MedDRA

Coding with MedDRA

ICH harmonisation for better health

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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 Steering Committee. The MedDRA SC is composed of the EC, Europe; EFPIA; FDA, United States; Health Canada, Canada; JPMA; MHLW/PMDA, Japan; MHRA UK; PhRMA; and WHO (as Observer). In addition, since May 2025, the following representatives have been appointed by the ICH MC to join the MedDRA SC and will serve until the next appointment in 2028: NMPA, China; SFDA, Saudi Arabia; and IFPMA (as Observer).

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Course Overview

- Describe MedDRA's background, scope, structure, and characteristics (including primary SOC allocation rules)
- Introduce and demonstrate the features of the MedDRA browser
- Discuss the maintenance of MedDRA, coding conventions, synonym lists, and coding quality assurance
- Introduce the MedDRA Version Analysis and WebCR tools
- Introduce the MedDRA Term Selection: Points to Consider document
- Discuss and present examples of coding exercises with MedDRA

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MedDRA

MedDRA Background

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MedDRA

What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities



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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'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

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MedDRA and the MSSO

MSSO
- International support and development of terminology
- "Custodians", not owners, of the terminology

Governance
- Governed by a Steering Committee (industry, regulators, multi-national, other interested parties)

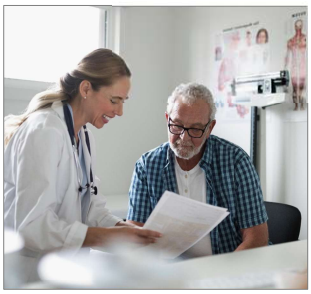
Educational offerings
- Foster use of MedDRA through communications and educational offerings

JMO
- Partner organization for Japanese-language MedDRA

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Where MedDRA is Used





Regulatory Authority and Industry Databases
ICSRs and Safety Summaries
Clinical Study Reports
Investigators' Brochures
Core Company Safety Information
Marketing Applications
Publications
Prescribing Information
Advertising

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Global View

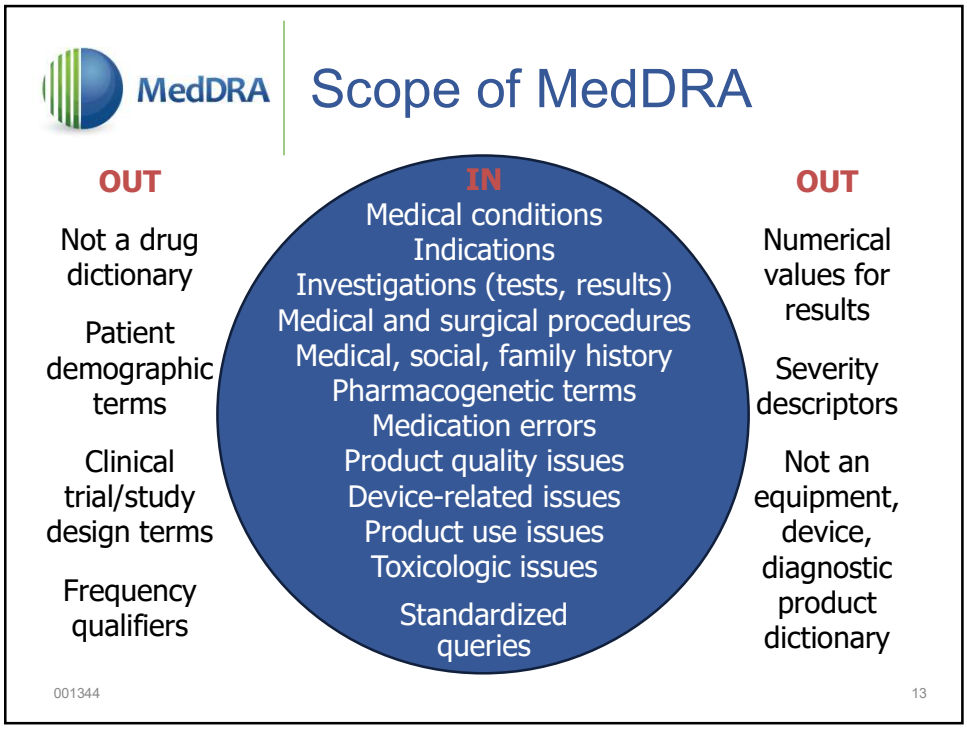
MedDRA is in over 140 countries



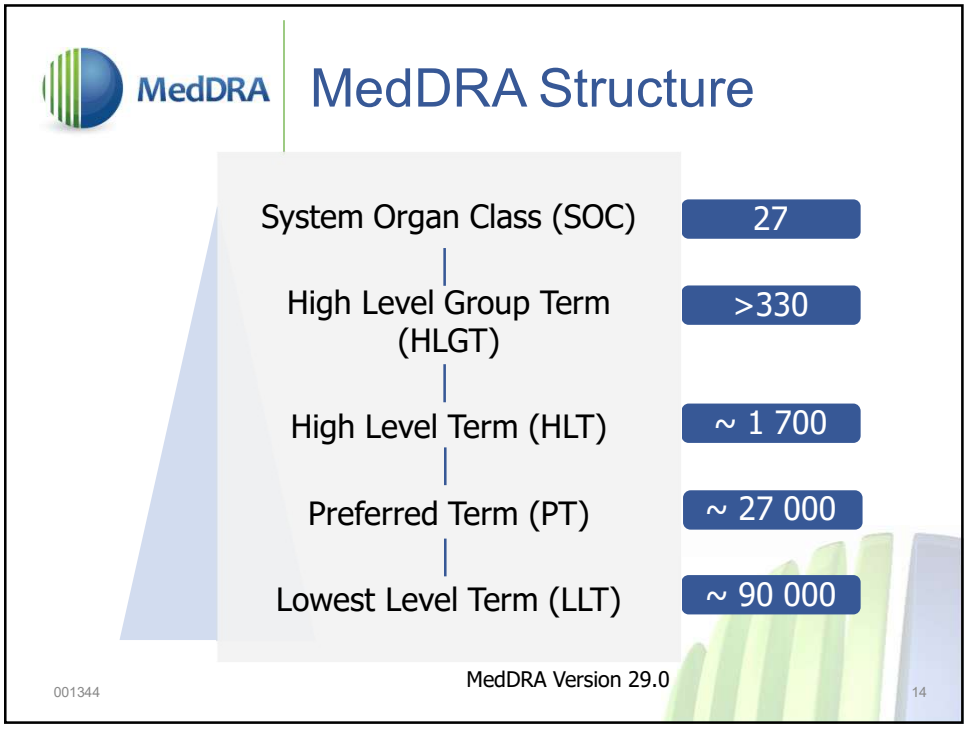
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MedDRA's Scope, Structure, and Characteristics

