions associated with product exposure
  - [+] HLT Non-occupational environmental exposures
  - [+] HLT Occupational exposures
  - [+] HLT Pathways and sources of exposure
  - [+] HLT Poisoning and toxicity
  - [+] HLT Injuries by physical agents
  - [+] HLT Injuries NEC

- [-] SOC Pregnancy, puerperium and perinatal conditions
  - [+] HLT Abortions and stillbirth
  - [+] HLT Foetal complications
  - [+] HLT Maternal complications of labour and delivery
  - [+] HLT Maternal complications of pregnancy
  - [+] HLT Neonatal and perinatal conditions
  - [+] HLT Placental, amniotic and cavity disorders (excl haemorrhages) ↖
  - [+] HLT Postpartum and puerperal disorders ↘
  - [-] HLT Pregnancy, labour, delivery and postpartum conditions
    - [-] HLT Exposures associated with pregnancy, delivery and lactation
      - [+] PT Exposure during pregnancy
      - [+] PT Exposure via breast milk
      - [+] PT Exposure via father
      - [+] PT Foetal exposure during delivery
      - [+] PT Foetal exposure during pregnancy
      - [+] PT Foetal exposure timing unspecified
      - [-] PT Maternal exposure before pregnancy
        - ... LLT Drug exposure before pregnancy
        - ... LLT Maternal exposure before pregnancy
        - ... LLT Vaccine exposure before pregnancy
      - [+] PT Maternal exposure during breast feeding
      - [+] PT Maternal exposure during delivery
      - [+] PT Maternal exposure during pregnancy
      - [+] PT Maternal exposure timing unspecified
      - [+] PT Paternal exposure before pregnancy
      - [+] PT Paternal exposure during pregnancy
      - [+] PT Paternal exposure timing unspecified
    - [+] HLT High risk pregnancies
    - [+] HLT Multiple pregnancies
    - [+] HLT Normal newborn status
    - [+] HLT Normal pregnancy, labour and delivery
    - [+] HLT Unintended pregnancies

# A Multi-Axial Terminology (cont)



# A Multi-Axial Terminology (cont)





# Coding exercises (2)

Verbatim term	LLT	PT	Primary SOC
Disconnected feeling	Feeling detached	Dissociation	Psychiatric disorders
Unspecified neurological condition	Neurological disorder NOS	Nervous system disorder	Nervous system disorders
Echoing in ears	Echoacousia	Dysacusis	Ear and labyrinth disorders
After the patient's drug was substituted with a generic drug, his response to therapy was different	Generic substitution altered therapeutic response	Therapeutic response changed	General disorders and administration site conditions
Severe bronchospasm on induction of anesthesia	Bronchospasm on induction	Airway complication of anaesthesia	Injury, poisoning and procedural complications
Elderly woman complained her arm was tender where she had received her seasonal flu vaccine	Vaccination site tenderness	Vaccination site pain	General disorders and administration site conditions
PANDAS	PANDAS	Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection	Psychiatric disorders
Influenza with body aches, fever, cough	Influenza	Influenza	Infections and infestations
72 year old man with aphasia and right hemiplegia. Stroke in middle cerebral artery territory is suspected.	Aphasia	Aphasia	Nervous system disorders
	Right hemiplegia	Hemiplegia	
	Middle cerebral artery stroke	Cerebrovascular accident	



# NARRATIVE #1

- A 75-year-old male developed anginal pain on 21 Feb 2017 resulting in hospitalization while enrolled in a randomized, open-label study. The patient's medical history is significant for triple bypass graft surgery 2014, postural hypotension and stage D prostate carcinoma. On 26 Feb 2017, the patient underwent percutaneous transluminal coronary angioplasty with stent placement in the right coronary and proximal left anterior descending arteries.



# NARRATIVE #1

- A 75-year-old male developed anginal pain on 21 Feb 2017 resulting in hospitalization while enrolled in a randomized, open-label study. The patient's medical history is significant for triple bypass graft surgery 2014, postural hypotension and stage D prostate carcinoma. On 26 Feb 2017, the patient underwent percutaneous transluminal coronary angioplasty with stent placement in the right coronary and proximal left anterior descending arteries.



