



Advanced MedDRA Coding



MedDRA was developed under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Committee, which is composed of the ICH parties, the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the WHO (as Observer).



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Course Overview

- Discuss important principles in the MedDRA Term Selection: Points to Consider document
- Demonstrate some features of a MedDRA browser
- Discuss coding examples using a MedDRA browser
- Present some MedDRA coding "pearls"
- Conclude with a question and answer session
- Appendix – MedDRA's scope, structure, and characteristics/Browsers

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MedDRA Term Selection: Points to Consider Document

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ICH M1 Points to Consider Working Group (PtC WG)



- Regulators and industry from EU, US, and Japan
- Health Canada, Canada
- MFDS, Republic of Korea
- ANVISA, Brazil
- NMPA, China
- MSSO
- JMO
- WHO (Observer)

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PtC Documents

PtC Category	PtC Document	Purpose	Languages	Release Cycle
Term Selection	MedDRA Term Selection: Points to Consider	Promote accurate and consistent coding with MedDRA	English, Japanese, and other selected languages	Updated annually with the March release of MedDRA (starting with MedDRA Version 23.0)
	MedDRA Term Selection: Points to Consider Condensed Version	Shorter version focusing on general coding principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except English, Japanese, and other languages with an available translation of the full MTS:PTC document)	Update as needed
Data Retrieval and Presentation	MedDRA Data Retrieval and Presentation: Points to Consider	Demonstrate how data retrieval options impact the accuracy and consistency of data output	English, Japanese, and other selected languages	Updated annually with the March release of MedDRA (starting with MedDRA Version 23.0)
	MedDRA Data Retrieval and Presentation: Points to Consider Condensed Version	Shorter version focusing on general retrieval and analysis principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except English, Japanese, and other languages with an available translation of the full DRP:PTC document)	Update as needed

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PtC Documents (cont)

PtC Category	PtC Document	Purpose	Languages	Release Cycle
General	MedDRA Points to Consider Companion Document	More detailed information, examples, and guidance on specific topics of regulatory importance. Intended as a "living" document with frequent updates based on users' needs. First edition covers data quality and medication errors. New section on product quality is being drafted.	English and Japanese	Updated as needed

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

**MedDRA® TERM SELECTION:
POINTS TO CONSIDER**
ICH-Endorsed Guide for MedDRA Users

Release 4.19
Based on MedDRA Version 23.0

1 March 2020

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- 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

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MedDRA Term Selection: PTC (cont)

- Developed by a working group of the ICH Management Committee
- Updated annually in step with the March release of MedDRA (starting with MedDRA Version 23.0)
- Available on MedDRA and JMO websites
 - English, Japanese, and other selected languages
 - Word ("clean" and "redlined"), PDF, HTML formats
 - "Redlined" document identifies changes made from previous to current release of document

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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

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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

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Always Select a Lowest Level Term

Select Only Current LLTs

- Lowest Level Term that most accurately reflects the reported verbatim information should be selected
- Degree of specificity may be challenging
 - Example: "*Abscess on face*" → select "*Facial abscess*," not simply "*Abscess*"
- Select current LLTs only
 - Non-current terms for legacy conversion/historical purposes

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Diagnoses and Provisional Diagnoses

SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	PROVISIONAL DIAGNOSIS
Single diagnosis without signs and symptoms •Diagnosis (only possible option)	Single provisional diagnosis without signs and symptoms •Provisional diagnosis (only possible option)
Example: " <i>Myocardial infarction</i> " → select " <i>Myocardial infarction</i> "	Example: " <i>Possible myocardial infarction</i> " → select " <i>Myocardial infarction</i> " (select term as if definitive diagnosis)

Similar principles apply for multiple diagnoses

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Diagnoses and Provisional Diagnoses (cont)

SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	PROVISIONAL DIAGNOSIS
Single diagnosis with signs/symptoms •Preferred: Diagnosis only	Single provisional diagnosis with signs/symptoms •Preferred: Provisional diagnosis and signs/symptoms
Example: " <i>Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm</i> " → select " <i>Anaphylactic reaction</i> "	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> "

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Similar principles apply for multiple diagnoses

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Diagnoses and Provisional Diagnoses (cont)

SINGLE DIAGNOSIS	
DEFINITIVE DIAGNOSIS	PROVISIONAL DIAGNOSIS
Single diagnosis with signs/symptoms •Alternate: Diagnosis and signs/symptoms	Single provisional diagnosis with signs/symptoms •Alternate: Signs/symptoms only (as provisional diagnosis may change)
Example: " <i>Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm</i> " → select " <i>Anaphylactic reaction</i> ", " <i>Rash</i> ", " <i>Dyspnoea</i> ", " <i>Hypotension</i> ", and " <i>Laryngospasm</i> "	Example: " <i>Possible myocardial infarction with chest pain, dyspnoea, diaphoresis</i> " → select " <i>Chest pain</i> ", " <i>Dyspnoea</i> ", and " <i>Diaphoresis</i> "

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Similar principles apply for multiple diagnoses

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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 Jaundice (note that jaundice is not typically associated with myocardial infarction)

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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>

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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

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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>

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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.