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MedDRA
Scope of MedDRA
OUT
Not a drug dictionary
Patient demographic terms
Clinical trial/study design terms
Frequency qualifiers
IN
Medical conditions
Indications
Investigations (tests, results)
Medical and surgical procedures
Medical, social, family history
Pharmacogenetic terms
Medication errors
Product quality issues
Device-related issues
Product use issues
Toxicologic issues
Standardized queries
OUT
Numerical values for results
Severity descriptors
Not an equipment, device, diagnostic product dictionary
001344
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MedDRA
MedDRA Structure
System Organ Class (SOC)
27
High Level Group Term (HLGT)
>330
High Level Term (HLT)
~ 1 700
Preferred Term (PT)
~ 27 000
Lowest Level Term (LLT)
~ 90 000
MedDRA Version 29.0
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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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Five Level Hierarchy

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

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

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Non-Current Terms

LLT

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

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MedDRA Codes

PT *Anaemia*
[10002034]

- Each MedDRA term is assigned an 8-digit numeric code
  - Non-expressive, assigned sequentially
  - Each term has a unique code
  - Codes link terms across versions and translations
- 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

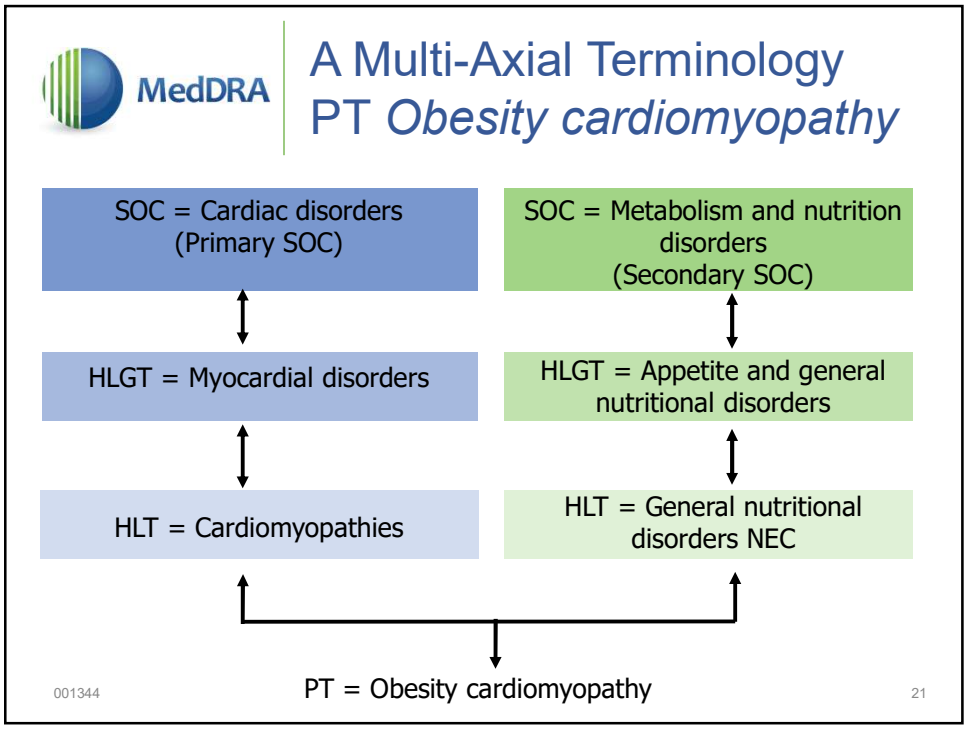
- ✓ Determines which SOC will represent a PT during cumulative data outputs
- ✓ Prevents "double counting"
- ✓ Supports standardized data presentation
- ✓ Pre-defined allocations should not be changed by users

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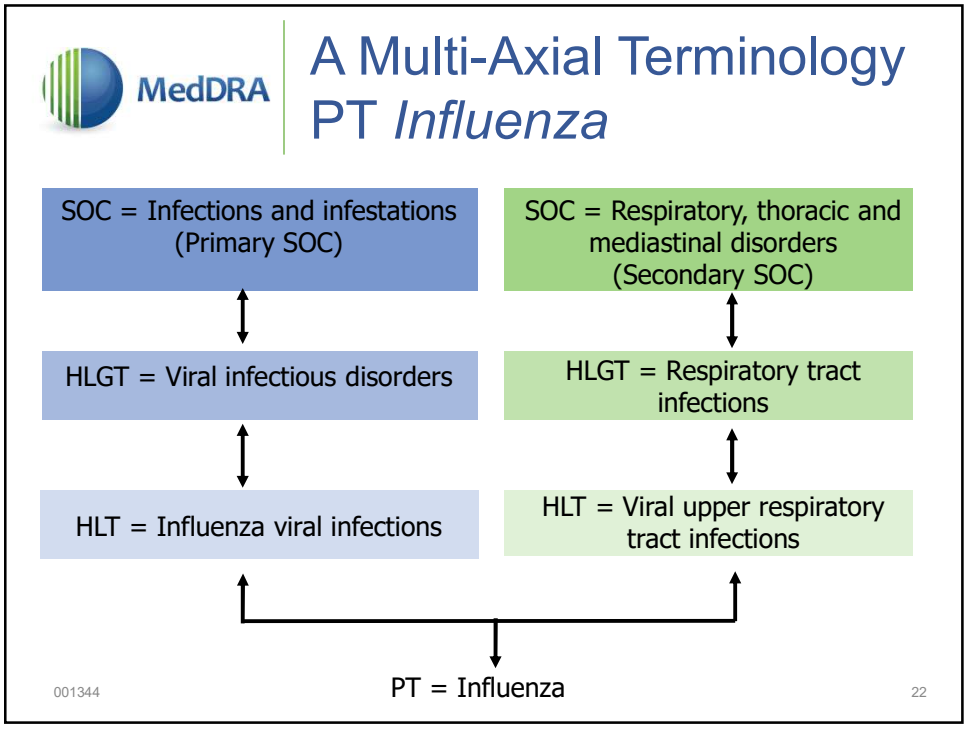
Rules for Primary SOC Allocation

