MedDRA simplified: Coding for clinical excellence

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What role do you perform at your organization?

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Your experience with MedDRA?

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What is coding?

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Coding in daily life?

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 comittee

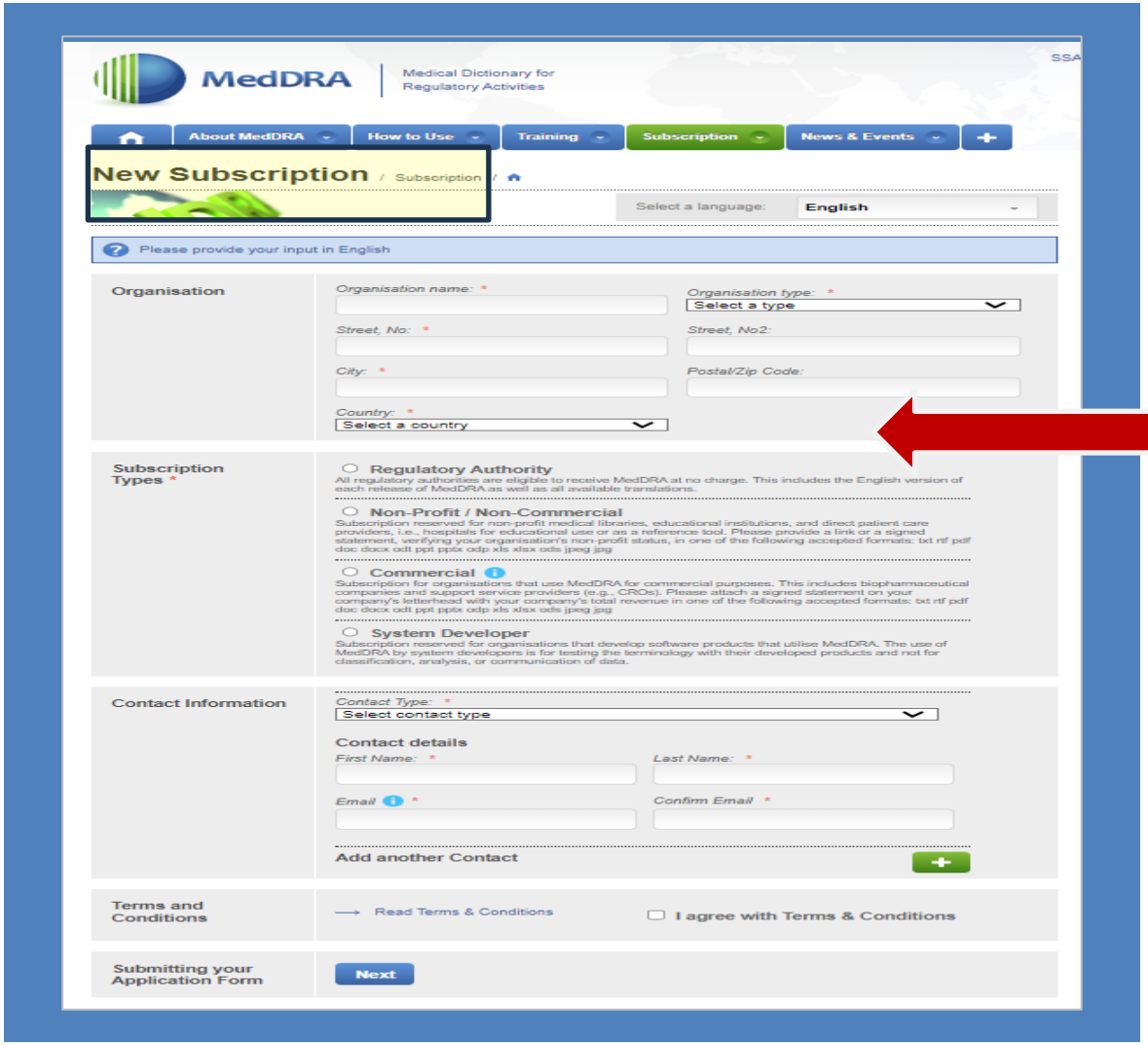
JMO for MedDRA Japanese

Types of Subscription

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?