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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.


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MedDRA Browser Demonstration



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Coding Exercises



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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.

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Which LLT Would You Select?

Verbatim: "Man with decreased fertility."

- A. Infertility
- B. Fertility decreased male
- C. Infertility male
- D. Fertility decreased

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Which LLT Would You Select?

Verbatim: "Became color blind in adolescence"

- A. Color blindness
- B. Blindness color
- C. Colour blindness acquired
- D. Color blindness acquired

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Which LLT Would You Select?

Verbatim: "Turned very greasy"

- A. Ill-defined disorder
- B. Unevaluable event
- C. Skin greasy
- D. Unevaluable reaction

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Which LLT Would You Select?

Verbatim: "Deliberately took an overdose"

- A. Intentional overdose
- B. Overdose NOS
- C. Deliberate overdose
- D. Overdose

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Which LLT Would You Select?

Verbatim: "Patient reported medical problem"

- A. Adverse event
- B. Unevaluable event
- C. Unevaluable reaction
- D. Ill-defined disorder

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Which LLT Would You Select?

Verbatim: "The 2-year-old accidentally took his mother's medication"

- A. Accidental overdose
- B. Accidental exposure to product by child
- C. Accidental drug intake by child
- D. Accidental ingestion

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Which LLT Would You Select?

Verbatim: "Infection after surgery"

- A. Infection
- B. Postoperative wound infection
- C. Surgical wound infection
- D. Postoperative infection

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Which LLT Would You Select?

Verbatim: "He sold his father's medication"

- A. Drug diversion
- B. Intentional product misuse
- C. Drug use for unapproved indication
- D. Intentional drug misuse

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Which LLT Would You Select?

Verbatim: "Had MI"

- A. Myocardial infarction
- B. Ill-defined disorder
- C. MI
- D. Unevaluable event

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Which LLT Would You Select?

Verbatim:

"Hypernatraemia (Serum sodium = 115 mEq/L)"

- A. Serum sodium abnormal
- B. Hypernatraemia
- C. Hyponatraemia
- D. Serum sodium decreased

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Which LLT Would You Select?

Verbatim: "Took intramuscular drug by mouth"

- A. Wrong route of administration
- B. Drug administered via inappropriate route
- C. Medication error
- D. Intramuscular formulation administered by other route

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Which LLT Would You Select?

Verbatim: "Death from cerebral haemorrhage"

- A. Sudden death
- B. Death
- C. Cerebral haemorrhage
- D. Brain death

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Which LLT Would You Select?

Verbatim: "Patient was found dead"

- A. Death from natural causes
- B. Death
- C. Died in sleep
- D. Found dead

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Which LLT Would You Select?

Verbatim: "The doctor mistakenly prescribed the wrong drug; the pharmacist noticed the error before dispensing the drug"

- A. Wrong drug dispensed
- B. Medication error
- C. Intercepted drug prescribing error
- D. Intercepted drug dispensing error

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Which LLT Would You Select?

Verbatim: "Died as a result of a suicide attempt"

- A. Suicide gesture
- B. Attempted suicide
- C. Completed suicide
- D. Death

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Which LLT Would You Select?

Verbatim: "Dose taken was below the minimum recommended dose in the product label"

- A. Underdose
- B. Drug administration error
- C. Accidental underdose
- D. Incorrect dosage administered

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Which LLT Would You Select?

Verbatim: "Abused by her husband"

- A. Physical abuse
- B. Battered wife
- C. Spousal abuse
- D. Victim of spousal abuse

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Which LLT Would You Select?

Verbatim: "A 27-year-old woman took a 2-week course of antibiotics during her second trimester of pregnancy. She did not experience any side effects."

What is the preferred option for the LLT(s) to be selected?

- A. Maternal exposure during pregnancy
- B. No adverse effect
- C. Normal pregnancy

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Which LLT Would You Select?

Verbatim: "After taking an antihistamine along with her prescribed proton pump inhibitor, a 53-year-old woman developed vertigo."

- A. Drug interaction NOS
- B. Vertigo subjective
- C. Vertigo
- D. Drug interaction

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Which LLT Would You Select?

Verbatim: "The medication was stored at room temperature instead of in the refrigerator where it belonged."

- A. Incorrect storage of drug
- B. Improper storage of unused product
- C. Intercepted medication error
- D. Product storage error temperature too high

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Which LLTs Would You Select?