- 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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MedDRA
A Multi-Axial Terminology
PT *Obesity cardiomyopathy*
SOC = Cardiac disorders (Primary SOC)
SOC = Metabolism and nutrition disorders (Secondary SOC)
HLGT = Myocardial disorders
HLGT = Appetite and general nutritional disorders
HLT = Cardiomyopathies
HLT = General nutritional disorders NEC
PT = Obesity cardiomyopathy
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MedDRA
A Multi-Axial Terminology
PT *Influenza*
SOC = Infections and infestations (Primary SOC)
SOC = Respiratory, thoracic and mediastinal disorders (Secondary SOC)
HLGT = Viral infectious disorders
HLGT = Respiratory tract infections
HLT = Influenza viral infections
HLT = Viral upper respiratory tract infections
PT = Influenza
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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:

1. *Congenital, familial and genetic disorders*
2. *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*
3. *Infections and infestations*

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Non multiaxial SOCs

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*

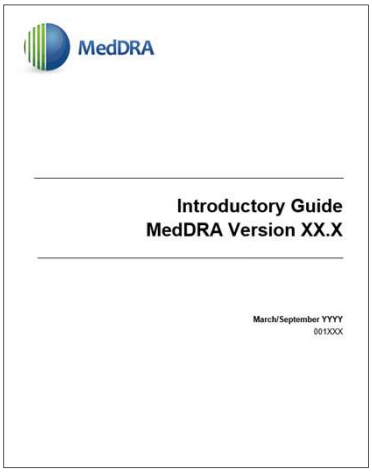
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Can You Select the Primary SOC for This PT?

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

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MedDRA Introductory Guide



- Provides information on MedDRA structure, scope, conventions and rules
- Released with each MedDRA version
- Available in most MedDRA languages

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MedDRA

MedDRA Browsers – Introduction and Demonstration

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MedDRA

MSSO's MedDRA Browsers



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

MedDRA Web-Based Browsers (WBB)

New WBB:
https://wbb.meddra.org

Legacy WBB:
https://tools.meddra.org/wbb/

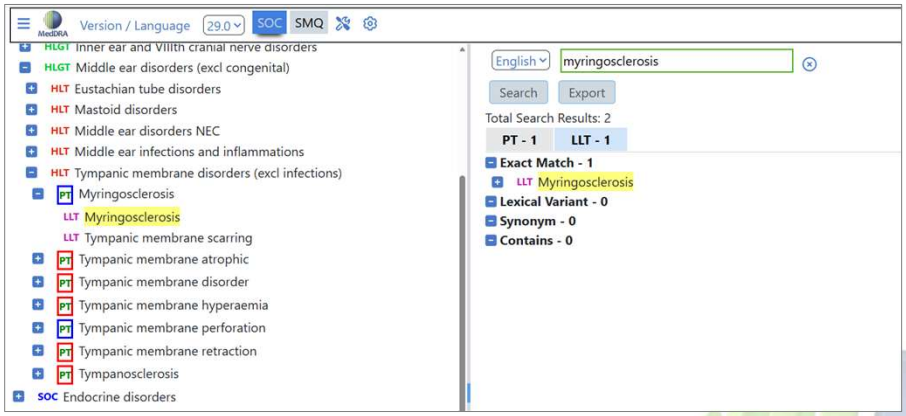


Mobile MedDRA Browser
https://mmb.meddra.org

001344 28

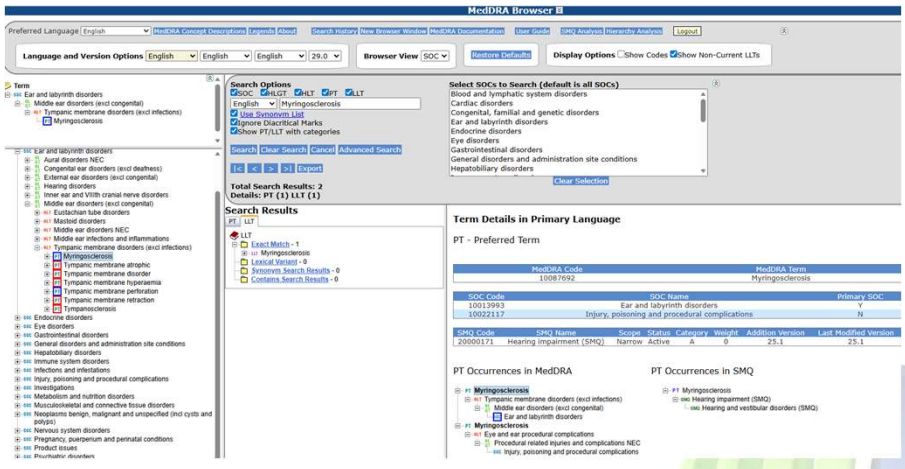
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New WBB Screenshot



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Legacy WBB Screenshot



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MSSO's MedDRA Browsers - 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

- View primary and secondary link information
- Upload terms to run against SMQs
- Advanced search options (e.g., NOT, OR)
- Preview upcoming (supplemental) changes in next release*
- For more information:
  - Instructional videos: https://www.meddra.org/instructional-videos

