



## Coding with 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).



MedDRA

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MedDRA

## Course Overview

- MedDRA background
- MedDRA's structure, scope, and characteristics
- MedDRA maintenance
- Coding conventions
- Synonym lists
- Quality assurance (QA) of coding
- MedDRA Term Selection: Points to Consider document
- Hands-on coding exercises

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## MedDRA Background



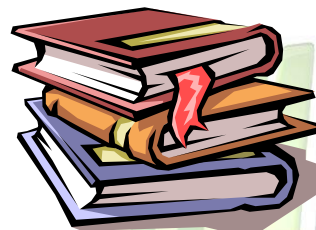
## What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities





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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## 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

- International support and development of terminology
- Foster use of MedDRA through communications and educational offerings
- “Custodians”, not owners, of the terminology
- JMO (partner organization for Japanese-language MedDRA)
- Governed by a Management Committee (industry, regulators, multi-national, other interested parties)

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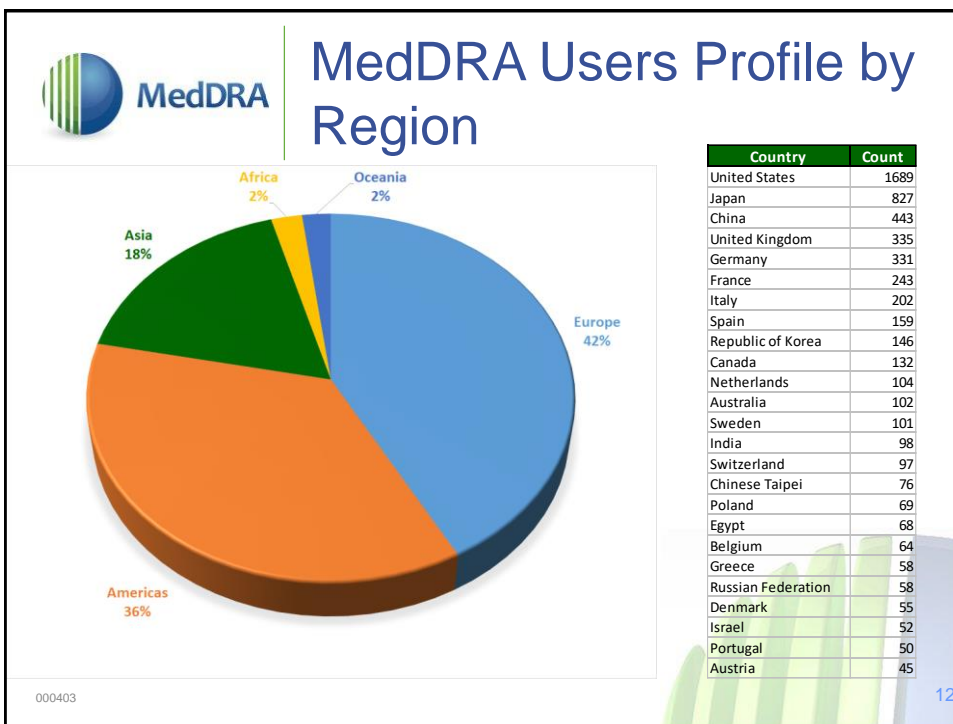
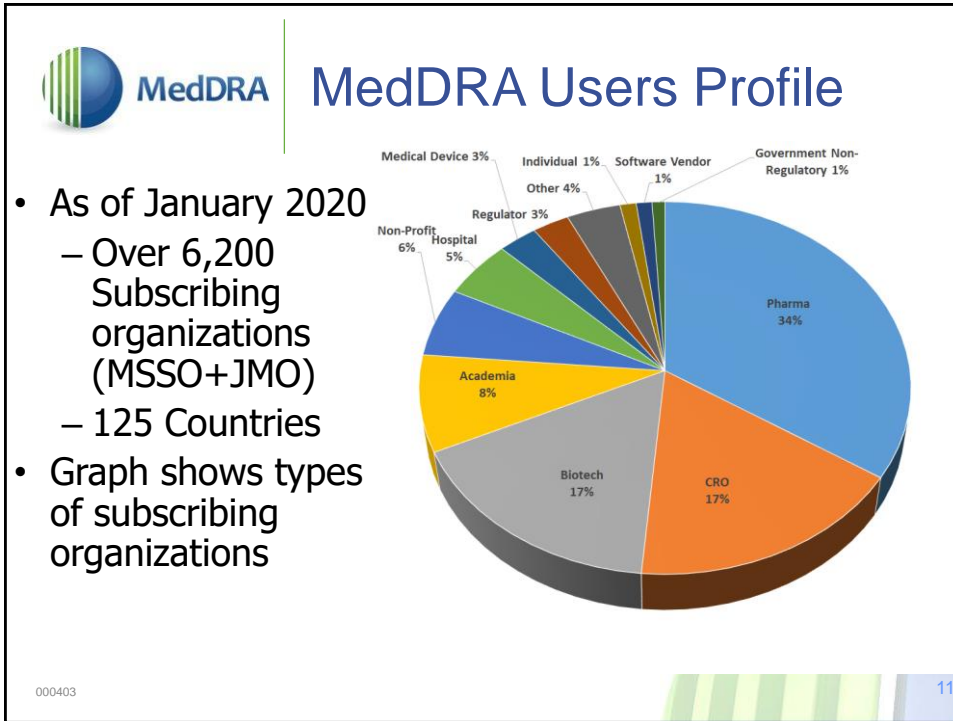
## Where MedDRA is Used



