MedDRA Coding Basics

MedDRA
Medical Dictionary
for Regulatory Activities

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MedDRA

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

- Gain knowledge of MedDRA's scope, structure, and characteristics
- Discuss coding conventions
- Learn about the MedDRA Term Selection: Points to Consider (MTS:PTC) document
- Learn about MedDRA browsers
- Watch a demonstration of coding with browser
- Use browser to code with MedDRA
- Conclude with question and answer session
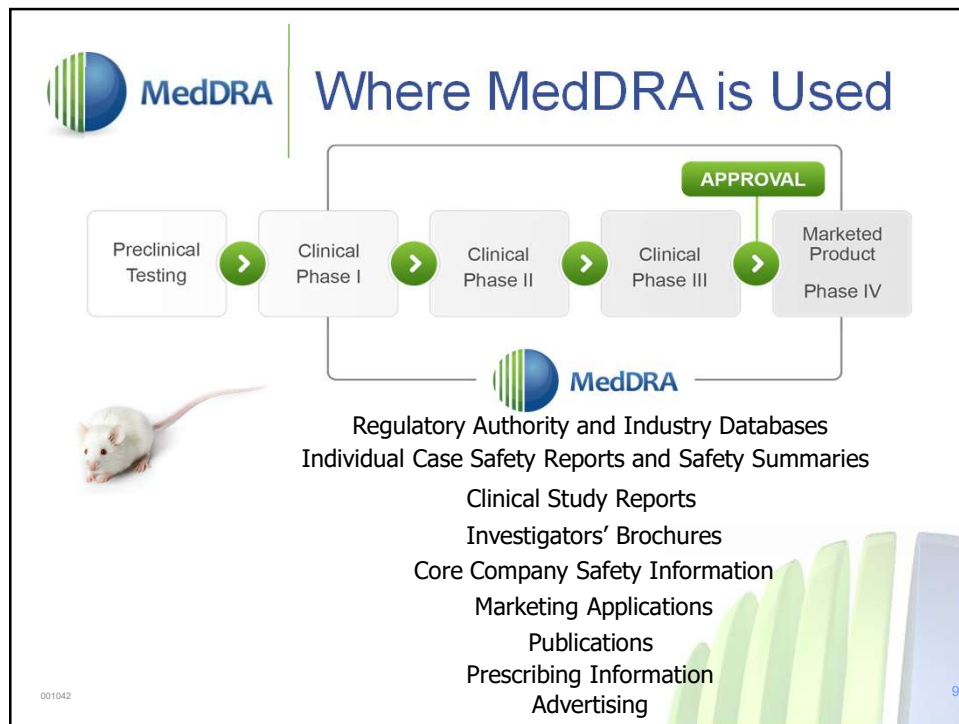
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MedDRA Overview

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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.
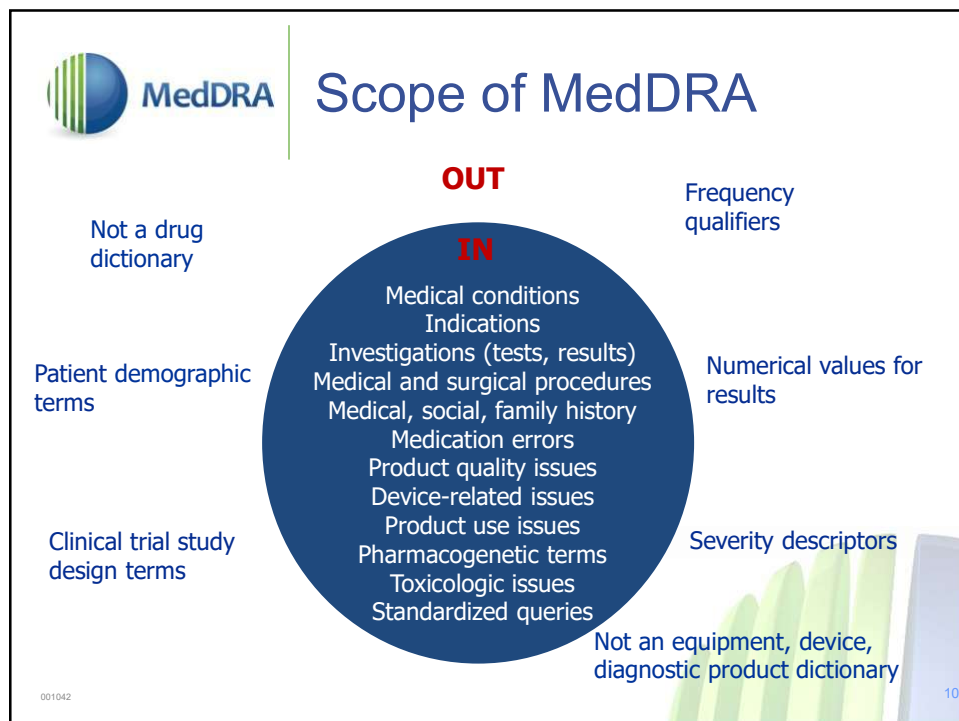
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MedDRA Structure