**Supplemental view not available on MDB*

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MedDRA

MedDRA Maintenance

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MedDRA

MedDRA Maintenance

- Long-term maintenance in response to
  - Medical and scientific advances
  - Changes in the regulatory environment
- Users can send change requests (CRs) to MSSO for consideration
  - Organizations allowed 100 CRs/month
  - Rigorous medical review by MSSO physicians
  - Response within 7-10 working days (PT/LLT level changes)
  - Complex changes (above PT level) posted for user community comments mid-year
- Two MedDRA updates/year
  - 1 March X.0 (Complex release)
  - 1 September X.1 (Simple release)

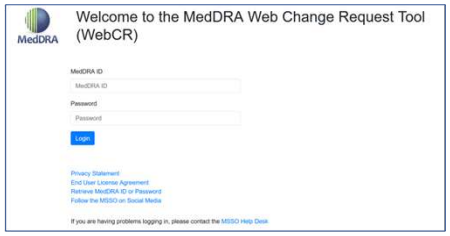
34

WebCR

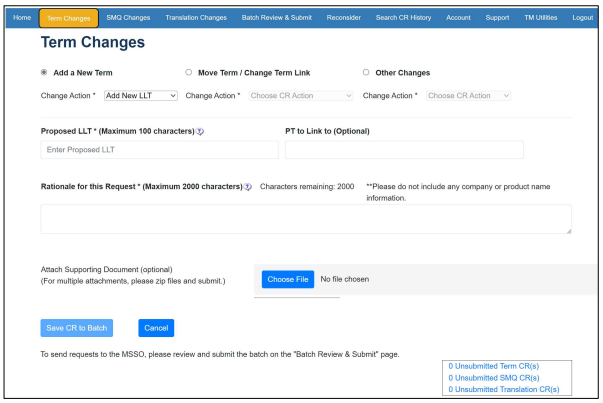
- Web-based tool for Change Requests (CR)
  - URL: https://webcr.meddra.org/
  - Via the Change Request Information page
- Requests must be in English
- Users may propose Term, SMQ and Translation change requests
- Immediate confirmation
- Ability to export change requests
- Ability to query CR history for requests back to v5.1

Submitting Changes

- MedDRA ID and Change Request password
  - Term and SMQ changes to English MedDRA version
- MedDRA ID and password
  - Translation change requests
- Online change request submission tool guides user to enter all needed information
- User guide available within the "Support" section of the application or on the Change Request Information page



Submitting Changes (cont)



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

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Proactive MedDRA Maintenance

- What is the proactive approach?
  - Corrections/improvements made internally by the MSSO
  - General changes suggested by users
- Submitting ideas
  - Send to MSSO Help Desk. Justification is helpful.
  - Example: Review placement of bruise and contusion terms to facilitate coding and analysis
- Evaluation of proposals
  - Final disposition is not time limited; MSSO may take time to review
  - Proactive approach does not replace usual CR process

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MedDRA

MedDRA Version Analysis Tool (MVAT)

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MedDRA

MedDRA Version Analysis Tool (MVAT)

- Web-based (https://tools.meddra.org/mvat)
- Free to all users
- Features
  - Version Report Generator:
    Produces exportable report comparing any two versions
  - Data Impact Report:
    Identifies changes to a specific set of MedDRA terms or codes uploaded to MVAT

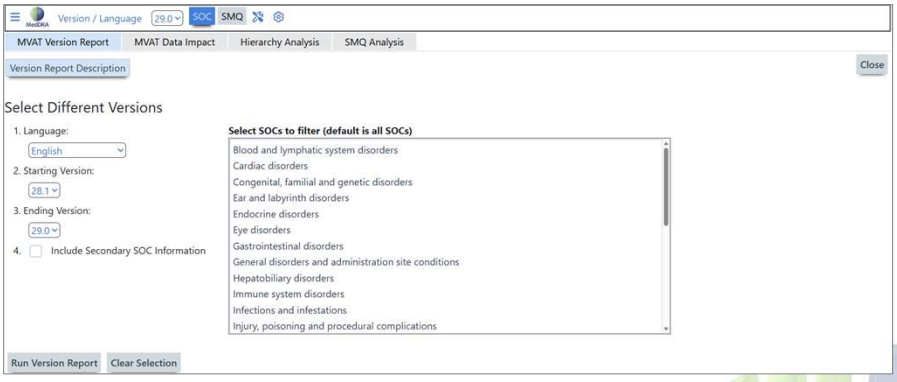
40

MedDRA Version Analysis Tool (MVAT) (cont)

- User interface and report output available in all MedDRA languages
- Ability to run reports on supplemental changes
- Option to run reports on secondary SOC changes

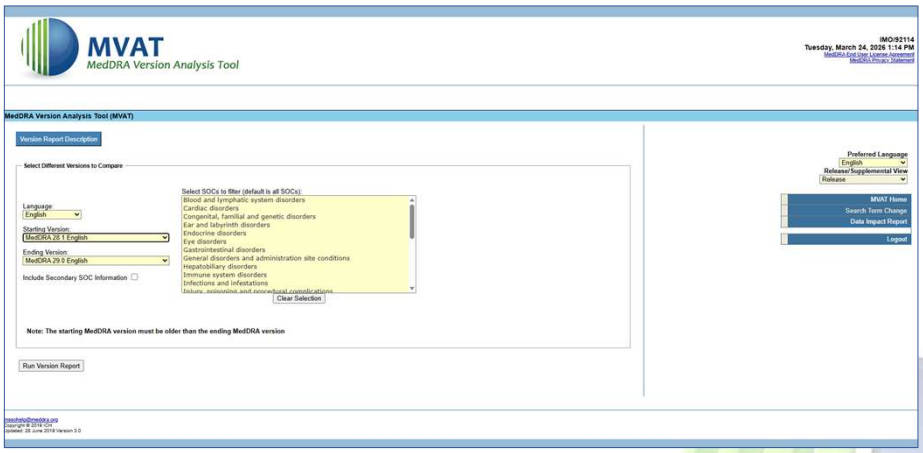
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MedDRA Version Analysis Tool (New WBB)



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Legacy MedDRA Version Analysis Tool



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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.