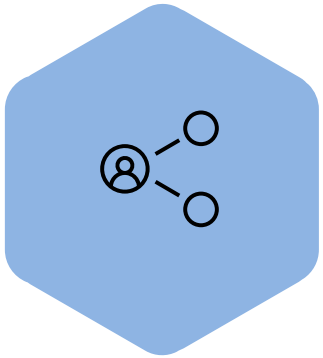


To subscribe to MedDRA, complete the online "New Subscription" form on the MedDRA website

MedDRA Data Sharing

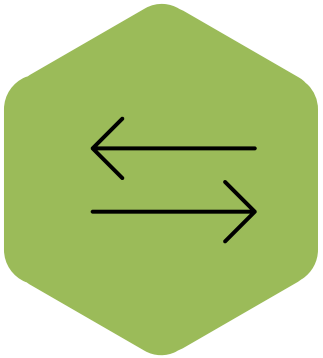
Access

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



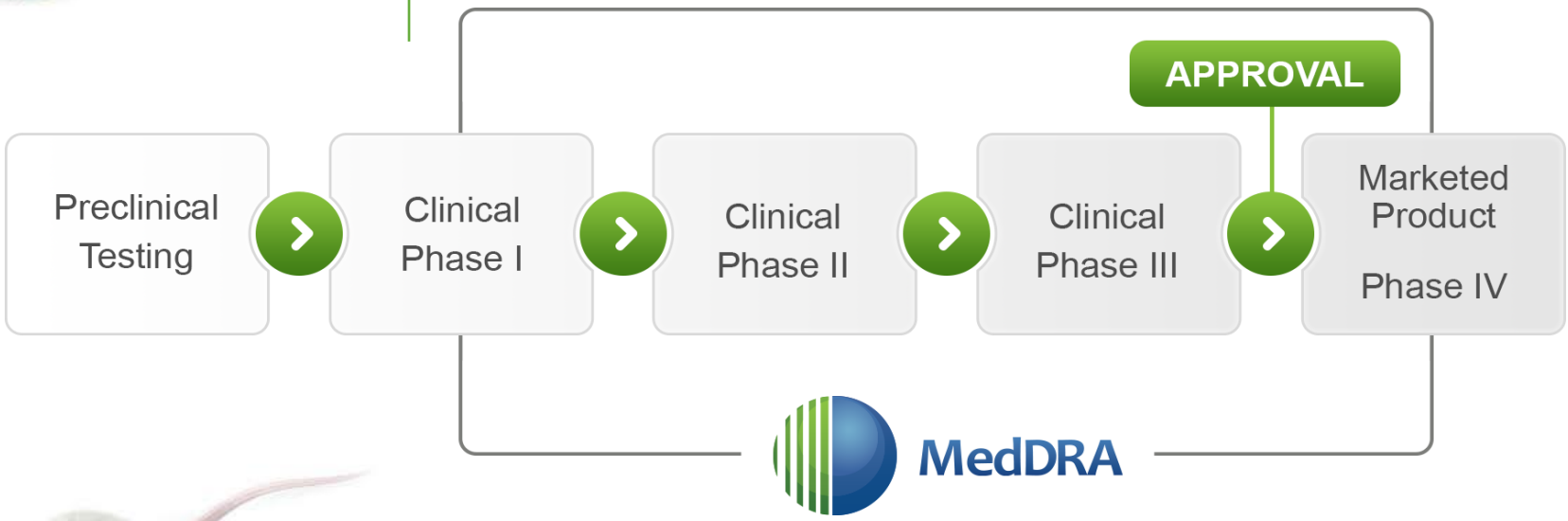
Free Exchange

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

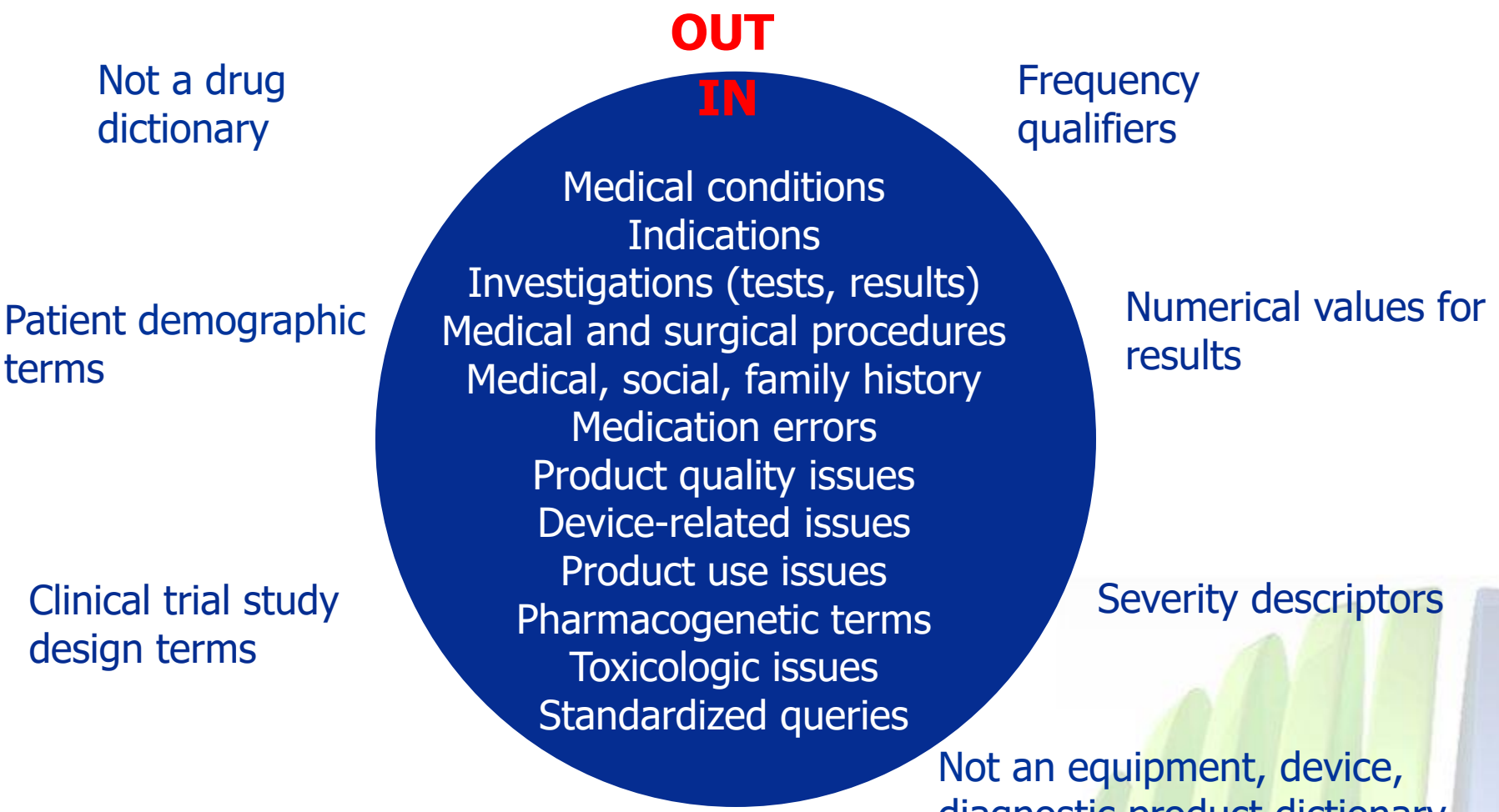
Marketing Applications

Publications

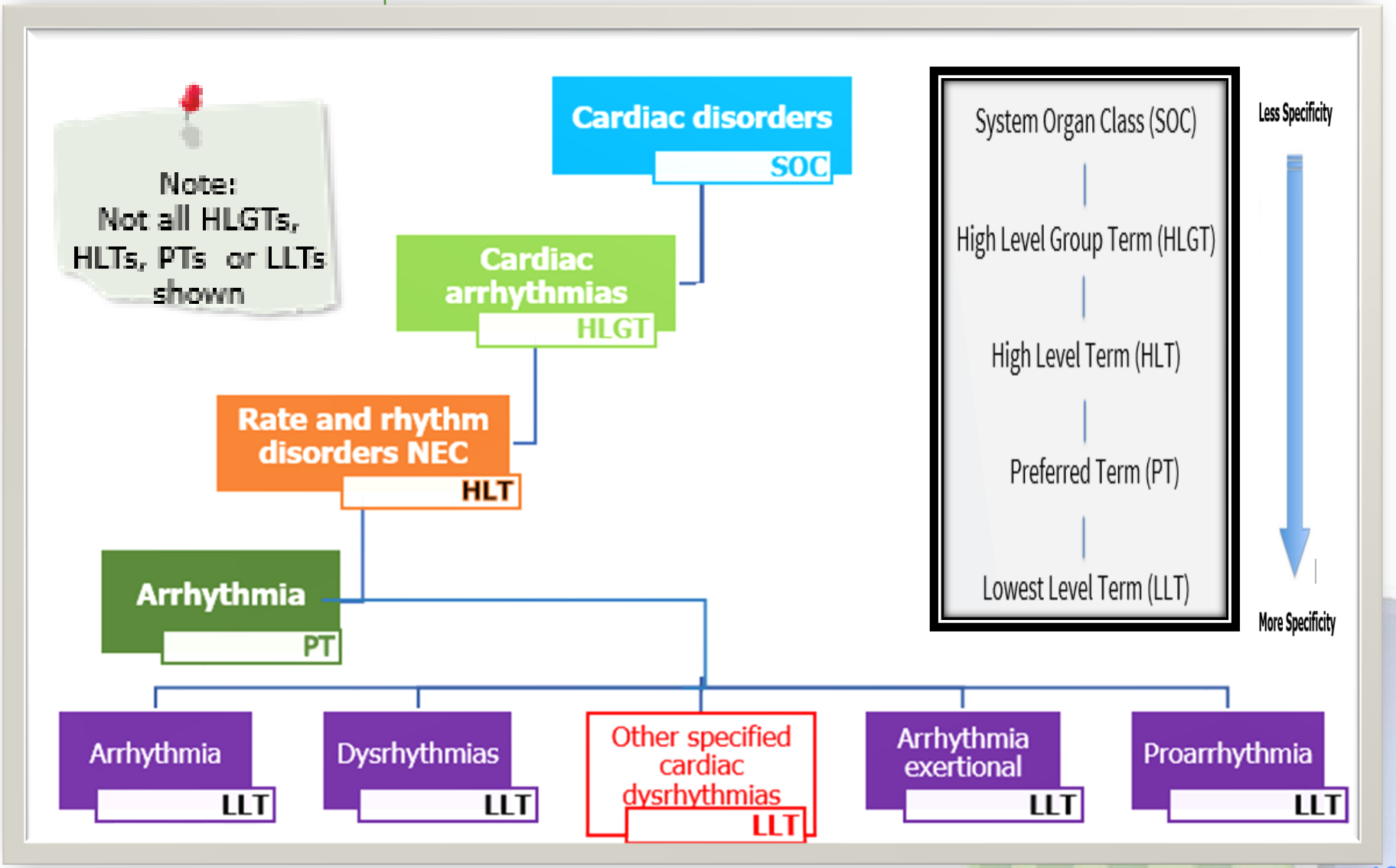
Prescribing Information