System Organ Class (SOC)	27
High Level Group Term (HLGT)	337
High Level Term (HLT)	1738
Preferred Term (PT)	26409
Lowest Level Term (LLT)	88345

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MedDRA Version 27.0   11

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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

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The Five Levels of MedDRA

SOC	Cardiac disorders
HLGT	Cardiac arrhythmias
HLT	Rate and rhythm disorders NEC
PT	Arrhythmia
LLT	LLT Arrhythmia NOS
	LLT Arrhythmia
	LLT (Non-current) Other specified cardiac dysrhythmias
	LLT Dysrhythmias

Note: Not all HLGTs, HLTs, PTs or LLTs shown

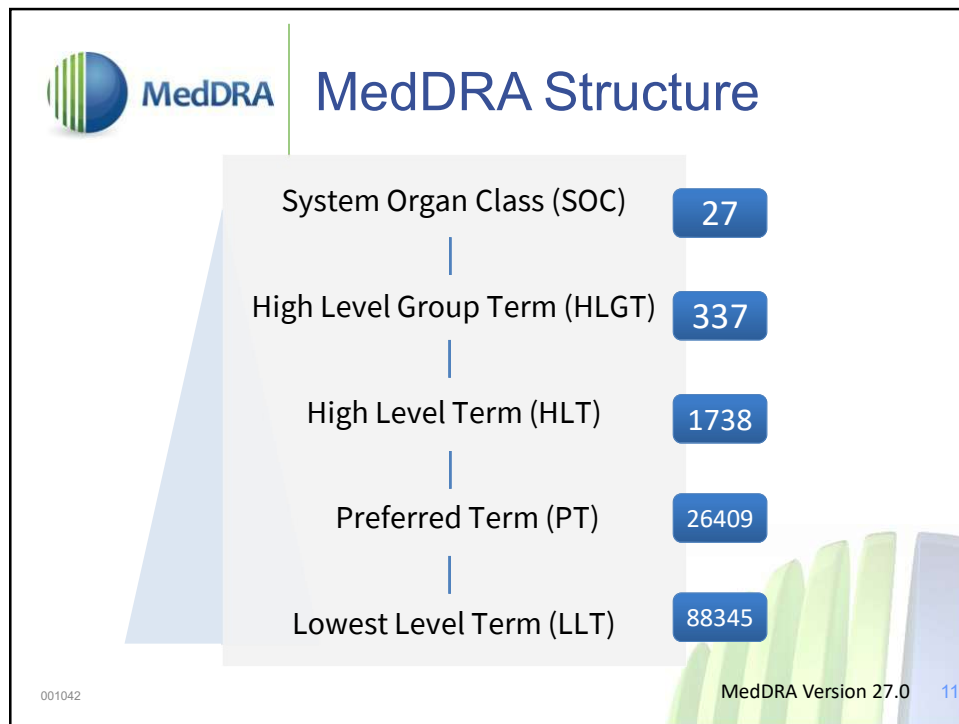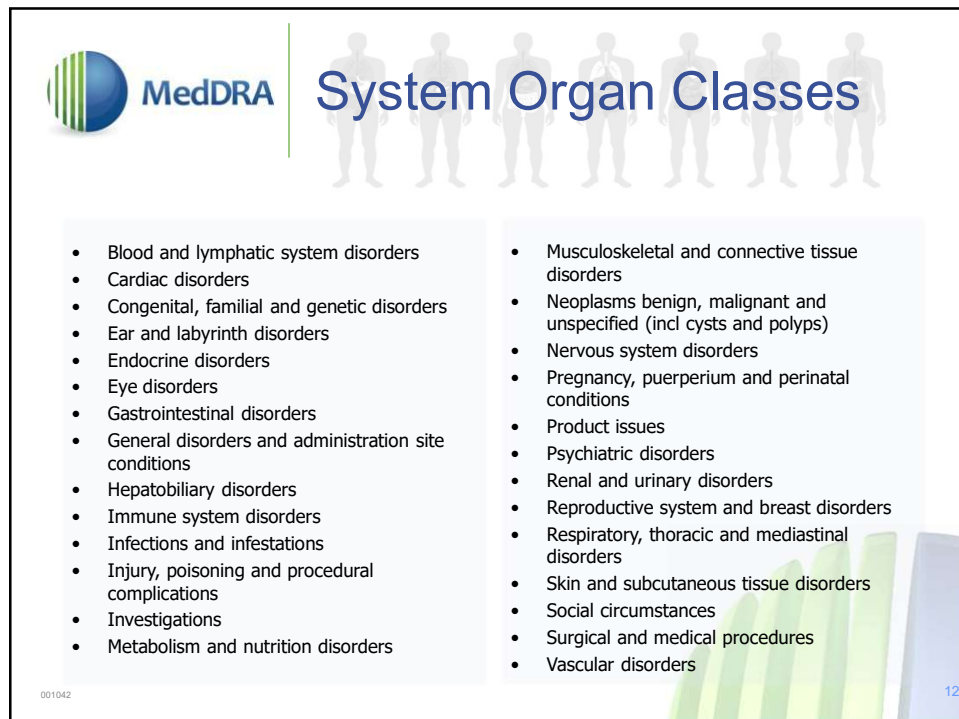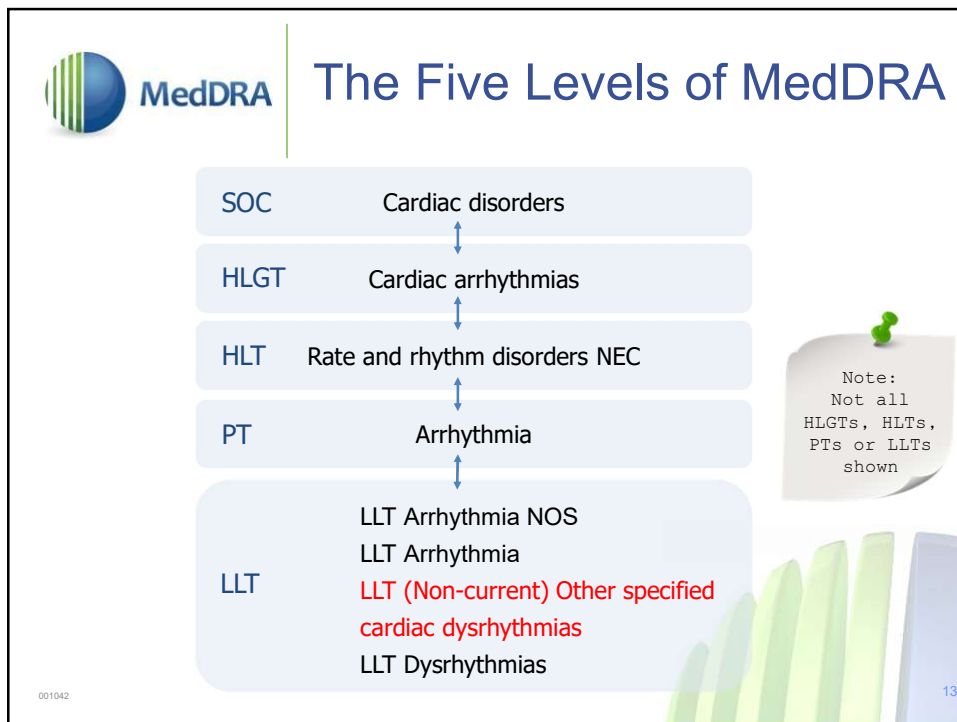001042