MedDRA Browsing Tips

- 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)

MedDRA Browsing Tips (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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Concept Descriptions

- Descriptions of how a concept is interpreted, used, and classified in MedDRA
- Not a definition
- Intended to aid accurate and consistent use of MedDRA
- Overcome differences in medical practice worldwide
- Accessible in MSSO's browsers

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Concept Descriptions (cont)

APPENDIX B: MedDRA CONCEPT DESCRIPTIONS

This appendix provides a list of MedDRA concept descriptions. A concept description is a description of how a concept is interpreted, used, and classified within the MedDRA terminology and is not a definition. The concept descriptions are intended to aid the consistent and accurate use of MedDRA in coding, retrieval, and analysis and to overcome the differences of medicine practice worldwide. The MSSO expects this appendix to be a working document and grow as subscribers request additional concepts to be documented.

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

A

Abuse

For the purposes of term selection and analysis of MedDRA-coded data, abuse is the intentional, non-therapeutic use by a patient or consumer of a product – over-the counter or prescription – for a perceived reward or desired non-therapeutic effect including, but not limited to, "getting high"(euphoria). Abuse may occur with a single use, sporadic use or persistent use of the product.

Acute

For use in medicine, the word means "reaching a crisis rapidly." In some instances, an "acute" condition may be interpreted as more severe than a "chronic" one. This was considered during the processing of proposed modified terms to assure that terms expressing only severity were not included.

Addiction

For the purposes of term selection and analysis of MedDRA-coded data, addiction is an overwhelming desire by a patient or consumer to take a

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Exercise 1

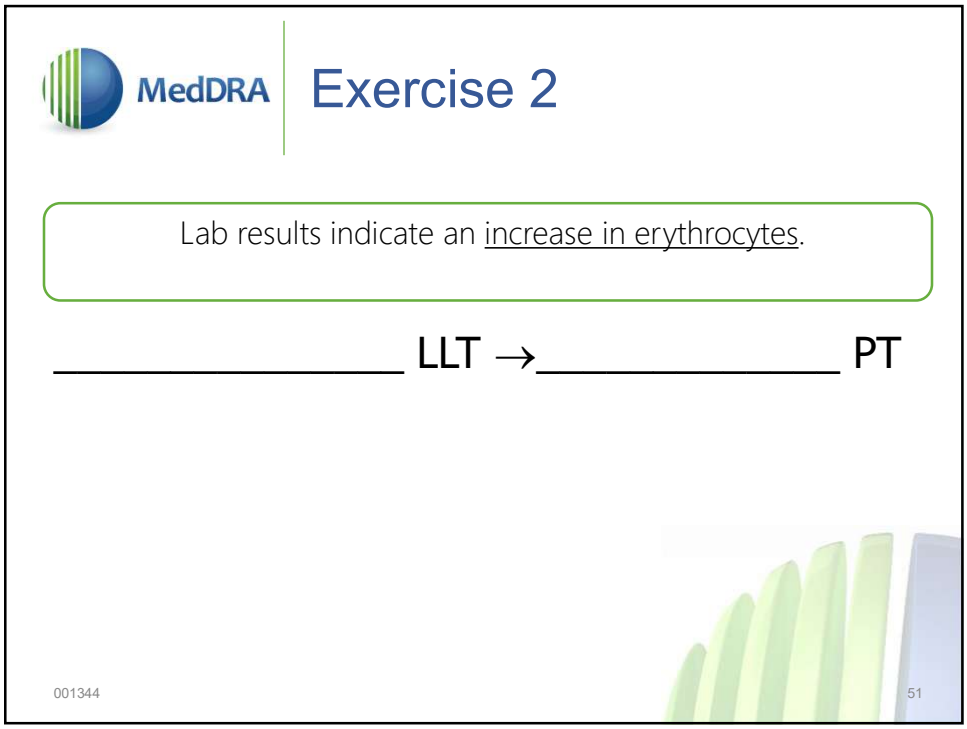
The patient states she has been experiencing headaches, dizziness and vertigo.