# NARRATIVE #1

- A 75-year-old male developed anginal pain on 21 February 2017 resulting in hospitalization while enrolled in a randomized, open-label study.
  - The patient's medical history is significant for triple bypass graft surgery 2014, postural hypotension and stage D prostate carcinoma.
- On 26 February 2017, the patient underwent percutaneous transluminal coronary angioplasty with stent placement in the right coronary and proximal left anterior descending arteries.



# MedDRA “Points to Consider” document







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

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

**ICH-Endorsed Guide for MedDRA Users**

***Release 4.13***

***Based on MedDRA Version 20.0***

**1 March 2017**

### **Disclaimer and Copyright Notice**

This document is protected by copyright and may be used, reproduced, incorporated into other works, adapted, modified, translated or distributed under a public license provided that ICH's copyright in the document is acknowledged at all times. In case of any adaption, modification or translation of the document, reasonable steps must be taken to clearly label, demarcate or otherwise identify that changes were made to or based on the original document. Any impression that the adaption, modification or translation of the original document is endorsed or sponsored by the ICH must be avoided.

The document is provided "as is" without warranty of any kind. In no event shall the ICH or the authors of the original document be liable for any claim, damages or other liability arising from the use of the document.

The above-mentioned permissions do not apply to content supplied by third parties. Therefore, for documents where the copyright vests in a third party, permission for reproduction must be obtained from this copyright holder.

MedDRA<sup>®</sup> trademark is owned by IFPMA on behalf of ICH

- 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



# MedDRA Term Selection: PTC (cont)

- Developed by a working group of the ICH Steering Committee
  - Regulators and industry representatives from EU, Japan, and USA
  - Canadian and Korean regulatory authorities
  - WHO
  - MSSO and JMO
- Updated twice yearly with each MedDRA release
- Available on MedDRA and JMO websites
  - English and Japanese
  - Word (“clean” and “redlined”), PDF, HTML formats
  - “Redlined” document identifies changes made from previous to current release of document



# 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	



# Term Selection Points

- Diagnoses and Provisional Diagnoses with or without Signs and Symptoms
- Death and Other Patient Outcomes
- Suicide and Self-Harm
- Conflicting/Ambiguous/Vague Information
- Combination Terms
- Age vs. Event Specificity
- Body Site vs. Event Specificity
- Location-Specific vs. Microorganism-Specific Information
- Modification of Pre-existing Conditions
- Exposures During Pregnancy and Breast Feeding
- Congenital Terms
- Neoplasms
- Medical and Surgical Procedures
- Investigations



MedDRA

# Term Selection Points (cont)

- Medication Errors, Accidental Exposures and Occupational Exposures
- Misuse, Abuse and Addiction
- Transmission of Infectious Agent via Product
- Overdose, Toxicity and Poisoning
- Device-related Terms
- Drug Interactions
- No Adverse Effect and “Normal” Terms
- Unexpected Therapeutic Effect
- Modification of Effect
- Social Circumstances
- Medical and Social History
- Indication for Product Use
- Off Label Use
- Product Quality Issues

# Diagnoses and Provisional Diagnoses

SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	PROVISIONAL DIAGNOSIS
<p>Single diagnosis <b>without signs and symptoms</b></p> <ul style="list-style-type: none"> <li>•Diagnosis (only possible option)</li> </ul>	<p>Single provisional diagnosis <b>without signs and symptoms</b></p> <ul style="list-style-type: none"> <li>•Provisional diagnosis (only possible option)</li> </ul>
<p>Example: <i>“Myocardial infarction”</i> → select <i>“Myocardial infarction”</i></p>	<p>Example: <i>“Possible myocardial infarction”</i> → select <i>“Myocardial infarction”</i> (select term as if definitive diagnosis)</p>