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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

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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))

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A Multi-Axial Terminology

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

- ✓ Allows grouping by different classifications
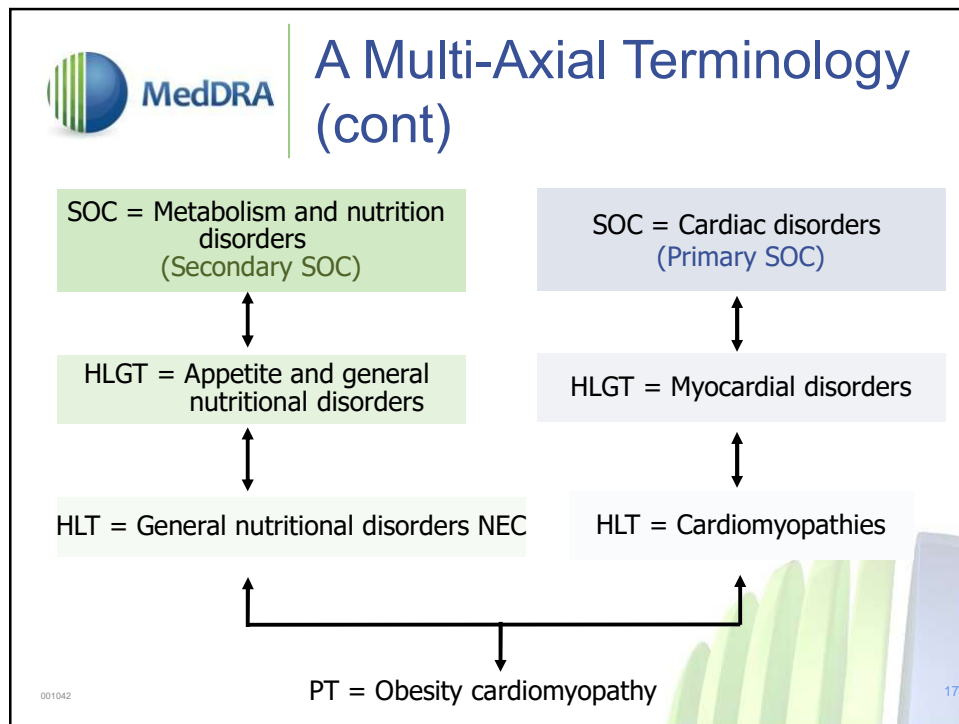- ✓ Allows retrieval and presentation via different data sets

All PTs assigned a primary SOC

- ✓ Determines which SOC will represent a PT during cumulative data outputs
- ✓ Prevents "double counting"
- ✓ Supports standardized data presentation
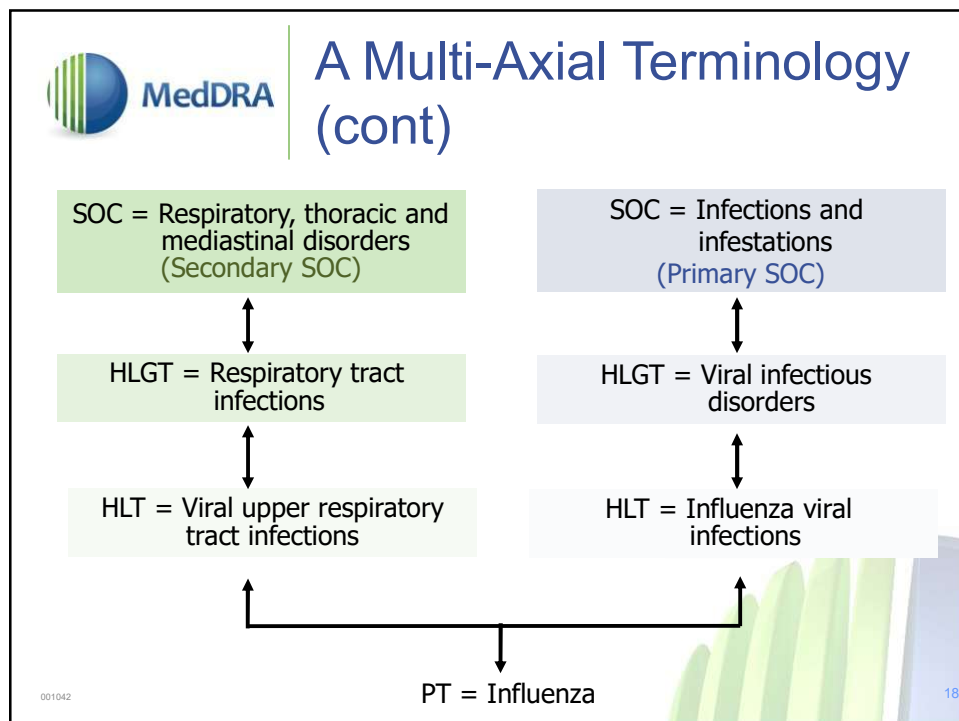- ✓ Pre-defined allocations should not be changed by users