_____ LLT → _____ PT

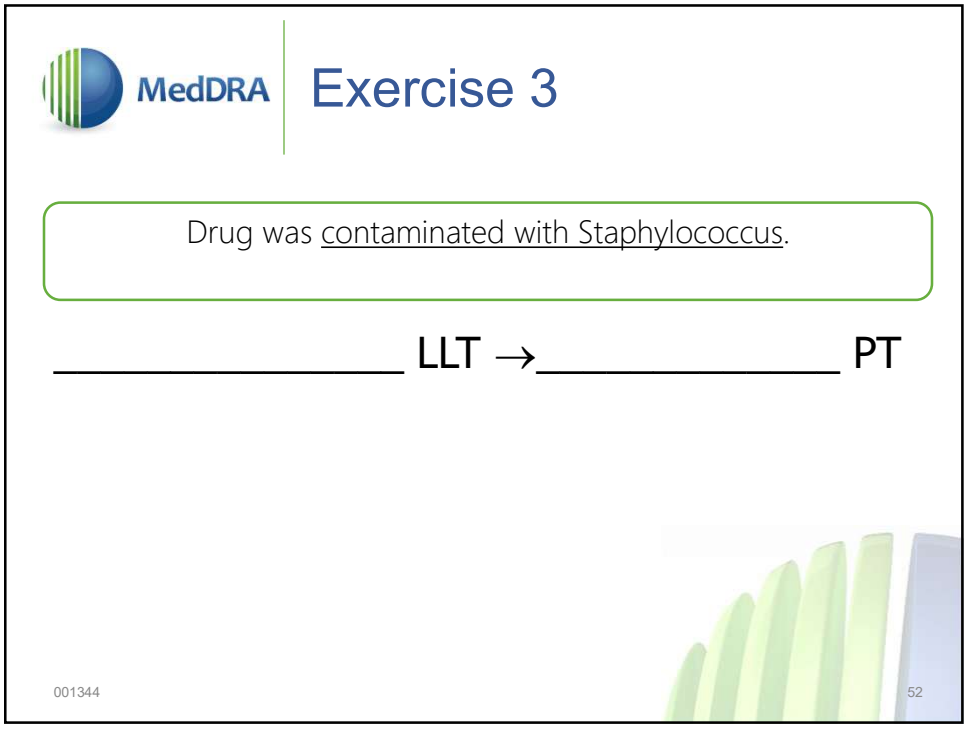
_____ LLT → _____ PT

_____ LLT → _____ PT

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MedDRA
Exercise 2
Lab results indicate an increase in erythrocytes.
_____ LLT →_____ PT
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MedDRA
Exercise 3
Drug was contaminated with Staphylococcus.
_____ LLT →_____ PT
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Exercise 4

A six year old boy was admitted for toxicity after accidentally ingesting the remaining antihypertensive tablets in the bottle.

_____ LLT →_____ PT

_____ LLT →_____ PT

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Exercise 5

The patient's urinary catheter was blocked.

_____ LLT →_____ PT

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MedDRA

Coding with MedDRA

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MedDRA

Quality coding considerations

- Processes
  - Make sure that all relevant information is available for term selection
  - Coding conventions
- Appropriately trained and qualified individuals
- Tools
  - Autoencoding tools
  - Synonym lists
  - Quality assurance reports
    - Unqualified test name term list

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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 versus older terminologies)
- Autoencoded data need human oversight and may still need manual coding



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Can I Make Coding Conventions Specific to My Company/Product?

- MedDRA may reduce the need to do this because:
  - Increased size/granularity results in more accurate representation of data
  - Secondary SOC allocations allow for different "views" of the data
- This type of approach should be done cautiously

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Autoencoder Pitfalls

- 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*

→ Autoencoded data needs human oversight

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Synonym Lists

- Recurring verbatims – one-time assignment to an LLT
- Promotes consistency
- Increases likelihood of autoencoding "hit"
- Maintenance required

Verbatim	LLT	Comment
Aching all over head Terrible headache	Headache	
Muscular pain in legs	Myalgia of lower extremities	LLT *Myalgia of lower extremities* is a better choice than LLT *Muscular pain* since it captures both the event and body site

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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.)

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Example QA Report

QA Sample Report

SOC	HLT	PT	Verbatim	Count
Respiratory, thoracic and mediastinal disorders				
	Bronchospasm and obstruction			
		Wheezing		
			WHEEZING	16
			Wheeze	5
			INCREASED WHEEZING	1
			Breathing suppressed wheezing	1
			HYPERREACTIVITY AND WHEEZING	1
			wheeze in chest	1
	Laryngeal and adjacent sites disorders NEC (excl infections and neopla			
		Vocal cord disorder		
			SPASMODIC DYSTONIA OF THE VOCAL CORDS	1
	Newborn respiratory disorders NEC			
		Transient tachypnoea of the newborn		
			Transient hazy vision	1
			Transient tachypnea, neonatal	1
			Tachypnea of the newborn, transient	1

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Unqualified Test Name Term List

- MSSO developed and maintains list of unqualified test name terms
  - These terms (e.g., PT Blood glucose) should not be selected for capturing AE information
  - Intended for use in E2B test name field only
- List can be used to check data quality
  - Identifies inappropriate terms in data fields other than test name data element
  - Intended as recommendation only

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Unqualified Test Name Term List (cont)

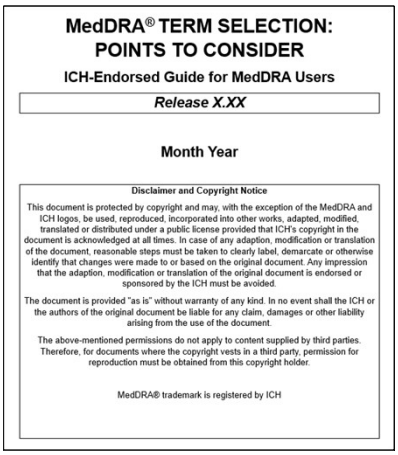
- Link on Support Documentation page on MedDRA website
- Spreadsheet of LLT/PT names and codes from SOC *Investigations*
  - Approximately 4 900 terms in v29.0
- Explanatory document
  - Purpose, uses, development of list
- Also available in Japanese on JMO website

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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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MedDRA® trademark is registered by ICH

- 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
- Released annually in March
- Complete versions available in
  - English, Japanese, Brazilian Portuguese, Chinese, French, Korean, Spanish, and Russian
- Condensed versions available for other MedDRA languages*
- Available on MedDRA and JMO websites

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

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MTS:PTC Points of Note

- MTS:PTC sometimes provides more than one option for selecting terms
  - "Preferred option" is identified
- MedDRA users can decide which option to apply
  - Organizations should be consistent with their choice of option
  - Organizations should document their decision on an option in coding conventions

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PtC Documents

	PtC Document	Purpose	Languages	Release Cycle
Term Selection	MedDRA Term Selection: Points to Consider (MTS:PTC)	Promote accurate and consistent coding with MedDRA	English, Japanese, Brazilian Portuguese, Chinese, French, Korean, Russian and Spanish	Annual March release
	MTS:PTC Condensed Version	Shorter version focusing on general coding principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except languages with full MTS:PTC document, and EEA languages*)	Update as needed
Data Retrieval and Presentation	MedDRA Data Retrieval and Presentation: PtC (DRP:PTC)	Demonstrate how data retrieval options impact the accuracy and consistency of data output	English, Japanese, Brazilian Portuguese, Chinese, French, Korean, Russian and Spanish	Annual March release
	DRP:PTC Condensed Version	Shorter version focusing on general retrieval and analysis principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except languages with full DRP:PTC document, and EEA languages*)	Update as needed