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

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Non-Current Terms

LLT

- 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, out-dated, truncated, or misspelled
- Terms derived from other terminologies that do not fit MedDRA rules

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))

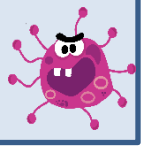
A Multi-Axial Terminology

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

HLGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

SOC = Infections and infestations (Primary SOC)



HLGT = Viral infectious disorders

HLT = Influenza viral infections

PT = Influenza

MedDRA Maintenance

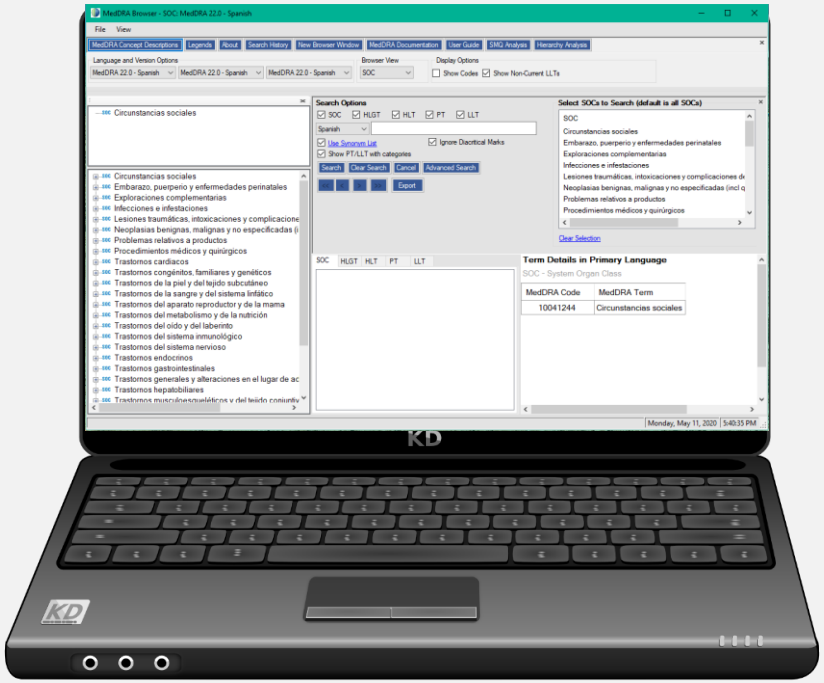
- Users can send change requests (CRs) to MSSO for consideration
  - Organizations allowed 100 CRs/month
  - Rigorous medical review by MSSO physicians
  - For simple changes (PT and LLT levels), response within 7-10 working days
  - Complex changes (above PT level) posted for comments mid-year
- Web-based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