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A Multi-Axial Terminology (cont)

MedDRA

SOC = Metabolism and nutrition disorders
(Secondary SOC)

SOC = Cardiac disorders
(Primary SOC)

HLGT = Appetite and general nutritional disorders

HLGT = Myocardial disorders

HLT = General nutritional disorders NEC

HLT = Cardiomyopathies

PT = Obesity cardiomyopathy

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A Multi-Axial Terminology (cont)

MedDRA

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

SOC = Infections and infestations
(Primary SOC)

HLGT = Respiratory tract infections

HLGT = Viral infectious disorders

HLT = Viral upper respiratory tract infections

HLT = Influenza viral infections

PT = Influenza

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Rules for Primary SOC Allocation

MedDRA

- 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

MedDRA

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

Congenital, familial and genetic disorders

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Infections and infestations

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A Multi-Axial Terminology (cont)

MedDRA

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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MedDRA

Coding Conventions

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What are Coding Conventions?

- Written guides and sets of principles for using MedDRA that help achieve consistency in coding and data retrieval

- Conventions harmonize exchange of MedDRA coded data worldwide

- Common topics
  - Misspellings, abbreviations and acronyms
  - Combination terms and "due to" concepts
  - "Always query" terms, e.g., "Chest pain"

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Why Do We Need Coding Conventions?

- Differences in medical aptitude of coders

- Consistency concerns (many more "choices" in MedDRA vs. older terminologies)

- Even with autoencoder, may still need manual coding

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Autoencoder Pitfalls

MedDRA

- Inappropriate terms may be selected by autoencoder

- Review all autoencoding carefully
  - "Allergic to CAT scan" autoencoded as:
    - LLT *Allergic to cats*
  - "Myocardial infarction in the fall of 2000" autoencoded as:
    - LLT *Myocardial infarction*
    - LLT *Fall*

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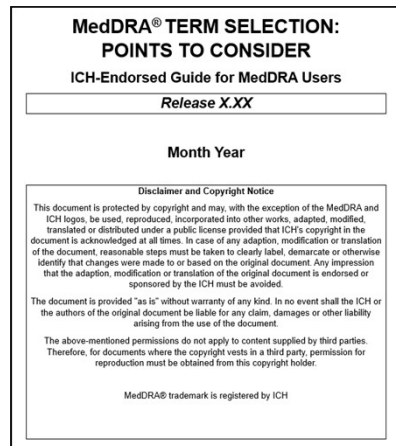
MedDRA

MedDRA Term Selection
Points to Consider Document

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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 X.XX

Month Year

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- Provides term selection advice for industry and regulatory purposes
- Objective is to promote accurate and consistent term selection to facilitate 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 March
- Complete versions available in
  - English, Japanese, Chinese, Korean, Spanish, and Russian
- Condensed versions available for other MedDRA languages*
- Available on MedDRA and JMO websites

*Arabic, Brazilian Portuguese, Czech, Dutch, French, German, Hungarian, Italian, Portuguese

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MTS:PTC Points of Note

- In some cases, with more than one option for selecting terms, a "preferred option" is identified but this does not limit MedDRA users to applying that option. Organizations should be consistent in their choice of option.