Verbatim: "Because the label on the package was missing the wording on dosing information, the patient took the drug twice daily instead of once daily, resulting in the administration of an overdose."

- A. Product label issue
- B. Product label missing
- C. Product label missing text
- D. Wrong dose administered
- E. Once daily dose taken more frequently
- F. Inappropriate schedule of drug administration
- G. Overdose
- H. Accidental overdose

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Some MedDRA Coding “Pearls”

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Remember That MedDRA Can Be Used to Code More Than AEs

Narrative vignette

A 75-year-old male receiving Drug X for rheumatoid arthritis developed symptomatic aortic valve stenosis. The patient’s medical history is significant for colon cancer and cigarette smoking. He underwent an aortic valve replacement and developed a sternal wound infection three days post-surgery.

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MedDRA Coding “Pearls”

- First, try using reporter’s actual words
- Be aware of MedDRA’s specificity
- Exploit MedDRA’s hierarchy – if an LLT is close to what you need, look at its “siblings” and “parent”
- Check where the LLT lies in MedDRA (i.e., check the hierarchy above to be sure it represents the verbatim term accurately)

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MedDRA Coding “Pearls” (cont)

- Use “top-down” and “bottom-up” navigation
- Use available resources for difficult verbatim terms (web search, medical dictionaries, colleagues)
- Use advanced Boolean search terms features (i.e., “begins with”, “exact match”, “ends with”, “not contains”, “and”, “or”) when needed
- Become familiar with MedDRA Concept Descriptions

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MedDRA Coding “Pearls” (cont)

- And most important of all... get more coding training!

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Summary

- Discussed important principles presented in the MedDRA Term Selection: Points to Consider document
- Demonstrated some features of a MedDRA browser
- Discussed coding examples using a MedDRA browser
- Presented some MedDRA coding “pearls”

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MSSO Contacts

- Website
 - www.meddra.org
- Email
 - mssohelp@meddra.org
- Frequently Asked Questions
 - www.meddra.org/faq
- MedDRA Browsers
 - <https://www.meddra.org/meddra-desktop-browsers> (Desktop Browser)
 - <https://tools.meddra.org/wbb/> (Web-Based Browser)
 - <https://mmb.meddra.org> (Mobile Browser)

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MSSO Contacts (cont)

- Self-Service Application
 - <https://www.meddra.org/meddra-self-service-application>
- Training Schedule
 - <https://www.meddra.org/training/schedule>
- Change Request Submission
 - <https://www.meddra.org/how-to-use/change-requests>
- MedDRA Support Documentation
 - <https://www.meddra.org/how-to-use/support-documentation>

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Question and Answer Session

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Appendix: MedDRA's Scope, Structure, and Characteristics/Browsers

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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.

