



MedDRA simplified: Coding for clinical excellence

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Your experience with MedDRA?

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What is 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's Purpose

- Facilitate the exchange of clinical information through standardization
- Important tool for product evaluation, monitoring, communication, electronic records exchange, and oversight
- Supports coding (data entry) and retrieval and analysis of clinical information about human medical products including pharmaceuticals, biologics, vaccines, and drug-device combination products



MedDRA and the MSSO



International
support &
development
terminology



"Custodians" of
the terminology



Foster use of
MedDRA



Governed by a
Management
committee



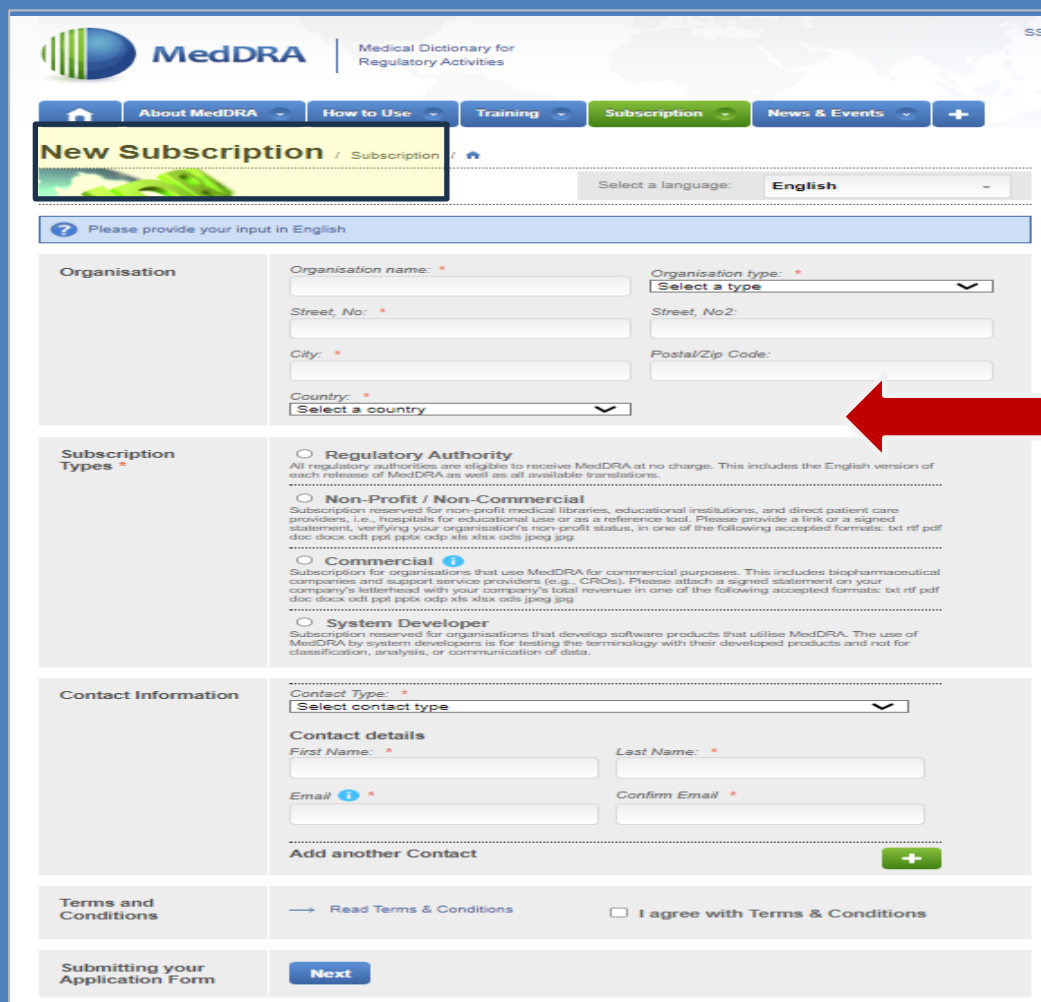
JMO for MedDRA
Japanese

Four types of subscription are available from the MSSO:

- Regulatory Authority
- Non-Profit/Non-Commercial (such as medical library, educational institution, organisation engaged in not-for-profit activities)
- Commercial
- System Developer (developer of software products that utilise MedDRA).



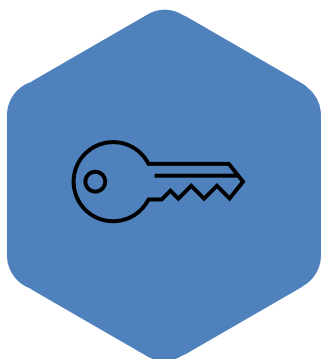
How to subscribe?



The screenshot shows the MedDRA website's 'New Subscription' form. The form is titled 'New Subscription' and includes a language selector set to 'English'. The form is divided into several sections: 'Organisation', 'Subscription Types', 'Contact Information', 'Terms and Conditions', and 'Submitting your Application Form'. The 'Organisation' section includes fields for 'Organisation name', 'Organisation type' (a dropdown menu with 'Select a type' selected), 'Street, No:', 'City', 'Postal/Zip Code', and 'Country' (a dropdown menu with 'Select a country' selected). The 'Subscription Types' section has four radio button options: 'Regulatory Authority', 'Non-Profit / Non-Commercial', 'Commercial', and 'System Developer'. The 'Contact Information' section includes a 'Contact Type' dropdown menu, 'Contact details' with 'First Name', 'Last Name', 'Email', and 'Confirm Email' fields, and an 'Add another Contact' button. The 'Terms and Conditions' section has a link to 'Read Terms & Conditions' and a checkbox for 'I agree with Terms & Conditions'. The 'Submitting your Application Form' section has a 'Next' button. A red arrow points to the 'Organisation type' dropdown menu.