- Section 4 – Appendix
  - 4.1 Versioning (which refers reader to MedDRA Best Practices document)
  - 4.2 Links and References

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General Term Selection Principles

- Quality of Source Data
- Quality Assurance
- Do Not Alter MedDRA
- Always Select a Lowest Level Term
- Select Only Current Lowest Level Terms
- When to Request a Term
- Use of Medical Judgment in Term Selection
- Select Terms for All Reported Information, Do Not Add Information
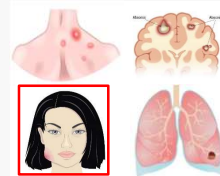
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Quality of Source Data Quality Assurance

- 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

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Do Not Alter MedDRA

- MedDRA is a standardized terminology with a pre-defined term hierarchy
- Users must not make *ad hoc* structural alterations, including changing the primary SOC allocation

WebCR
MedDRA Change Request

If terms are incorrectly placed, submit a change request to the MSSO

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Select Terms for All Reported 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

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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	

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Term Selection Points

Section 3

- 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 Infection
- 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

Section 3

- 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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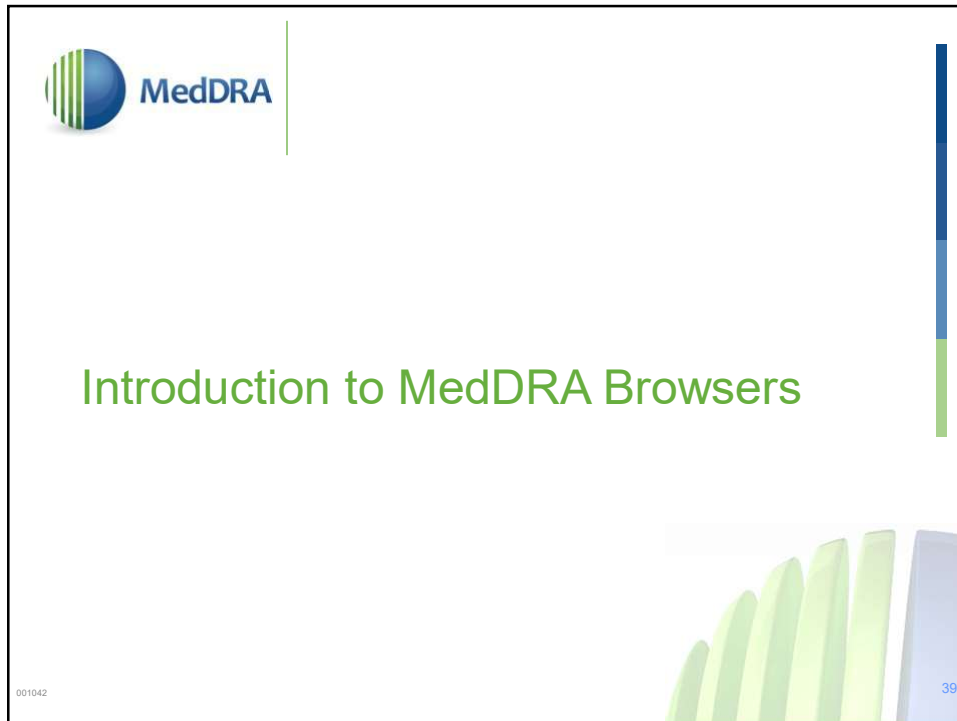
Introduction to MedDRA Browsers

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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
https://mmb.meddra.org

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MSSO's MedDRA Browsers (cont)

- 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*
  Supplemental view not available on MDB
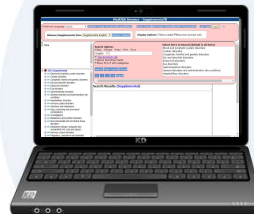
- View primary **and** secondary link information
- Upload terms to run against SMQs
- Advanced search options (e.g., NOT, OR)

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MedDRA Browser Demonstration

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Approach to Finding Best LLTs

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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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Coding Example 1