Similar principles apply for multiple diagnoses

# Diagnoses and Provisional Diagnoses (cont)

SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	PROVISIONAL DIAGNOSIS
<p>Single diagnosis <b>with signs/symptoms</b></p> <ul style="list-style-type: none"> <li>•Preferred: Diagnosis only</li> </ul>	<p>Single provisional diagnosis <b>with signs/symptoms</b></p> <ul style="list-style-type: none"> <li>•Preferred: Provisional diagnosis and signs/symptoms</li> </ul>
<p>Example: <i>“Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm”</i> → select <i>“Anaphylactic reaction”</i></p>	<p>Example: <i>“Possible myocardial infarction with chest pain, dyspnoea, diaphoresis”</i> → select <i>“Myocardial infarction”</i> <i>“Chest pain”</i>, <i>“Dyspnoea”</i>, and <i>“Diaphoresis”</i></p>

# Diagnoses and Provisional Diagnoses (cont)

SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	PROVISIONAL DIAGNOSIS
<p>Single diagnosis with signs/symptoms</p> <ul style="list-style-type: none"> <li>•Alternate: Diagnosis and signs/symptoms</li> </ul>	<p>Single provisional diagnosis with signs/symptoms</p> <ul style="list-style-type: none"> <li>•Alternate: Signs/symptoms only (as provisional diagnosis may change)</li> </ul>
<p>Example: <i>“Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm”</i> → select <i>“Anaphylactic reaction”, “Rash”, “Dyspnoea”, Hypotension”, and “Laryngospasm”</i></p>	<p>Example: <i>“Possible myocardial infarction with chest pain, dyspnoea, diaphoresis”</i> → select <i>“Chest pain”, “Dyspnoea”, and “Diaphoresis”</i></p>



# Diagnoses and Provisional Diagnoses (cont)

- Always include signs/symptoms not associated with diagnosis

Reported	LLT Selected
Myocardial infarction, chest pain, dyspnoea, diaphoresis, ECG changes and jaundice	Myocardial infarction <b>Jaundice</b> (note that jaundice is not typically associated with myocardial infarction)



# What Terms to Select?

- Sepsis leading to shock from possible spontaneous bacterial peritonitis or bowel perforation

Sepsis

Shock

Septic shock

Spontaneous bacterial peritonitis

Bowel perforation

# Conflicting/Ambiguous Information

- First, try to obtain more specific information

Reported	LLT Selected	Comment
Hyperkalaemia with a serum potassium of 1.6 mEq/L	Serum potassium abnormal	LLT <i>Serum potassium abnormal</i> covers both of the reported concepts (note: serum potassium of 1.6 mEq/L is a low result, not high)
GU pain	Pain	“GU” could be either “genito-urinary” or “gastric ulcer”. If additional information is not available, then select a term to reflect the information that is known, i.e., LLT <i>Pain</i>



# Vague Information

- First, try to obtain more specific information

Reported	LLT Selected	Comment
Turned green	Unevaluable event	“Turned green” reported alone is vague; this could refer to a patient condition or even to a product (e.g., pills)
Patient had a medical problem of unclear type	Ill-defined disorder	Since it is known that there is some form of a medical disorder, LLT <i>Ill-defined disorder</i> can be selected



# What Terms to Select?

- Clinical complication of IUD
  - IUD complication (PT Complication associated with device)
  - Intra-uterine death (PT Foetal death)
  - Unevaluable event
- Hypoglycemia (blood glucose = 200 mg/dL)
  - Blood glucose abnormal
  - Blood glucose increased
  - Hypoglycemia





# Combination Terms

- One condition is more specific than the other

Reported	LLT Selected
Arrhythmia due to atrial fibrillation	Atrial fibrillation
Hepatic function disorder (acute hepatitis)	Hepatitis acute

- A MedDRA combination term is available

Reported	LLT Selected
Retinopathy due to diabetes	Diabetic retinopathy
Rash with itching	Itchy rash



# Combination Terms (cont)

- If splitting provides more clinical information, select more than one term
- In all cases of combination terms, apply medical judgment

Reported	LLT Selected
Diarrhoea and vomiting	Diarrhoea Vomiting
Wrist fracture due to fall	Wrist fracture Fall



# What Terms to Select?

- Retinal disease from HIV with near total blindness (R and L)