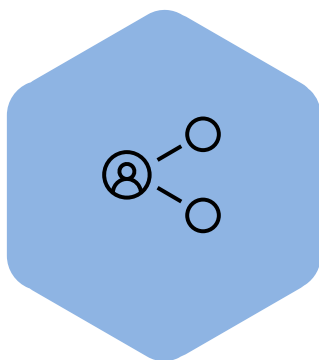
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MedDRA Data Sharing



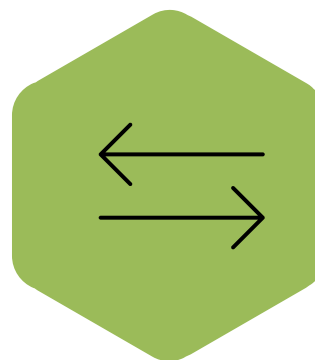
Access

Subscription grants access to MedDRA for one year



3rd Party Distribution

Subscriber cannot grant any sublicense, publish or otherwise distribute MedDRA to a third party



Free Exchange

Data may be freely exchanged between current MedDRA subscribers



Violation

Sharing MedDRA with a non-subscribing organization is a violation of the MedDRA license

Where MedDRA is Used



Regulatory Authority and Industry Databases
Individual Case Safety Reports and Safety Summaries

Clinical Study Reports

Investigators' Brochures

Core Company Safety Information

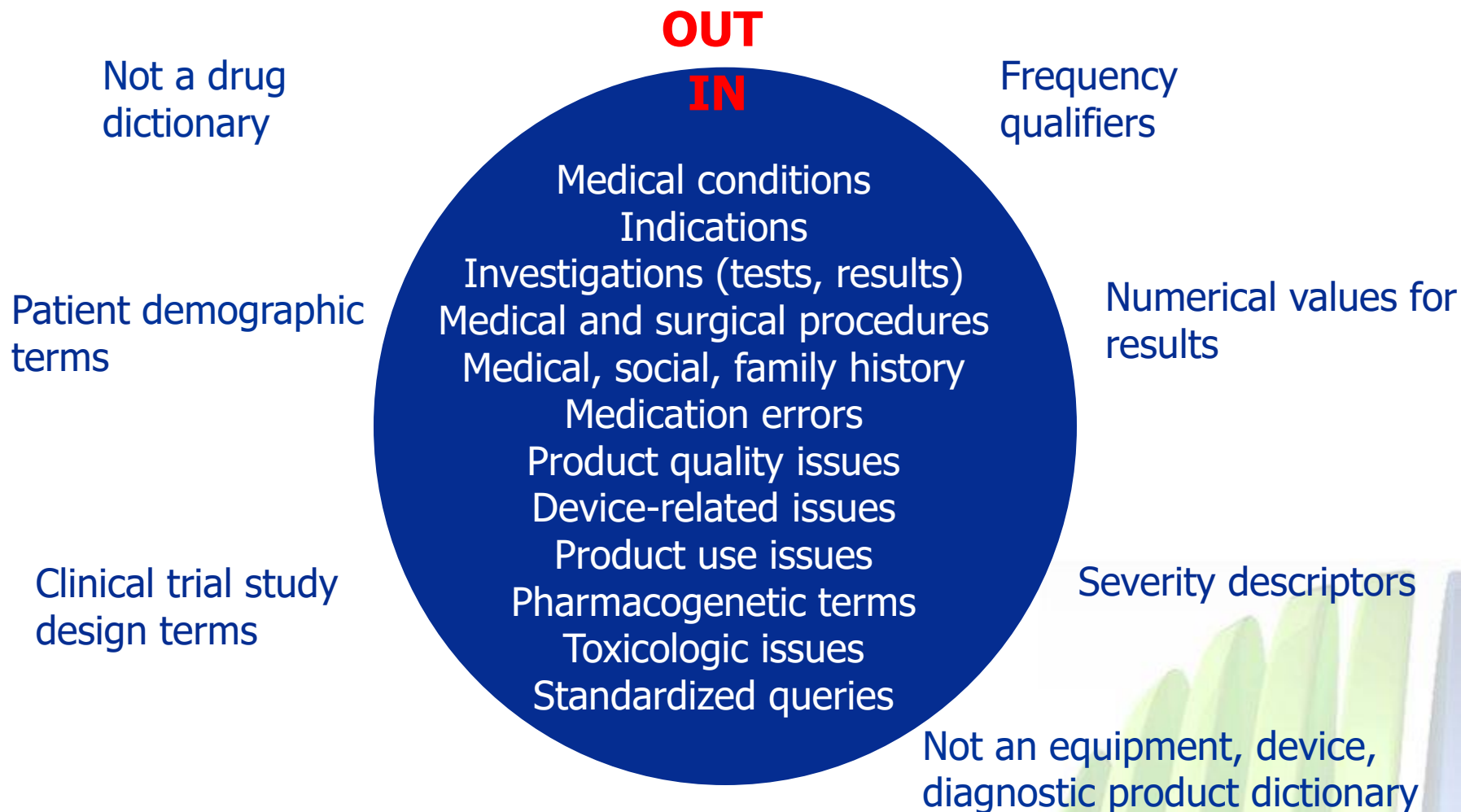
Marketing Applications

Publications

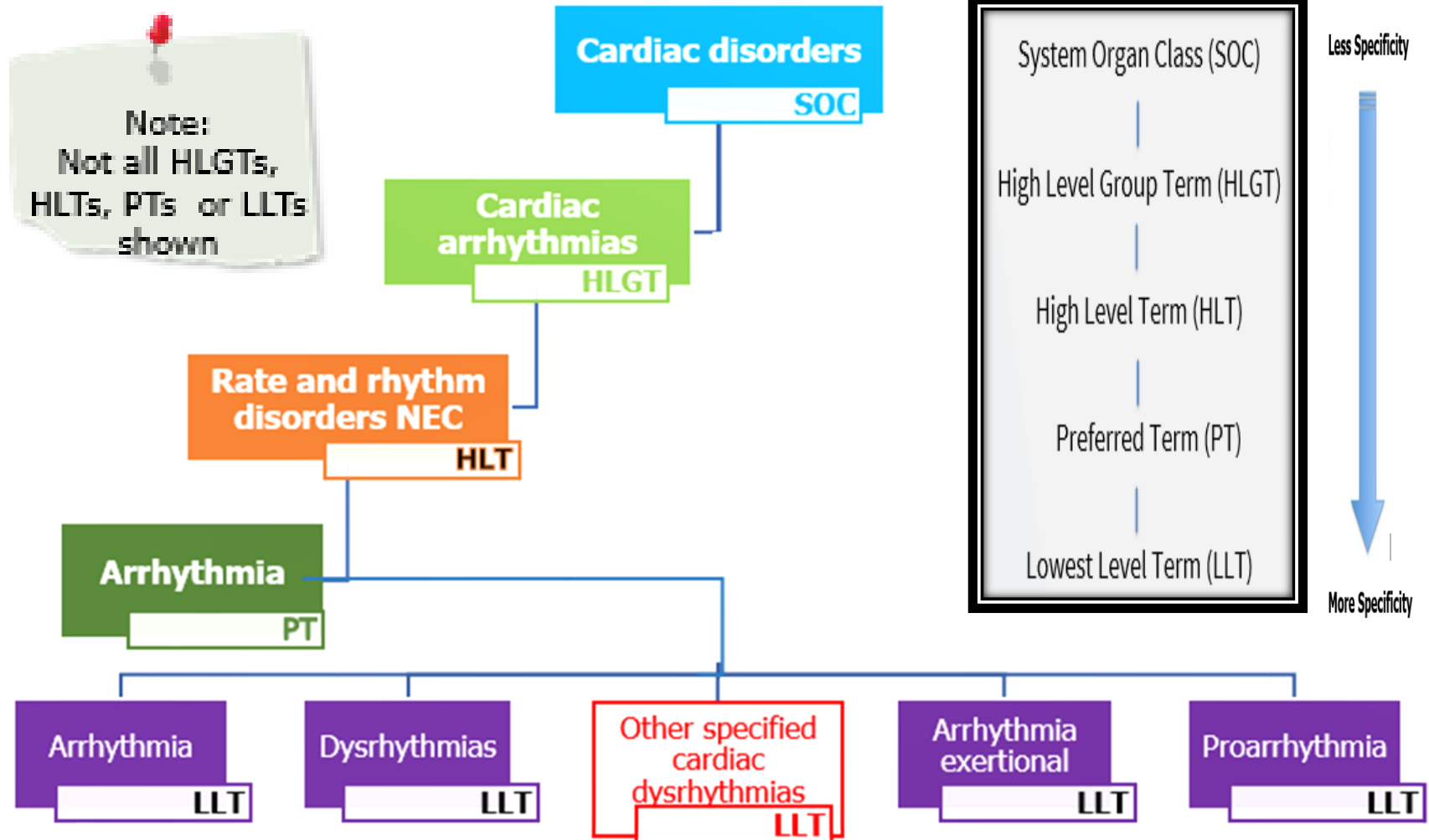
Prescribing Information

Advertising

Scope of MedDRA

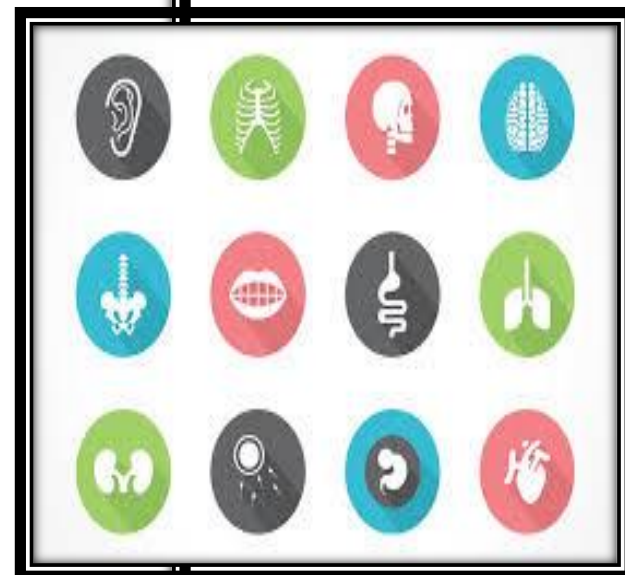


Structure of MedDRA



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



- 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

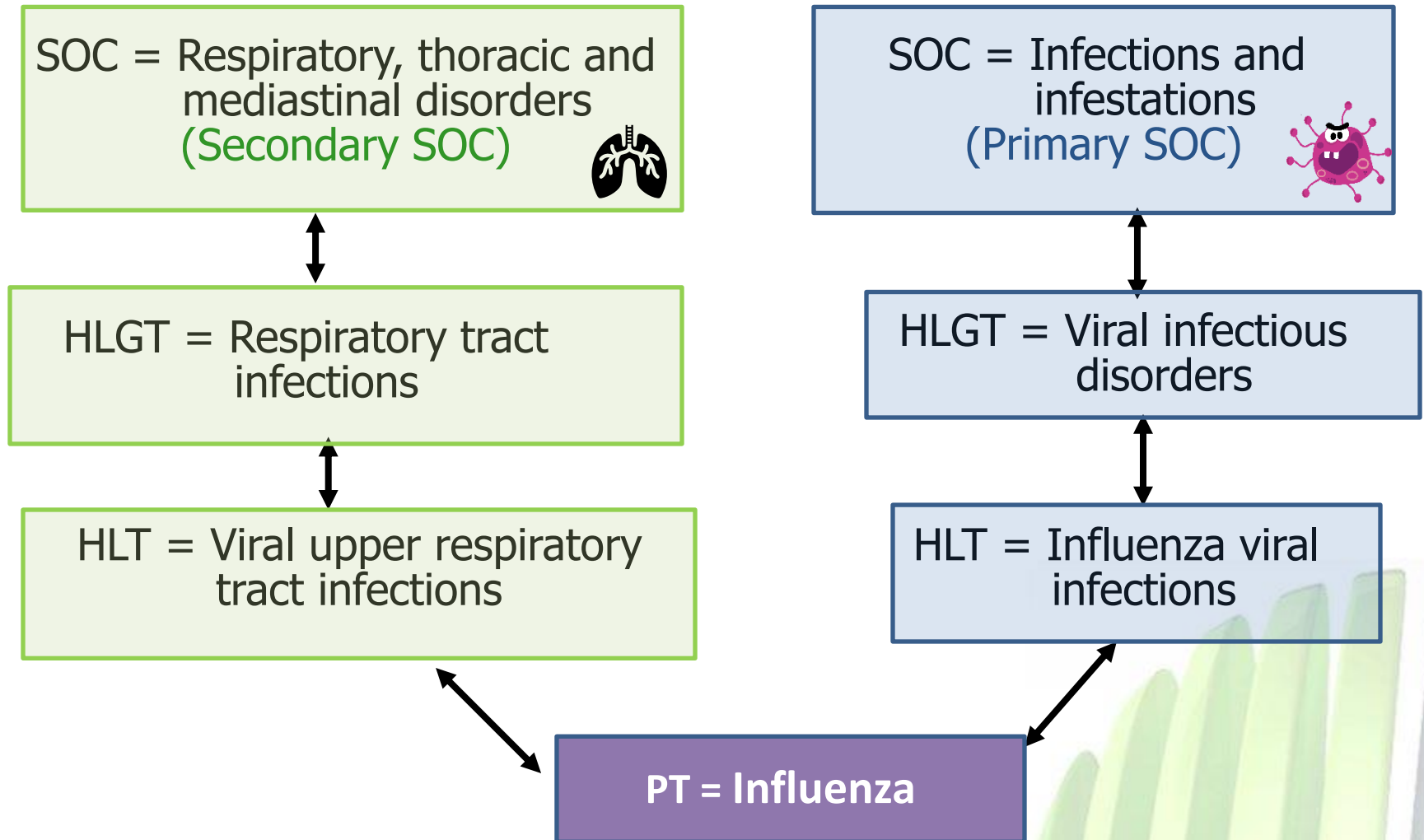
MedDRA Codes

PT Anaemia

[10002034]

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

A Multi-Axial Terminology



- Users can send change requests (CRs) to MSSO for consideration
 - Organizations allowed 100 CRs/month
 - Rigorous medical review by MSSO physicians
 - For simple changes (PT and LLT levels), response within 7-10 working days
 - Complex changes (above PT level) posted for comments mid-year
- Web-based tool for Change Requests (CR)
 - URL: <https://webcr.meddra.org/>
 - Via the Change Request Information page