MedDRA 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 Tools

MSSO's MedDRA Browsers

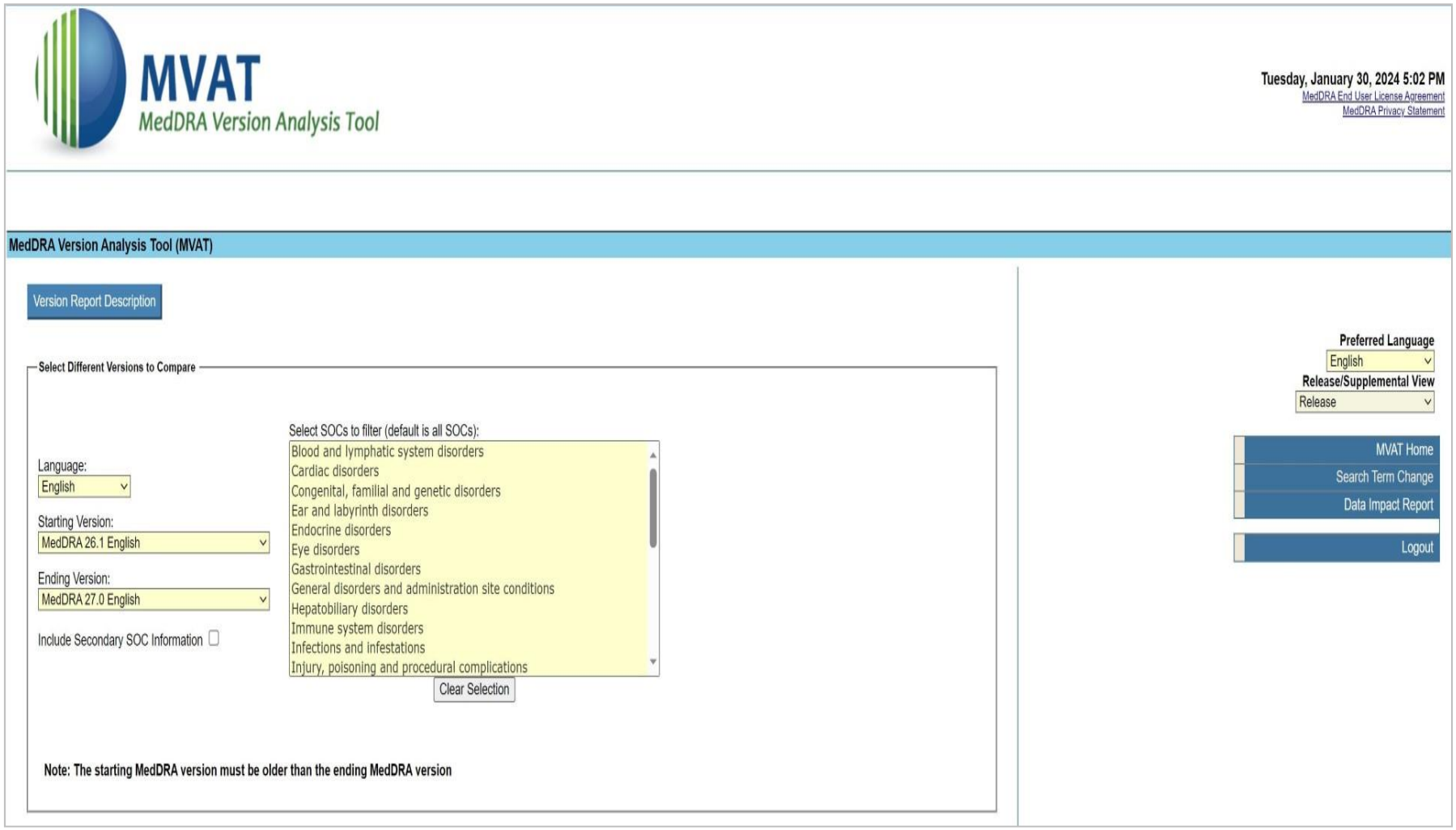


MedDRA Desktop Browser (MDB)
Download MDB and release files from MedDRA website

MedDRA Web-Based Browser (WBB)
https://tools.meddra.org/wbb/

Mobile MedDRA Browser
https://mmb.meddra.org

MedDRA Version Analysis Tool (MVAT)



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)

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

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	

Do not make diagnosis if only signs/symptoms reported

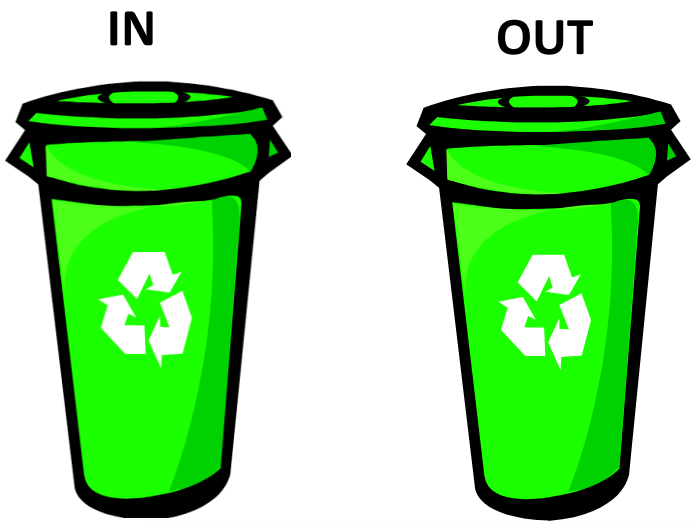
Coding: Translating into MedDRA

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

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 (verbatims 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)