Retinal damage

Retinal disorder

HIV disease

Blindness

HIV retinopathy

Blindness, both eyes





# Investigations

- Medical condition vs. investigation result

Reported	LLT Selected	Comment
Hypoglycaemia	Hypoglycaemia	LLT <i>Hypoglycaemia</i> links to SOC <i>Metabolism and nutrition disorders</i>
Decreased glucose	Glucose decreased	LLT <i>Glucose decreased</i> links to SOC <i>Investigations</i>



# Investigations (cont)

- Unambiguous investigation result

Reported	LLT Selected	Comment
Glucose 40 mg/dL	Glucose low	Glucose is clearly below the reference range

- Ambiguous investigation result

Reported	LLT Selected	Comment
His glucose was 40	Glucose abnormal	No units have been reported. Select LLT <i>Glucose abnormal</i> if clarification cannot be obtained.



# Investigations (cont)

- Investigation results consistent with diagnosis

Reported	LLT Selected	Comment
Elevated potassium, K 7.0 mmol/L, and hyperkalaemia	Hyperkalaemia	It is not necessary to select LLT <i>Potassium increased</i>

- Grouped investigation result terms

Reported	LLT Selected	Comment
Increased alkaline phosphatase, increased SGPT, increased SGOT and elevated LDH	Alkaline phosphatase increased SGPT increased SGOT increased LDH increased	Select four individual terms. A single term such as LLT <i>Liver function tests abnormal</i> should not be selected.



# What Terms to Select?

- Testing showed increased serum creatinine and BUN, with increased BUN/creatinine ratio

Increased serum creatinine

BUN increased

Blood urea nitrogen/creatinine ratio increased

Renal function tests NOS abnormal



# What Terms to Select?

- Due to a prescribing error, the child was given drug X, which is labeled for use in adults only

Adult product administered to child

Accidental overdose

Drug prescribing error

Medication error

# Medication Errors (cont)

See Appendix B of MedDRA Introductory Guide or MedDRA Browser (both WBB and MDB) for Concept Descriptions

“Top-down” navigation in HLGT *Medication errors and other product use errors and issues* is best approach for term selection

- Medication error with clinical consequences

Reported	LLT Selected	Comment
Patient was administered wrong drug and experienced hypotension	Wrong drug administered Hypotension	
Insulin was given using the wrong syringe resulting in the administration of an overdose. The patient developed hypoglycaemia.	Drug administered in wrong device Accidental overdose Hypoglycaemia	If an overdose is reported in the context of a medication error, the more specific term <i>LLT Accidental overdose</i> can be selected



# Medication Errors (cont)

- Medication error without clinical consequences

Reported	LLT Selected	Preferred Option
Medication was given intravenously instead of intramuscularly without any adverse effect	Intramuscular formulation administered by other route	✓
	Intramuscular formulation administered by other route  No adverse effect	



MedDRA

# New Medication Errors/Product Use Issues Hierarchy

- [-] soc Injury, poisoning and procedural complications
  - [+] HL GT Administration site reactions
  - [+] HL GT Bone and joint injuries
  - [+] HL GT Exposures, chemical injuries and poisoning
  - [+] HL GT Injuries by physical agents
  - [+] HL GT Injuries NEC
  - [-] HL GT Medication errors and other product use errors and issues
    - [+] HLT Accidental exposures to product
    - [+] HLT Medication errors, product use errors and issues NEC
    - [+] HLT Product administration errors and issues
    - [+] HLT Product confusion errors and issues
    - [+] HLT Product dispensing errors and issues
    - [+] HLT Product monitoring errors and issues
    - [+] HLT Product preparation errors and issues
    - [+] HLT Product prescribing errors and issues
    - [+] HLT Product selection errors and issues
    - [+] HLT Product storage errors and issues in the product use system
    - [+] HLT Product transcribing errors and communication issues
  - [-] HL GT Off label uses and intentional product misuses/use issues
    - [+] HLT Intentional product misuses
    - [+] HLT Intentional product use issues
    - [+] HLT Off label uses
  - [-] HL GT Overdoses and underdoses NEC
    - [+] HLT Overdoses NEC
    - [+] HLT Underdoses NEC