MedDRA

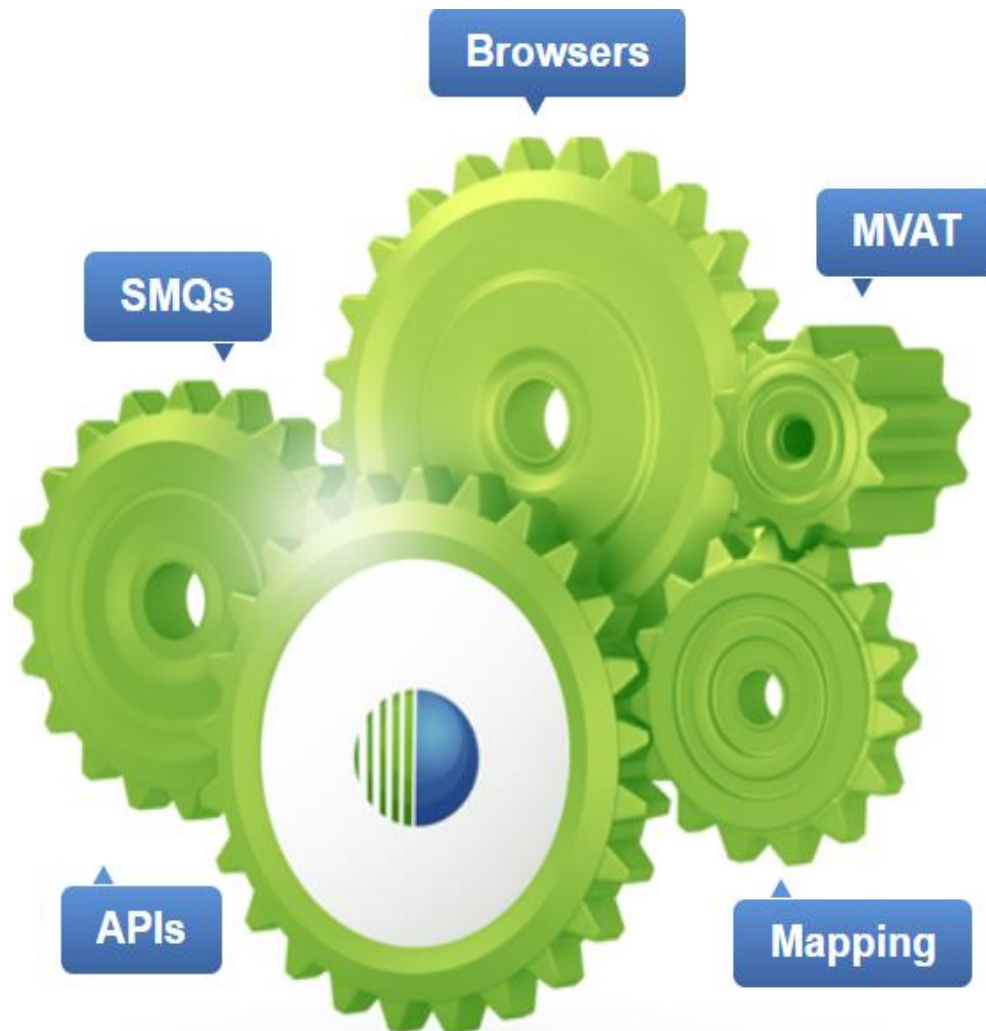
MedDRA Versioning

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



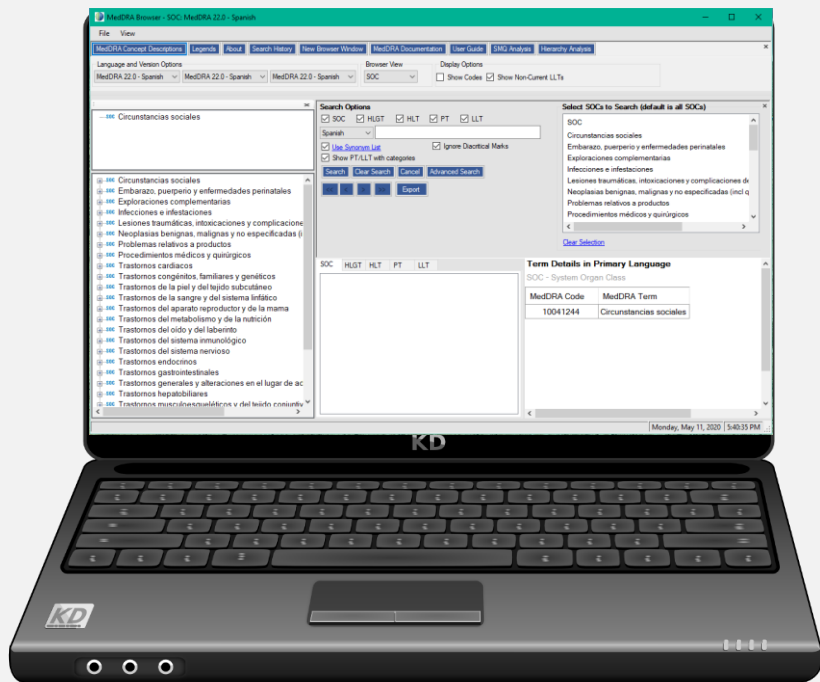
MedDRA

MedDRA Tools





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 Version Analysis Tool (MVAT)



Tuesday, January 30, 2024 5:02 PM

[MedDRA End User License Agreement](#)

[MedDRA Privacy Statement](#)

MedDRA Version Analysis Tool (MVAT)

Version Report Description

Select Different Versions to Compare

Language:

English

Starting Version:

MedDRA 26.1 English

Ending Version:

MedDRA 27.0 English

Include Secondary SOC Information ☐

Select SOCs to filter (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
Infections and infestations
Injury, poisoning and procedural complications

Clear Selection

Note: The starting MedDRA version must be older than the ending MedDRA version

Preferred Language

English

Release/Supplemental View

Release

MVAT Home


Search Term Change

Data Impact Report


Logout




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



Provides term selection advice for industry and regulatory purposes



Promote accurate and consistent term selection to facilitate a common understanding of shared data



Recommended to be used as basis for individual organization's own coding conventions

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

SECTION 2 – GENERAL TERM SELECTION PRINCIPLES

- 2.1 Quality of Source Data
- 2.2 Quality Assurance
- 2.3 Do Not Alter MedDRA
- 2.4 Always Select a Lowest Level Term
- 2.5 Select Only Current Lowest Level Terms
- 2.6 When to Request a Term
- 2.7 Use of Medical Judgment in Term Selection
- 2.8 Selecting More than One Term
- 2.9 Check the Hierarchy
- 2.10 Select Terms for All Reported Information, Do Not Add Information

SECTION 3 – TERM SELECTION POINTS

- 3.1 Definitive and Provisional Diagnoses with or without Signs and Symptoms
- 3.2 Death and Other Patient Outcomes
 - 3.2.1 Death with ARs/AEs
 - 3.2.2 Death as the only reported information
 - 3.2.3 Death terms that add important clinical information
 - 3.2.4 Other patient outcomes (non-fatal)
- 3.3 Suicide and Self-Harm
 - 3.3.1 If overdose is reported
 - 3.3.2 If self-injury is reported
 - 3.3.3 Fatal suicide attempt
- 3.4 Conflicting/Ambiguous/Vague Information
 - 3.4.1 Conflicting information
 - 3.4.2 Ambiguous information
 - 3.4.3 Vague information
- 3.5 Combination Terms
 - 3.5.1 Diagnosis and sign/symptom
 - 3.5.2 One reported condition is more specific than the other
 - 3.5.3 A MedDRA combination term is available
 - 3.5.4 When to "split" into more than one MedDRA term
 - 3.5.5 Event reported with pre-existing condition
- 3.6 Age vs. Event Specificity
 - 3.6.1 MedDRA term includes age and event information
 - 3.6.2 No available MedDRA term includes both age and event information
- 3.7 Body Site vs. Event Specificity
 - 3.7.1 MedDRA term includes body site and event information
 - 3.7.2 No available MedDRA term includes both body site and event information
 - 3.7.3 Event occurring at multiple body sites
- 3.8 Location-Specific vs. Microorganism-Specific Infection
 - 3.8.1 MedDRA term includes microorganism and anatomic location
 - 3.8.2 No available MedDRA term includes both microorganism and anatomic location
- 3.9 Modification of Pre-existing Conditions
- 3.10 Exposures during Pregnancy and Breast Feeding
 - 3.10.1 Events in the mother