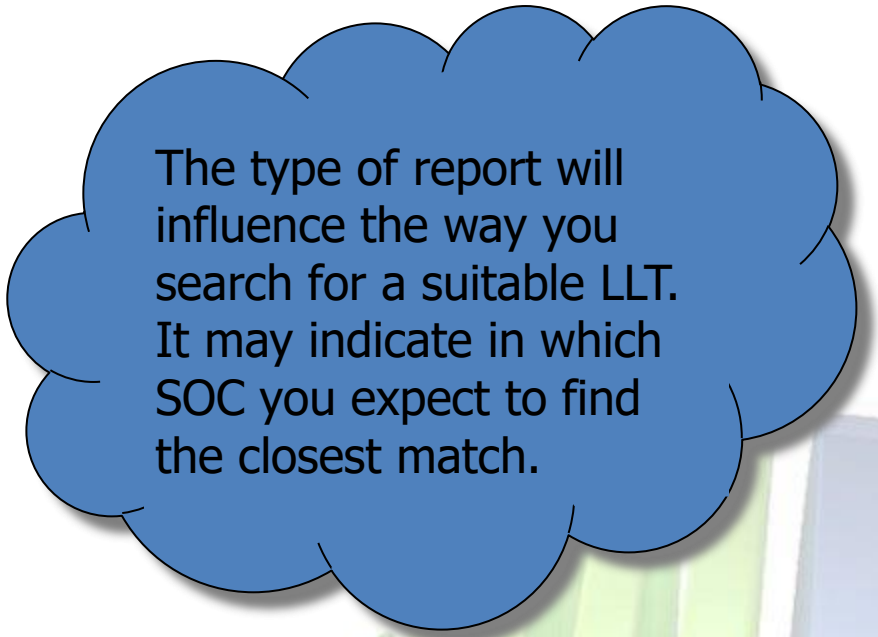
- Exercise caution with abbreviations that could be misinterpreted
- Example: Ambiguous abbreviations
  - MI (myocardial infarction or mitral incompetence?)
  - Decreased BS (breath sounds, bowel sounds or blood sugar?)
- Try to avoid combination terms, they should be split
- Example: Nausea and vomiting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

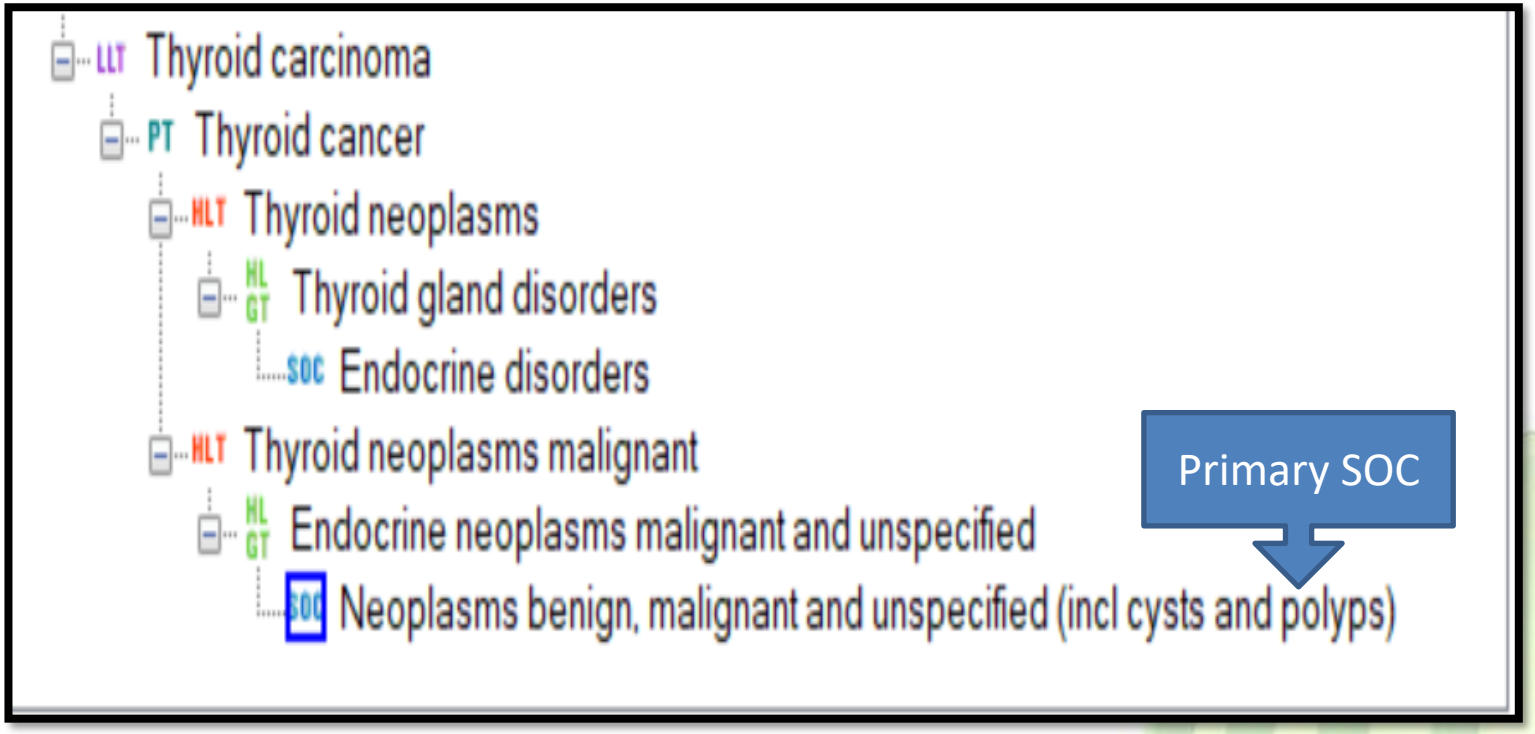
Assessing the Reported Information

- 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?**



How to code? Example:

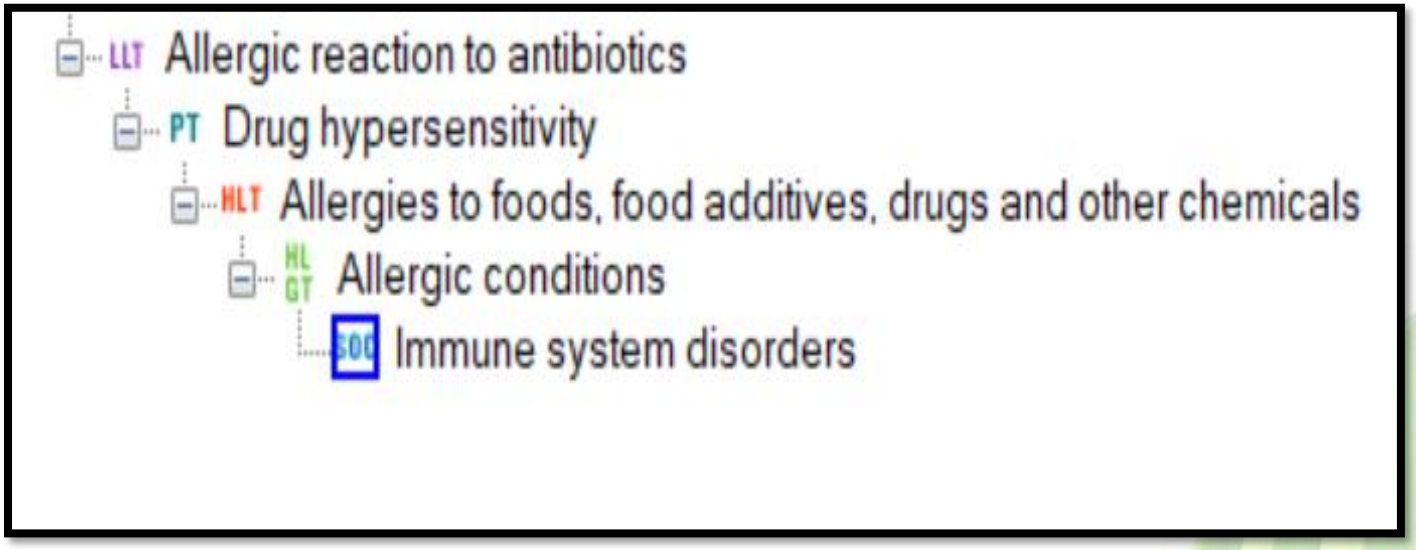
- Verbatim: THYROID CARCINOMA
  - Coded to LLT : Thyroid carcinoma



How to code? Example:

- Verbatim: The patient suffered from an allergic reaction to an antibiotic

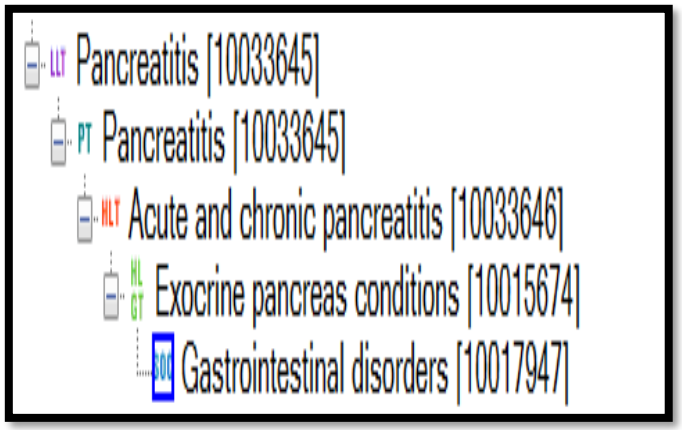
  — Coded to LLT : Allergic reaction to antibiotics



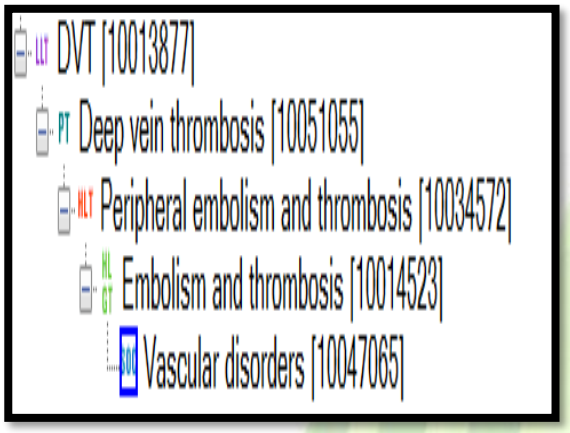
How to code? Example:

- 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".