Concept	Intentional?	By Whom?	Therapeutic Use?	Additional Sections in this Document
Misuse	Yes	Patient/consumer	Yes*	3.16.1
Abuse	Yes	Patient/consumer	No	3.16.2
Addiction	Yes	Patient/consumer	No	3.16.3
Medication error	No	Patient/consumer or healthcare provider	Yes	3.15
Off label use	Yes	Healthcare provider	Yes	3.27

\* Definitions of misuse may not always include the concept of therapeutic use; misuse may be similar to the concept of abuse in some regions.



# Exercises

Verbatim term	LLT	MTS:PTC Section	Section #
Disconnected feeling	Feeling detached	Always Select a Lowest Level Term	2,4
Unspecified neurological condition	Neurological disorder NOS	Always Select a Lowest Level Term	2,4
Echoing in ears	Echoacousia	Always Select a Lowest Level Term	2,4
After the patient's drug was substituted with a generic drug, his response to therapy was different	Generic substitution altered therapeutic response	Modification of Effect	3,23
Severe bronchospasm on induction of anesthesia	Bronchospasm on induction	Always Select a Lowest Level Term	2,4
Elderly woman complained her arm was tender where she had received her seasonal flu vaccine	Vaccination site tenderness	Always Select a Lowest Level Term	2,4
PANDAS	PANDAS	Always Select a Lowest Level Term	2,4
Influenza with body aches, fever, cough	Influenza	Definitive and Provisional Diagnoses with or without Signs and Symptoms	3,1
72 year old man with aphasia and right hemiplegia. Stroke in middle cerebral artery territory is suspected.	Aphasia	Definitive and Provisional Diagnoses with or without Signs and Symptoms	3.1
	Right hemiplegia		
	Middle cerebral artery stroke		
Patient said she received flu vaccine 3 months before she became pregnant	Vaccine exposure before pregnancy	Exposures during Pregnancy and Breast Feeding	3,10



# 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)
  - Example: "*The patient took drug X and developed interstitial nephritis which later deteriorated into renal failure*". Manufacturer only codes interstitial nephritis (missed renal failure concept)

Acknowledgement: Dr. Toni Piazza-Hepp, Office of Surveillance and Epidemiology, CDER, FDA



MedDRA

# Important Coding Errors (cont)

- “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
  - Example: “*Aplastic anemia*” coded as unspecified anemia
  - Example: “*Rash subsequently diagnosed as Stevens Johnson syndrome*” coded as rash

Acknowledgement: Dr. Toni Piazza-Hepp, Office of Surveillance and Epidemiology, CDER, FDA