- 3.10.2 Events in the child or foetus
- 3.11 Congenital Terms
 - 3.11.1 Congenital conditions
 - 3.11.2 Acquired conditions (not present at birth)
 - 3.11.3 Conditions not specified as either congenital or acquired
- 3.12 Neoplasms
 - 3.12.1 Do not infer malignancy
- 3.13 Medical and Surgical Procedures
 - 3.13.1 Only the procedure is reported
 - 3.13.2 Procedure and diagnosis are reported
- 3.14 Investigations
 - 3.14.1 Results of investigations as ARs/AEs
 - 3.14.2 Investigation results consistent with diagnosis
 - 3.14.3 Investigation results not consistent with diagnosis
 - 3.14.4 Grouped investigation result terms
 - 3.14.5 Investigation terms without qualifiers
- 3.15 Medication Errors, Accidental Exposures and Occupational Exposures
 - 3.15.1 Medication errors
 - 3.15.2 Accidental exposures and occupational exposures
- 3.16 Misuse, Abuse and Addiction
 - 3.16.1 Misuse
 - 3.16.2 Abuse
 - 3.16.3 Addiction
 - 3.16.4 Drug diversion
- 3.17 Transmission of Infectious Agent via Product
- 3.18 Overdose, Toxicity and Poisoning
 - 3.18.1 Overdose reported with clinical consequences
 - 3.18.2 Overdose reported without clinical consequences
- 3.19 Device-related Terms
 - 3.19.1 Device-related event reported with clinical consequences
 - 3.19.2 Device-related event reported without clinical consequences
- 3.20 Drug Interactions
 - 3.20.1 Reporter specifically states an interaction
 - 3.20.2 Reporter does not specifically state an interaction
- 3.21 No Adverse Effect and "Normal" Terms
 - 3.21.1 No adverse effect
 - 3.21.2 Use of "normal" terms
- 3.22 Unexpected Therapeutic Effect
- 3.23 Modification of Effect
 - 3.23.1 Lack of effect
 - 3.23.2 Do not infer lack of effect
 - 3.23.3 Increased, decreased and prolonged effect
- 3.24 Social Circumstances
 - 3.24.1 Use of terms in this SOC
 - 3.24.2 Illegal acts of crime or abuse
- 3.25 Medical and Social History
- 3.26 Indication for Product Use
 - 3.26.1 Medical conditions
 - 3.26.2 Complex indications
 - 3.26.3 Indications with genetic markers or abnormalities
 - 3.26.4 Prevention and prophylaxis
 - 3.26.5 Procedures and diagnostic tests as indications
 - 3.26.6 Supplementation and replacement therapies
 - 3.26.7 Indication not reported
- 3.27 Off Label Use
 - 3.27.1 Off label use when reported as an indication
 - 3.27.2 Off label use when reported with an AR/AE
- 3.28 Product Quality Issues
 - 3.28.1 Product quality issue reported with clinical consequences
 - 3.28.2 Product quality issue reported without clinical consequences
 - 3.28.3 Product quality issue vs. medication error

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SECTION 4 – APPENDIX

- 4.1 Versioning
 - 4.1.1 Versioning methodologies
 - 4.1.2 Timing of version implementation
- 4.2 Links and References


Detailed coding instructions




General term selection principles




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




Select current LLTs only




Degree of specificity may be challenging



Use medical judgment when appropriate



Avoid company-specific “work-arounds” for MedDRA deficiencies



Submit change request to MSSO

General term selection principles



Select Terms for All Reported Information



Do Not Add Information

Select terms for every AR/AE reported, regardless of causal association; Select terms for device-related events, product quality issues, medication errors, medical and social history, investigations, and indications as appropriate

Do not make diagnosis if only signs/symptoms reported

Reported	LLT Selected	Comment
Abdominal pain, increased serum amylase, and increased serum lipase	Abdominal pain	It is inappropriate to assign an LLT for diagnosis of "pancreatitis"
	Serum amylase increased	
	Lipase increased	

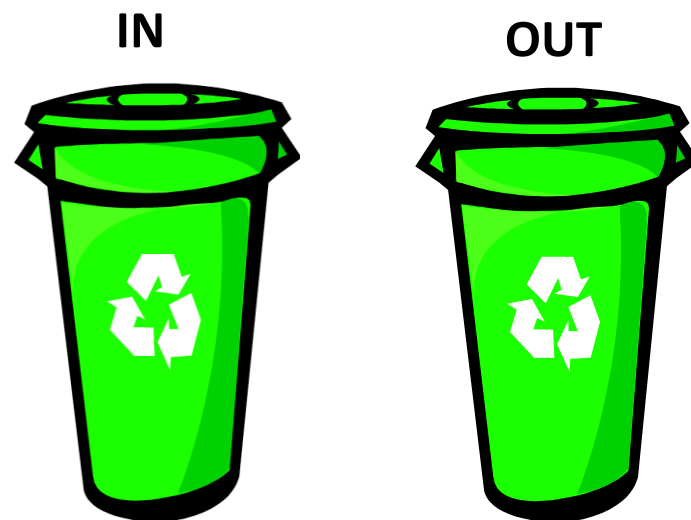
Coding: Translating into MedDRA

Reported Information	MedDRA Coding Term (LLT)
<p>Throbbing above temple</p> <p>Aching all over head</p> <p>Pulsing pain in head</p> <p>Really bad headache</p> <p>Headache</p>	Headache
Infection in lungs	Lung infection
<p>Patient took Drug A instead of Drug B and experienced hypertension</p>	<p>Wrong drug administered</p> <p>Hypertension</p>

Data Quality

- Quality of original information impacts quality of output
- Obtain clarification of data
- Can be optimized by careful design of data collection forms and proper training of staff
- Organizations' coding guidelines should be consistent with MTS:PTC
- Review of term selection by qualified individuals
- Human oversight of automated coding results

Quality of Input = Quality of Output



Quality Assurance (QA) Reports

- Allows reviewers to check for consistency (both auto-encoded and human-coded terms)
- Check for adherence to/deviation from coding conventions
- Check for emerging drifts/biases
- Multiple data views (verbatim to coded terms; coded term to verbatims; by SOC, etc.)

Important Coding Errors

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

Making the Most of MedDRA

- To take advantage of MedDRA's richness and specificity, the source data should be
 - Clear
 - Concise
 - Complete
 - Accurate
- General principles apply to all clinical data

Problems With Coding Data

- Appropriate coding requires clear initial data
- What is clear to the investigator at the point of data entry may be unclear to the sponsor at the point of data coding
- Sponsor must only code reported verbatim term; not permitted to interpret or draw information from other sources
- Example: Ambiguous information
 - Congestion (nasal, liver, sinus, pulmonary?)
 - Cramp (muscle, menstrual, abdominal?)
 - Pain (pain where?)