Specificity

The patient suffered from an <u>allergic reaction to an antibiotic</u>

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MedDRA | Coding Example 2

Symptoms

The patient states she has been experiencing <u>cold sweats</u>

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MedDRA | Coding Example 3

Investigations

Lab results indicate the patient has <u>increased troponin and increased CPK-MB</u>

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MedDRA | Coding Example 4

Medication errors

Patient accidentally took drug Y instead of drug X and became short of breath

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MedDRA | Coding Example 5

Patient demographics

A 2 day old baby was noted to have a mild fever

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Coding Example 6

Indications

A 35 year old woman was taking Drug X to <u>prevent relapses</u> of <u>multiple sclerosis</u>

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Coding Example 7

Specificity

She had a <u>pathologic fracture</u> of the <u>neck of </u>the left <u>femur</u>

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MedDRA | Coding Example 8

Specificity

Following the procedure, the patient experienced several days of constipation

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MedDRA | Coding Example 9

Death and other patient outcomes

The 66 year old man died from a ruptured aortic aneurysm

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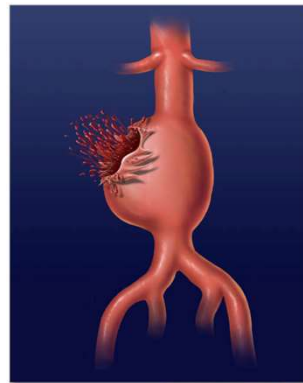
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MedDRA | Coding Example 10

Product quality issues

It was determined that the <u>product</u> was <u>counterfeit</u>

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MedDRA | Coding Example 11

Social circumstances

The patient was <u>confined to a wheelchair</u>

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MedDRA | Coding Example 12

Medication errors/Product use errors and issues

The pharmacist made a <u>mistake in compounding the medication</u>

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MedDRA | Coding Example 13

Narrative vignette

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

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MedDRA

Additional Coding Exercises

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MedDRA | ## Try to Code Some Verbatims

- Open either the Desktop or Web-Based Browser
- Try to find the best LLT to code several short verbatims
- Select an LLT from MedDRA using either a "top down" or "bottom up" approach
- Use Poll Everywhere to submit your proposed answers
- Correct LLTs for each verbatim will be discussed

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MedDRA | Short Verbatim #1

"She was diagnosed with pneumonia
caused by COVID-19 infection"

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Enter the correct LLT

Start the presentation to see live content. Still no live content? Install the app or get help at **PollEv.com/app**

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Correct Answer - Verbatim #1

MedDRA

LLT *COVID-19 pneumonia*

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Short Verbatim #2

MedDRA

"Woman ingested her husband's blood pressure drug by mistake"

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Enter the correct LLT

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Correct Answer - Verbatim #2

MedDRA

LLT *Accidental ingestion of drug*

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Short Verbatim #3

MedDRA

"The patient developed hyponatraemia while hospitalised"

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Enter the correct LLT

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Correct Answer - Verbatim #3

MedDRA

LLT *Hospital acquired hyponatraemia*

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Short Verbatim #4

MedDRA

"Nurse noticed that the injection solution had an unusual odor"

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Enter the correct LLT

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![MedDRA] **Correct Answer - Verbatim #4**

LLT *Product odor abnormal*

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Short Verbatim #5

MedDRA

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

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Enter the correct LLT

Start the presentation to see live content. Still no live content? Install the app or get help at PollEv.com/app

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Correct Answer - Verbatim #5

MedDRA

LLT *Vaccination site tenderness*

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Summary

MedDRA

✓ Discussed scope, structure, and characteristics of MedDRA

✓ Discussed coding conventions

✓ Introduced the MedDRA Term Selection: Points to Consider document

✓ Introduced the MedDRA browser and showed how it is used for coding

✓ Performed some coding exercises on your own

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MedDRA | 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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MedDRA | MSSO Contacts (cont)

- Change Request Submission
  - https://www.meddra.org/how-to-use/change-requests
- Training Schedule
  - https://www.meddra.org/training/schedule
- MedDRA Support Documentation
  - https://www.meddra.org/how-to-use/support-documentation

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Question and Answer Session

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