MedDRA

# MedDRA subscription

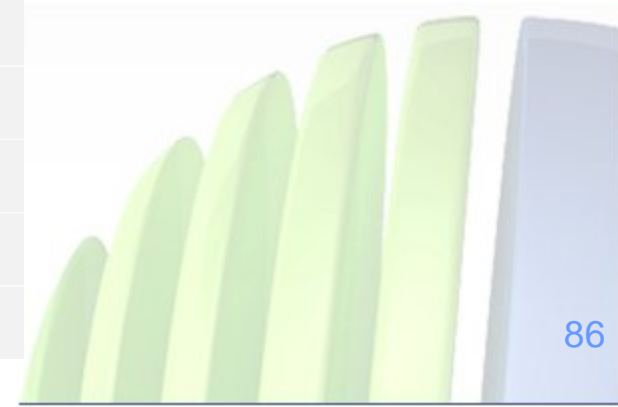




# 2018 MedDRA Subscription Rate Table

MedDRA Subscription Types	2018 Annual Subscription Rates	Additional Rates for Japanese Translation
Regulatory Authority	\$0 USD	\$0 USD
Non-Commercial / Non-Profit	\$0 USD	\$850 USD
Commercial (Parent Company Annual Revenue or Turnover)		
Level 0 (Annual Revenue < \$1 Million)	\$162 USD	\$850 USD
Level 1 (Annual Revenue \$1-\$10 Million)	\$688 USD	\$850 USD
Level 2 (Annual Revenue \$10-\$20 Million)	\$2,627 USD	\$850 USD
Level 3 (Annual Revenue \$20-\$500 Million)	\$4,976 USD	\$850 USD
Level 4 (Annual Revenue \$500 Million-\$1 Billion)	\$10,440 USD	\$850 USD
Level 5 (Annual Revenue \$1-\$5 Billion)	\$43,316 USD	\$850 USD
Level 6 (Annual Revenue \$5-\$20 Billion)	\$57,194 USD	\$850 USD
Level 7 (Annual Revenue > \$20 Billion)	\$74,620 USD	\$850 USD
System Developer	\$2,691 USD	\$850 USD