*The following languages do not have translations of PtC documents: Bulgarian, Croatian, Danish, Estonian, Finnish, Greek, Icelandic, Latvian, Lithuanian, Maltese, Norwegian, Polish, Romanian, Slovak, Slovenian, Swedish

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PtC Documents (cont)

	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 • "Living" document with updates based on users' needs • Data quality and medication errors (Release 1.0 and 1.1) • Product quality issues (Release 2.0 in October 2020) • Manufacturing and Quality System Issues and other updates (Release 3.0 in September 2024)	English and Japanese	Updated as needed

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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 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

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Quality Assurance

- Organizations' coding guidelines should be consistent with MTS:PTC
- Processes ensuring that all relevant information is available during term selection
- 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



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

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MTS:PTC General Principle

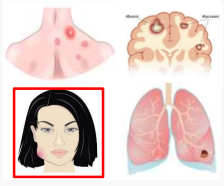
- Always Select a Lowest Level Term
  Select Only Current LLTs

✓ Select the Lowest Level Term that **most accurately reflects the reported verbatim** information

"Abscess on face"

→ Do not simply select LLT *Abscess*

→ Select a term with greater specificity
LLT *Facial abscess*



✓ Select current LLTs only
- Non-current terms for legacy conversion/historical purposes

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When to Request a Term Use of Medical Judgment

- Avoid company-specific "work-arounds" for MedDRA deficiencies. If concept not adequately represented in MedDRA, submit Change Request to MSSO.
- If no exact match in MedDRA, use medical judgment to match to an existing term that adequately represents the concept

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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	

General Principles

• Selecting More Than One Term

- Can select more than one LLT to represent reported information.
  - Selecting one term may lead to loss of specificity
  - Selecting more than one term may lead to redundant counts

Document your procedures!

Report: "Metastatic gingival cancer"

→ Select LLT Gingival cancer **OR** LLT Metastatic carcinoma

→ Select LLT Gingival cancer **AND** LLT Metastatic carcinoma

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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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)

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Important Coding Errors Specificity/Severity

- 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

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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: *"Myocardial infarction"* → select *"Myocardial infarction"*	Example: *"Possible myocardial infarction"* → select *"Myocardial infarction"* (select term as if definitive diagnosis)

TiP 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: *"Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm"* → select *"Anaphylactic reaction"*	Example: *"Possible myocardial infarction with chest pain, dyspnoea, diaphoresis"* → select *"Myocardial infarction"* *"Chest pain"*, *"Dyspnoea"*, and *"Diaphoresis"*

TiP 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: "*Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm*" → select "*Anaphylactic reaction*", "*Rash*", "*Dyspnoea*", *Hypotension*", and "*Laryngospasm*"	Example: "*Possible myocardial infarction with chest pain, dyspnoea, diaphoresis*" → select "*Chest pain*", "*Dyspnoea*", and "*Diaphoresis*"

TiP 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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About the Coding Exercises



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What Term(s) to Select?

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

- Sepsis
- Shock
- Septic shock
- Spontaneous bacterial peritonitis
- Bowel perforation

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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 *Serum potassium abnormal* 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 *Pain*

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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 *Ill-defined disorder* can be selected

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What Term(s) to Select?

Clinical complication of IUD

- IUD complication (PT Complication associated with device)
- Intra-uterine death (PT Foetal death)
- Unevaluable event

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What Term(s) to Select?

Hypoglycemia (blood glucose = 200 mg/dL)

- Blood glucose abnormal
- Blood glucose increased
- Hypoglycemia

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Combination Terms

- One condition is more specific than the other
  - Select a term for the more specific condition

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
Breast cancer (HER2 positive)	HER2 positive breast cancer

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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
BRAF positive malignant melanoma	BRAF gene mutation Malignant melanoma

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What Term(s) 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

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Investigations

- Medical condition vs. investigation result

Reported	LLT Selected	Comment
Hypoglycaemia	Hypoglycaemia	LLT *Hypoglycaemia* links to SOC *Metabolism and nutrition disorders*
Decreased glucose	Glucose decreased	LLT *Glucose decreased* links to SOC *Investigations*

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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 *Glucose abnormal* 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 *Potassium increased*

- 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 *Liver function tests abnormal* should not be selected.

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What Term(s) 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

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What Term(s) to Select?

Patient had features of aldosterone excess

- Aldosterone increased
- Aldosteronism
- Blood aldosterone abnormal

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Medication Errors
MedDRA Concept Description

For the purposes of term selection and analysis of MedDRA-coded data, medication errors are defined as any **unintentional** and **preventable** event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer.

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Medication Errors with Clinical Consequences

- If a medication error <u>with</u> clinical consequences is reported, select terms for the error <u>and</u> consequences

Reported	LLT Selected
Patient was administered wrong drug and experienced hypotension	Wrong drug administered Hypotension

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Medication Errors without Clinical Consequences

- Reported medication errors without clinical consequences are not ARs/AEs.
- Preferred option is to select a term for the medication error

Reported	LLT Selected	Preferred Option
Intramuscular formulation medication was given intravenously instead of intramuscularly but the patient did not experience any adverse effects	Intramuscular formulation administered by other route	✓
	Intramuscular formulation administered by other route No adverse effect	

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Medication Errors (cont)

- Important to record occurrence or potential occurrence of medication error by selecting term closest to the described error

Reported	LLT Selected	Comment
Pharmacist notices that the names of two drugs look similar and is concerned that this may result in someone getting a wrong drug	Drug name look-alike Potential for medication error, wrong drug	This example is a potential medication error. LLT *Drug name look-alike* is a contributing factor, and LLT *Potential for medication error, wrong drug* indicates that there is a potential medication error including the error type.