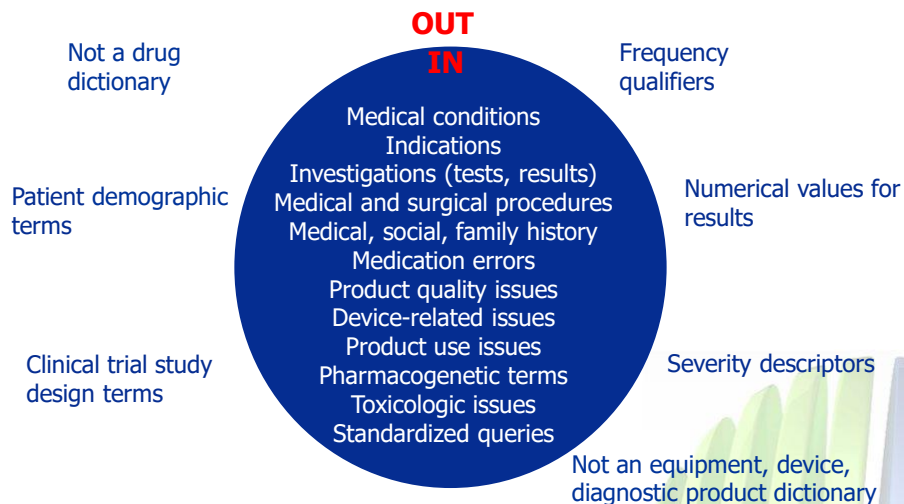
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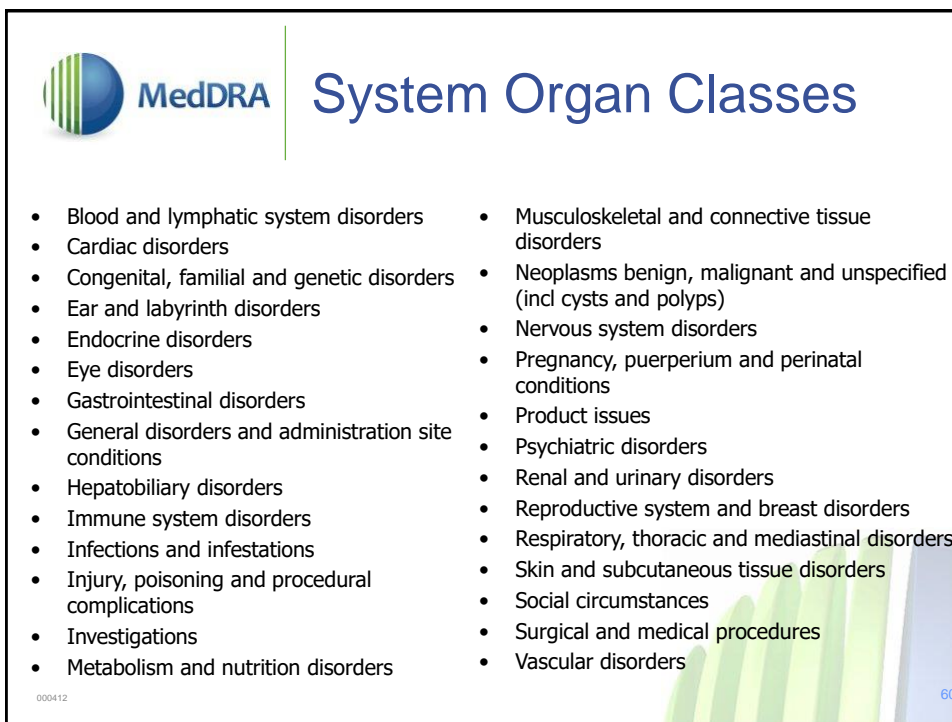
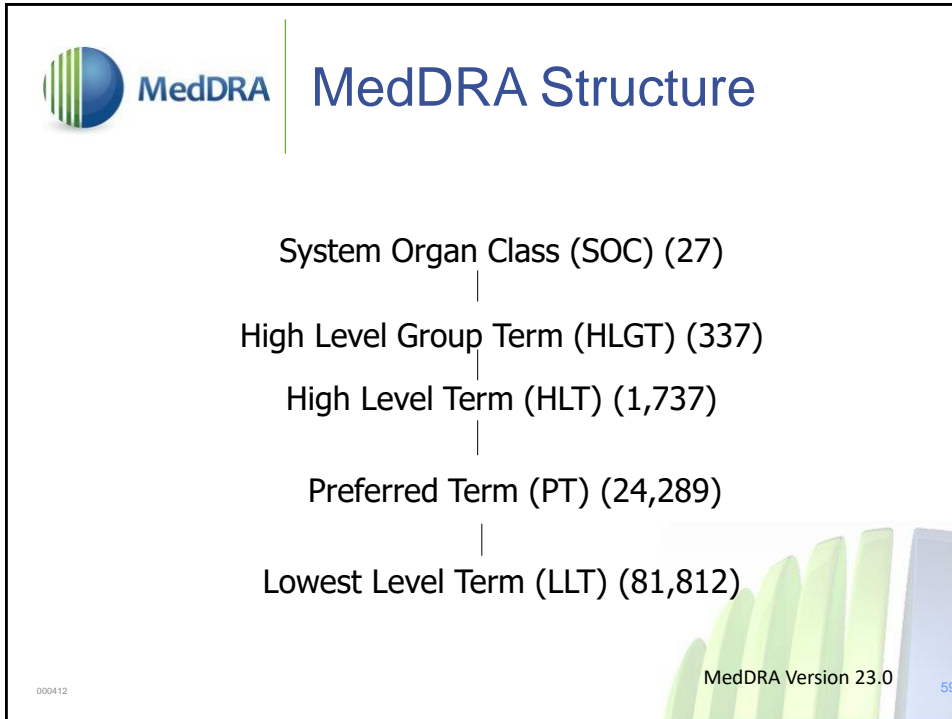
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Scope of MedDRA



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A Multi-Axial Terminology

- Multi-axial = the representation of a medical concept in multiple SOC
 - 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

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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

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Primary SOC Priority

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

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

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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*

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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 (MMB)
 - <https://mmb.meddra.org>
- Features
 - Each require MedDRA ID and password
 - View/search MedDRA and SMQs
 - Support for all MedDRA languages
 - Language specific interface
 - Ability to export search results and Research Bin to local file system (MDB and WBB only)

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MDB and WBB Special Features

- Preview upcoming (supplemental) changes in next release*
- View primary **and** secondary link information
- Upload terms to run against SMQs
- Advanced search options (e.g., NOT, OR)

*Supplemental view not available on MDB

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