**Note: 76% of all MedDRA users pay no fee or \$724 (or less)**

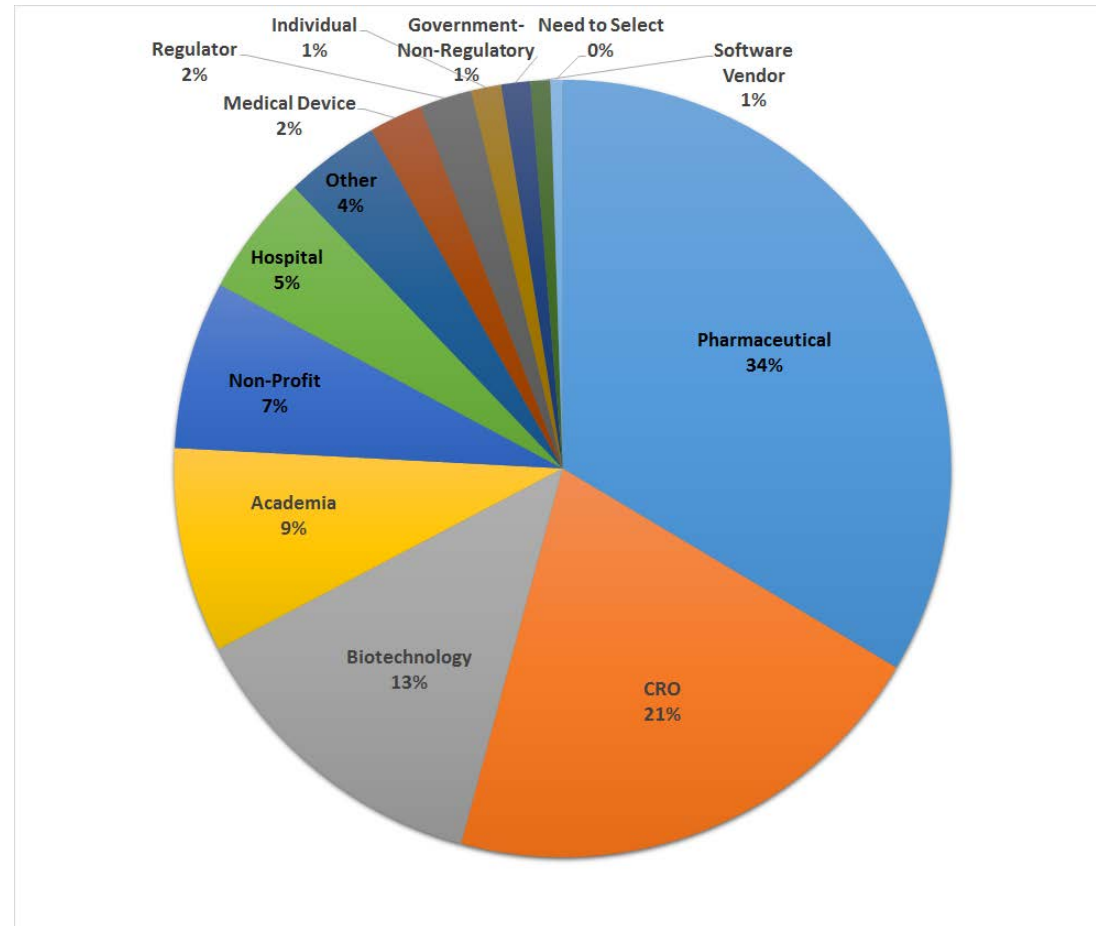




MedDRA

# MedDRA Users Profile

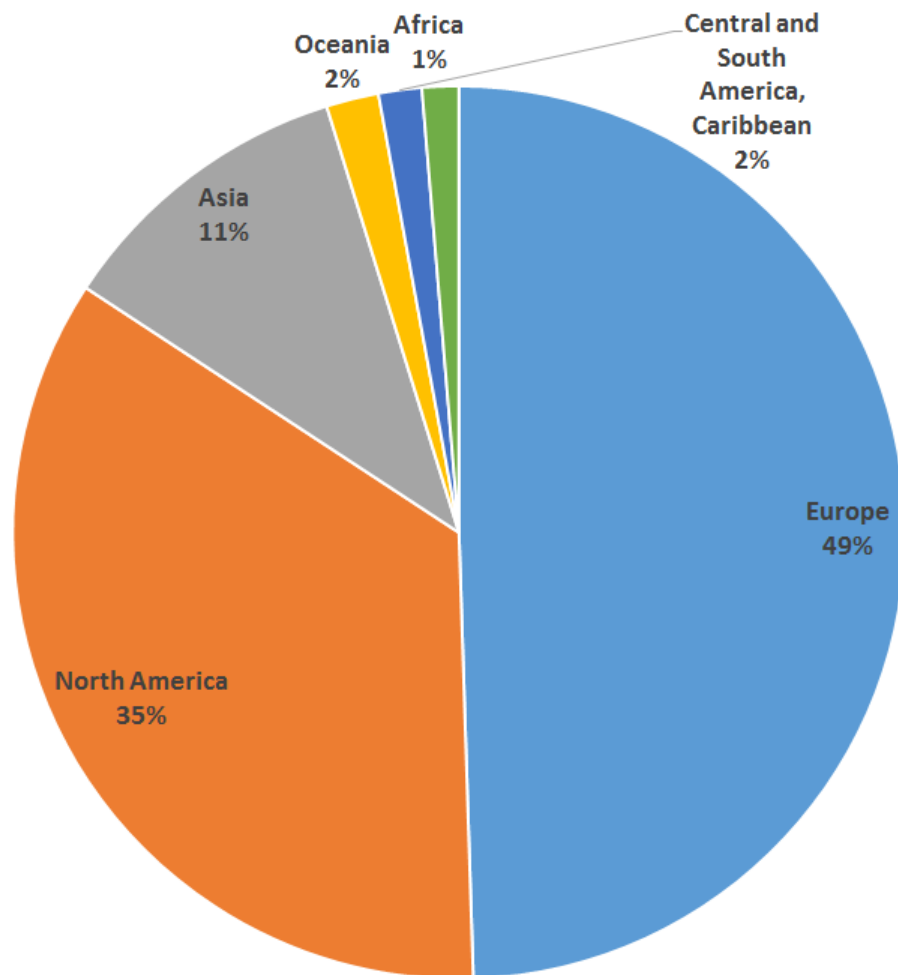
- As of August 2017
  - ~5,000 Subscribing organizations (MSSO+JMO)
  - 109 Countries
- Graph shows type of organizations (self identified)





MedDRA

# MedDRA Users by Region and Top 20 Countries



Country	Count
United States	1386
Germany	324
United Kingdom	310
France	242
Italy	218
Spain	139
China	129
Canada	115
Poland	78
Australia	77
South Korea	76
Netherlands	75
India	74
Switzerland	72
Sweden	70
Belgium	68
Greece	51
Denmark	47
Austria	46
Israel	46





MedDRA

# MSSO Contacts

- Website
  - [www.meddra.org](http://www.meddra.org)
- Email
  - [mssohelp@meddra.org](mailto:mssohelp@meddra.org)
- Frequently Asked Questions
  - [www.meddra.org/faq](http://www.meddra.org/faq)
- My email
  - [tomas.moraleda@meddra.org](mailto:tomas.moraleda@meddra.org)