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Medication Errors (cont)

- Do not infer a medication error has occurred unless specific information is provided
- Do not infer that extra dosing, overdose or underdose has occurred

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Learn More About Medication Errors

- Consult MTS:PTC, Section 3.15 – "Medication Errors, Accidental Exposures and Occupational Exposures"
- Read MedDRA Points to Consider Companion Document, Section 3 – "Medication Errors" (MEs)
  - Provides detailed coding examples
  - Has a "Questions and Answers" section on MEs
- Become familiar with the categories and terms under HLGT *Medication errors and other product use errors and issues* of the MedDRA browser

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Learn More About Medication Errors (cont)

- Review the relevant terms in the MedDRA Concept Descriptions
- Utilize other MedDRA training resources on MEs, including:
  - "MedDRA Coding of Medication Errors – General Principles" webinar
  - Learning Management System module, "Special Situations"
  - Other relevant videos on MedDRA YouTube channel

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Overdose, Toxicity and Poisoning

- If overdose, poisoning or toxicity is explicitly reported, select the appropriate term
- Overdose with clinical consequences

Reported	LLT Selected
Stomach upset from study drug Overdose	Stomach upset Overdose

- Overdose without clinical consequences

Reported	LLT Selected	Preferred Option
Patient received an overdose of medicine without any adverse consequences	Overdose	✓
	Overdose No adverse effect	

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What Term(s) to Select?

Syringe plunger couldn't be completely pushed down so the patient received only half of his scheduled dose

- Underdose
- Missed dose
- Partial dose delivery by device
- Syringe issue
- Wrong dose administered

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What Term(s) to Select?

Unintentionally took more than maximum recommended dose due to dispensing error

- Accidental overdose
- Incorrect dose administered
- Drug dispensing error

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Death and Other Patient Outcomes

- Death, disability and hospitalization are considered outcomes or seriousness criteria and not usually coded as adverse events (AE) or adverse reactions (AR)
- If one of these outcomes is the only reported information, select an appropriate LLT for coding
- If a death term in MedDRA adds important clinical information, code it along with reported ARs/AEs

Reported	LLT Selected
Patient experienced a rash and had sudden cardiac death	Rash Sudden cardiac death

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Drug Interactions

- Term includes reactions between drugs (including biologic products) and other drugs, foods, devices and alcohol
- If reporter states an interaction, select terms for interaction term and reported medical event(s)

Reported	LLT Selected
Torsade de pointes with suspected drug interaction	Drug interaction Torsade de pointes

- If reporter does not specifically state an interaction, select terms for reported medical event(s) only

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Suicide and Self-Harm

- Coding of suicide attempts, completed suicides and self-harm should be accurate and consistent
- Do not assume that an overdose, even if intentional, is a suicide attempt
- If a self-harm report does not mention suicide or suicide attempt, only code self-injury term
- If a suicide attempt is fatal, select a term that reflects the outcome instead of the attempt

Reported	LLT Selected	Comment
Suicide attempt resulted in death	Completed suicide	Report death as an outcome and seriousness criterion

115

What Term to Select?

Death from cerebral hemorrhage

- Sudden death
- Death
- Cerebral hemorrhage
- Brain death



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What Term to Select?

Patient was found dead

- Death from natural causes
- Death
- Died in sleep
- Found dead

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What Term(s) to Select?

After taking an antihistamine along with her prescription proton pump inhibitor, a 53-year-old woman developed vertigo

- Drug interaction NOS
- Vertigo subjective
- Vertigo
- Drug interaction



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What Term(s) to Select?

Deliberately took an overdose

- Intentional overdose
- Suicide attempt
- Deliberate overdose
- Overdose NOS

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Misuse, Abuse and Addiction

- Misuse, abuse and addiction may overlap in lay language
- Specific circumstances provide essential information clarifying the concept

Concept	Intentional?	By Whom?	Therapeutic Use?	Additional Sections in MTS:PTC
Misuse	Yes	Patient/consumer	Yes*	3.16.1
Abuse	Yes	Patient/consumer	No	3.16.2
Addiction	Yes	Patient/consumer	No	3.16.3
The concepts Medication error and Off label use are placed here for comparison reasons:				
Medication error	No	Patient/consumer **or** HCP	Yes	3.15
Off label use	Yes	HCP	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.

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Coding Exercises

- Narratives and short verbatims
- Assess the reported terms
  - Identify what concepts are reported (diagnosis, death, investigations, etc.)
- Refer to the appropriate sections of the MTS:PTC for guidance on term selection
  - For example, Section 3.2 for death terms
- Use MTS:PTC preferred options (forget your organization's conventions)
- Use browser to search for and select LLTs

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Specific Tips for Narrative Exercises

- Overall, coding principles are the same as for short verbatim exercises
- Code all of the following:
  - Events (including procedures and investigations as needed)
  - Indications
  - Medical history
  - Social history

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Sample Narrative

A 75-year-old male receiving Drug X for rheumatoid arthritis developed an area of darkened skin on his chest. The patient's medical history is significant for peripheral vascular disease and cigarette smoking. The skin lesion was excised; it was revealed to be a seborrhoeic wart.

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Course Summary

- ✓ Described MedDRA's background, scope, and structure (including primary SOC allocation rules)
- ✓ Introduced and demonstrated the features of the MedDRA browser
- ✓ Discussed maintenance of MedDRA, coding conventions, synonym lists, and coding QA
- ✓ Introduced the MedDRA Version Analysis and WebCR tools
- ✓ Introduced the MedDRA Term Selection: Points to Consider document
- ✓ Discussed and presented examples of coding exercises with MedDRA

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MedDRA
MSSO Contacts
• Website
– www.meddra.org
• Email
– mssohelp@meddra.org
• Frequently Asked Questions
– www.meddra.org/faq
MedDRA Browsers
• Desktop –
– https://www.meddra.org/meddra-desktop-browsers
• Web-Based
– New WBB: https://wbb.meddra.org
– Legacy WBB: https://tools.meddra.org/wbb/
• Mobile
– https://mmb.meddra.org
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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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MedDRA

Question and Answer Session

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MedDRA

Medical Dictionary
for Regulatory Activities

Thank you!

ICH
harmonisation for better health

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