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

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Infection after surgery

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

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?

ⓘ 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 !! "

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

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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.

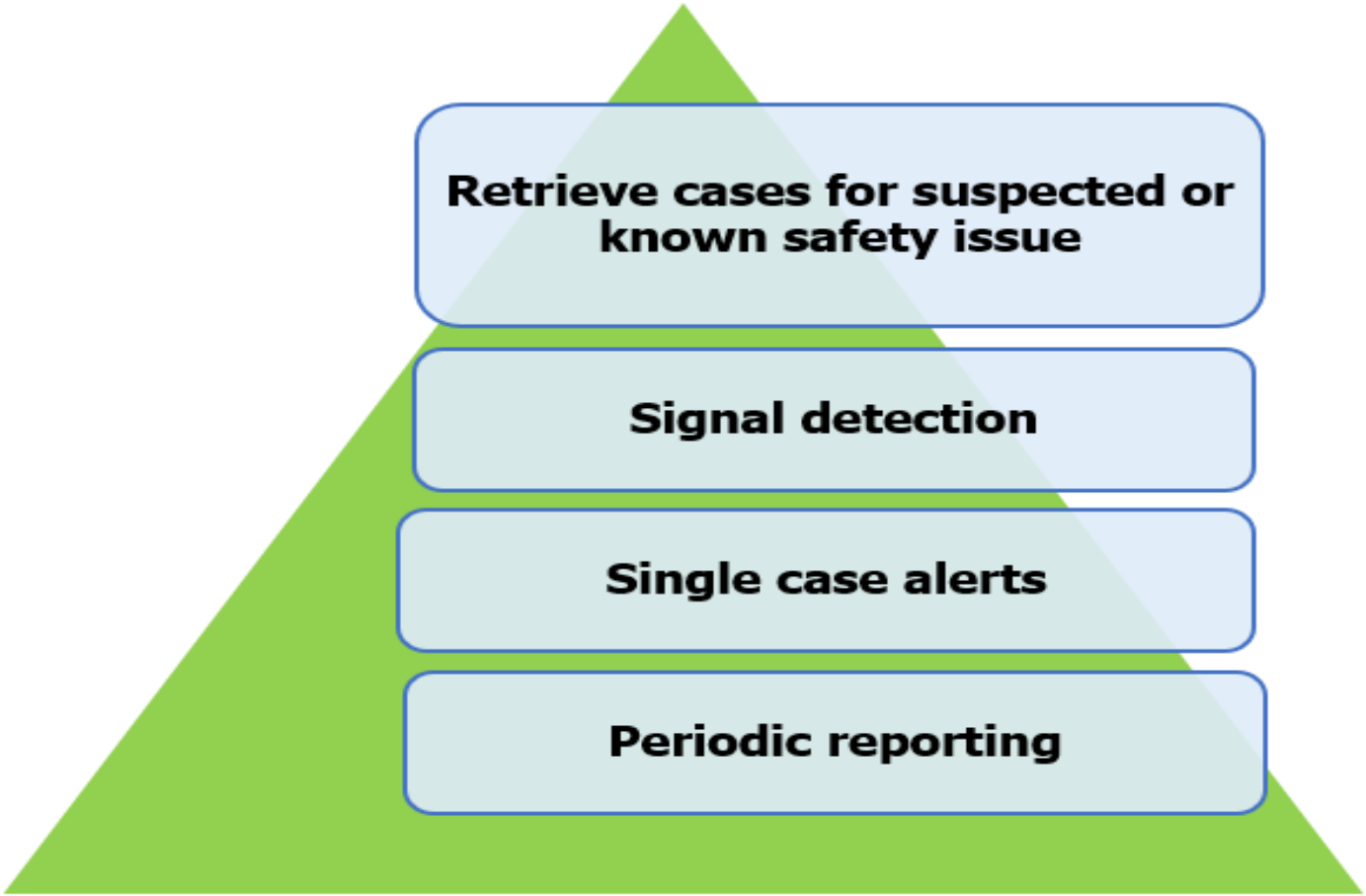
- Intended to aid in case identification

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

Standardised MedDRA Queries (SMQs) in Pharmacovigilance



Know more?

MedDRA | 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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Connect with us in: Please scan the appropriate QR code 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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Comment:
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Support Documentation / How to Use /

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 / Training /

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.

zendesk chat

Help Desk Live Chat

Type your message here

Thank You!

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anamika.dutta@meddra.org