Problems With Coding Data (cont)

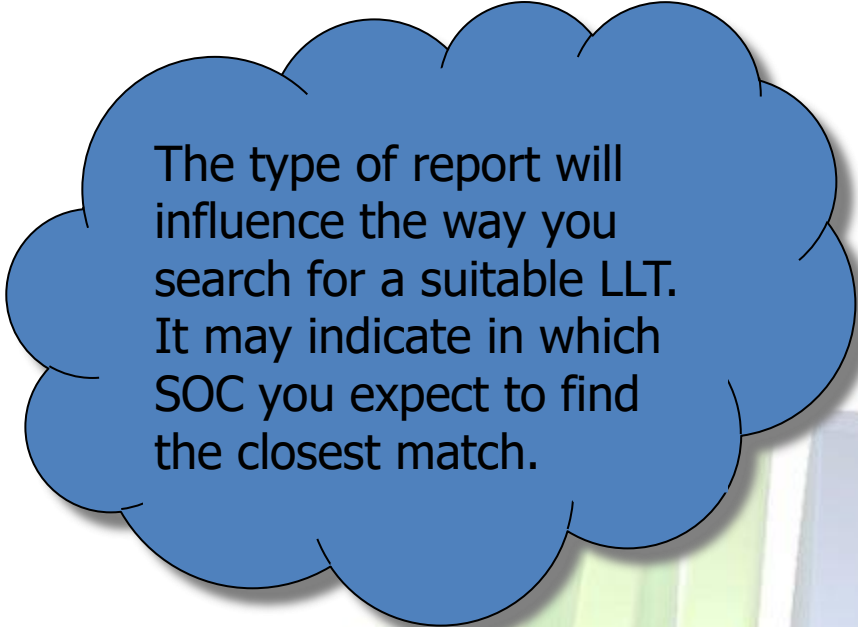
- Exercise caution with abbreviations that could be misinterpreted
- Example: Ambiguous abbreviations
 - MI (myocardial infarction or mitral incompetence?)
 - Decreased BS (breath sounds, bowel sounds or blood sugar?)
- Try to avoid combination terms, they should be split
- Example: Nausea and vomiting
 - Nausea
 - Vomiting

Problems With Coding Data (cont)

- Death, hospitalization, and disability are outcomes and are not usually considered to be adverse events
- Provide details of the underlying event, if known
- Examples:
 - “Death due to myocardial infarction” (Coded as *Myocardial infarction* with death captured as the outcome)
 - “Hospitalization due to congestive heart failure” (Coded as *Congestive heart failure* with hospitalization captured as the outcome)

Assessing the Reported Information

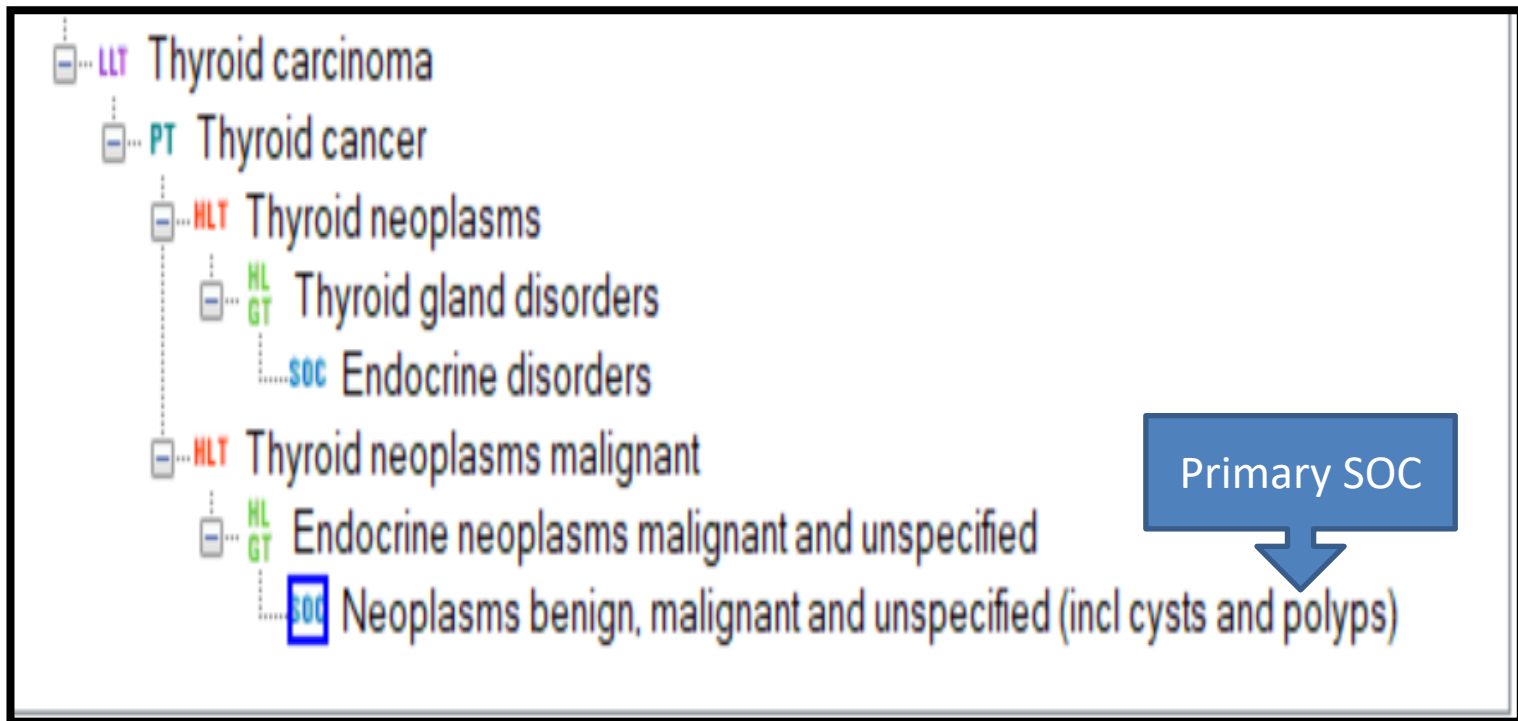
- Consider what is being reported. Is it a:
 - Clinical condition - Diagnosis, sign or symptom?
 - Indication?
 - Test result?
 - Injury?
 - Procedure?
 - Medication error?
 - Product use issue?
 - Product quality issue?
 - Social circumstance?
 - Device issue?
 - Procedural complication?
 - **Is it 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: THYROID CARCINOMA
— Coded to LLT : Thyroid carcinoma



How to code? Example:

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

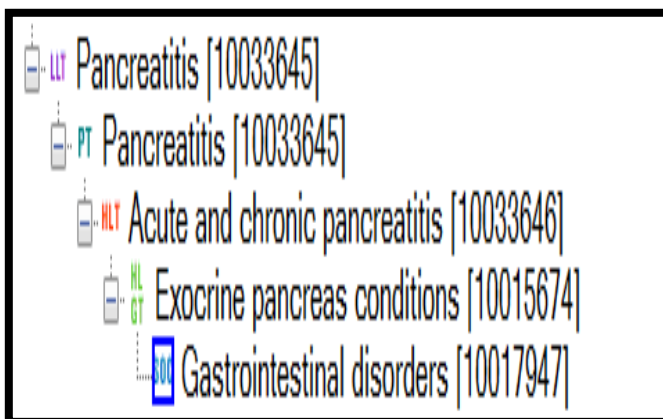


How to code? Example:

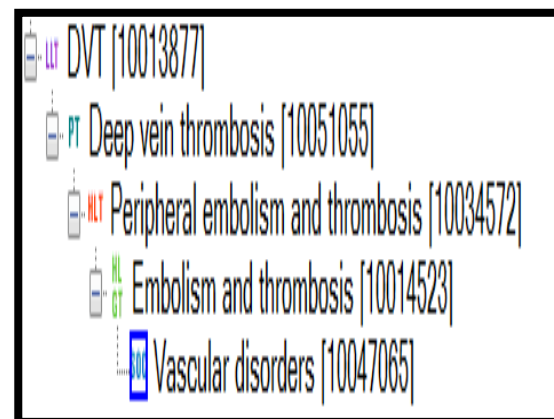
- Verbatim: 03/19/2012: Patient was hospitalized with severe upper abdominal burning pain radiating to the back, nausea, and vomiting that worsened with eating. Upon further investigation her serum amylase levels were found to be elevated and was diagnosed with Pancreatitis. During the hospitalization she was also found to have DVT.

— Coded to

1. LLT : Pancreatitis



2. LLT : DVT



How to code? Example:

Patient reported severe **eye irritation** after using **eye drops that had a cloudy appearance**. An investigation by the manufacturer revealed that the **batch of eye drops contained foreign material**.

- Coded to LLTs

LLT	PT	Primary SOC
Eye irritation	Eye irritation	Eye disorders
Product appearance cloudy	Liquid product physical issue	Product issues
Product contamination foreign material	Product contamination physical	Product issues

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Reported term: 'Abuse'

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**"Man with decreased
fertility."**

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**"Deliberately took an
overdose".**

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"Death from cerebral haemorrhage"

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

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

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Infection after surgery

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How would you handle this report?

A diabetic patient is anxious about his XXXX vaccination appointment, so he forgets that he took his morning insulin and administers a second dose. At the vaccination clinic, the diabetic patient seems confused, looks pale, and is sweaty.

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How would you handle this report?

① Start presenting to display the poll results on this slide.

What Terms to Select?

“Spray it in the nose as much as you can, and the septum is gone !! ”





**One of this terms was
not reported for coding.
Guess which one :)**

① Start presenting to display the poll results on this slide.

MedDRA Data Retrieval and Presentation: Points to Consider (DRP:PTC)

Provides data retrieval and presentation options for industry or regulatory purposes

Most effective when used in conjunction with MedDRA Term Selection: PTC document

Recommended to be used as basis for individual organization's own data retrieval conventions

Standardised MedDRA Queries (SMQs)

Groupings of terms from one or more MedDRA SOCs related to medical condition or area of interest

- Terms relate to
 - ✓ Signs/symptoms,
 - ✓ Diagnoses,
 - ✓ Syndromes,
 - ✓ Physical findings,
 - ✓ Laboratory and other test data, etc.
- Intended to aid in case identification

SMQs in Production - Examples

As of Version 27.0, a total of 110 level 1 SMQs in production

- Agranulocytosis
- Anaphylactic reaction
- Central nervous system vascular disorders
- Convulsions
- COVID-19
- Depression and suicide/self-injury
- Hepatic disorders
- Hypersensitivity
- Ischaemic heart disease
- Lack of efficacy/effect
- Medication errors
- Osteonecrosis
- Peripheral neuropathy
- Pregnancy and neonatal topics
- Pseudomembranous colitis
- Rhabdomyolysis/myopathy
- Severe cutaneous adverse reactions
- Shock
- Systemic lupus erythematosus



MedDRA

Standardised MedDRA Queries (SMQs) in Pharmacovigilance

Retrieve cases for suspected or known safety issue

Signal detection

Single case alerts

Periodic reporting



Know more?

www.meddra.org



Medical Dictionary for
Regulatory Activities

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Direct: +1 703.556.2950

Help Yourself

Get answers to some of your immediate questions
via the MedDRA Self-Service Application

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to join the MedDRA group on WhatsApp or WeChat.



WhatsApp

English/Spanish:

MedDRA Group



French:

MedDRA - French speakers



Russian:

MedDRA RU Users Support



WeChat

Chinese:



MedDRA MSSO

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Telephone:

E-mail: Confirm E-mail:

Organization:

Comment:

☒ Add me to the MSSO email list

☐ I'm not a robot

Support Documentation



Select a language: English

Additional Points to Consider Documents and MedDRA Best Practices Document (click here)

MedDRA Version 24.0 March 2021

MedDRA Version 23.1 September 2020

MedDRA Version 23.0 English March/April 2020

MedDRA Version 22.1 English September 2019

MedDRA Version 22.0 English March 2019

MedDRA Version 21.1 English September 2018

MedDRA Version 21.0 English March 2018

MedDRA Version 20.1 English September 2017

MedDRA Version 20.0 English March 2017

MedDRA Version 19.1 English September 2016

MedDRA Version 19.0 English March 2016

MedDRA Version 18.1 English September 2015

Training Materials

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

General / Basics		
> Topic	Presentation	Training Type
Coding		
> Topic	Presentation	Training Type
Retrieval / Analysis (SMQs)		
> Topic	Presentation	Training Type
MedDRA Versioning		
> Topic	Presentation	Training Type
Tools		
> Topic	Presentation	Training Type
Contributions from MedDRA User Groups		
A number of useful training materials (presentations and recordings) are developed for User Groups and are available for download on the User Group page.		

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MedDRA

Thank You!

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