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

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## MedDRA Data Sharing

- Subscription grants access to MedDRA for one year
- Subscriber cannot grant any sublicense, publish or otherwise distribute MedDRA to a third party
- Data may be freely exchanged between current MedDRA subscribers
  - Sponsor-sponsor, sponsor-CRO, vendor-user, etc.
  - Use Self-Service Application to check organization's subscription status
- Sharing MedDRA with a non-subscribing organization is a violation of the MedDRA license

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## MedDRA Data Sharing (cont)

- For details, see the Statement on MedDRA Data Sharing

The screenshot shows the MedDRA website interface. At the top, there is a navigation menu with links for Home, About MedDRA, How to Use, Training, Subscription, News & Events, and a search bar. The main content area is titled 'Process / Subscription' and contains the following text:

Under the governance of the ICH MedDRA Management Committee, MedDRA is continuously enhanced to meet the evolving needs of all its users around the world. Sustainability of a high quality terminology needs an income stream and the ICH MedDRA Management Committee has opted for a licensing model that provides access to the terminology free of charge to regulatory authority, non-profit, direct patient care provider, educational institutes and at a fair cost shared by its commercial users through an annual subscription fee.

**Here's how to subscribe to MedDRA:**

1. If your organisation is headquartered in Japan, please contact the Japanese Maintenance Organization at <https://www.pmsj.jp/mo/tp/index.php>, otherwise continue to Step 2.
2. Determine the type of subscription applicable for your organisation.
3. Determine the rate that is applicable for the subscription type.
4. Complete the online subscription form.
5. If you are requesting a commercial subscription, please upload an annual report or a signed statement from your organisation on letterhead describing total revenue or turnover for its most recently completed fiscal year.
6. Your subscription includes English, Chinese, Czech, Dutch, French, German, Hungarian, Italian, Portuguese, and Spanish. If you wish to purchase MedDRA in Japanese, please select Japanese under Additional Language at the bottom of the online subscription form page.
7. Submit your online subscription form.
8. You may save or print a copy of the completed subscription form after submission.
9. The MSSO will email an invoice to the designated billing point of contact for payment if applicable. Upon receipt of payment, the MSSO will provide the information to download MedDRA.

For subscription renewals complete the online renewal form.


On the right side of the page, there are sections for 'Help Yourself' (Get answers to some of your immediate questions via the MedDRA Self-Service Application), 'Contact the JMO to subscribe to MedDRA in Japan', and 'Related Documents' (Overview of Services and Tools, How to share MedDRA data, Renewal Form, Subscription Form, Subscription Types, Subscription Rates, Special License Agreement).

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# MedDRA Overview

## Scope of MedDRA

Not a drug dictionary

Patient demographic terms

Clinical trial study design terms

**OUT**

**IN**

- Medical conditions
- Indications
- Investigations (tests, results)
- Medical and surgical procedures
- Medical, social, family history
- Medication errors
- Product quality issues
- Device-related issues
- Product use issues
- Pharmacogenetic terms
- Toxicologic issues
- Standardized queries


Frequency qualifiers

Numerical values for results

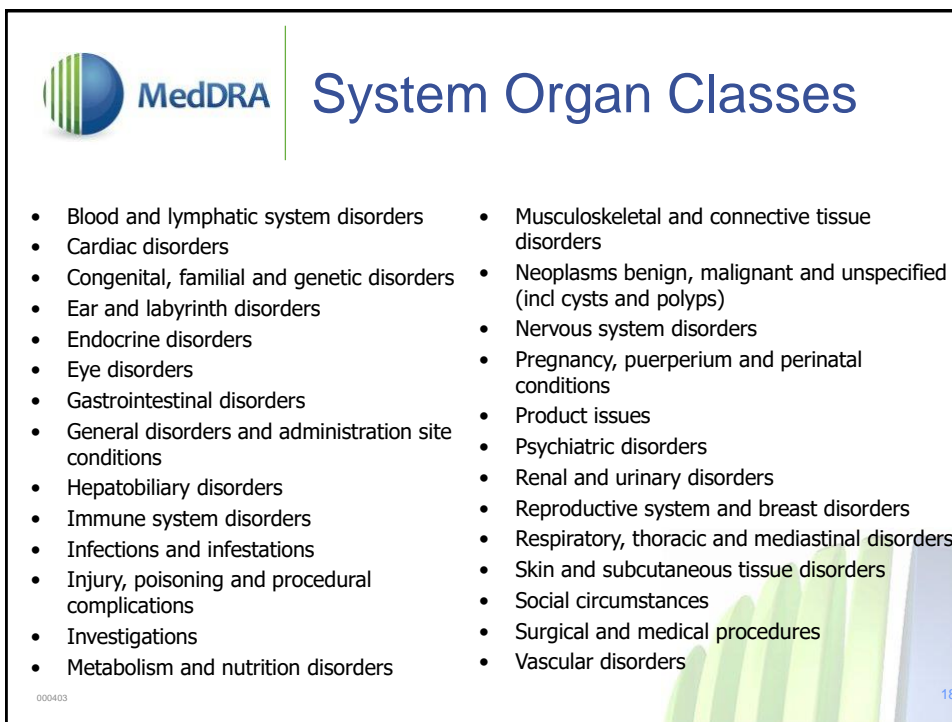
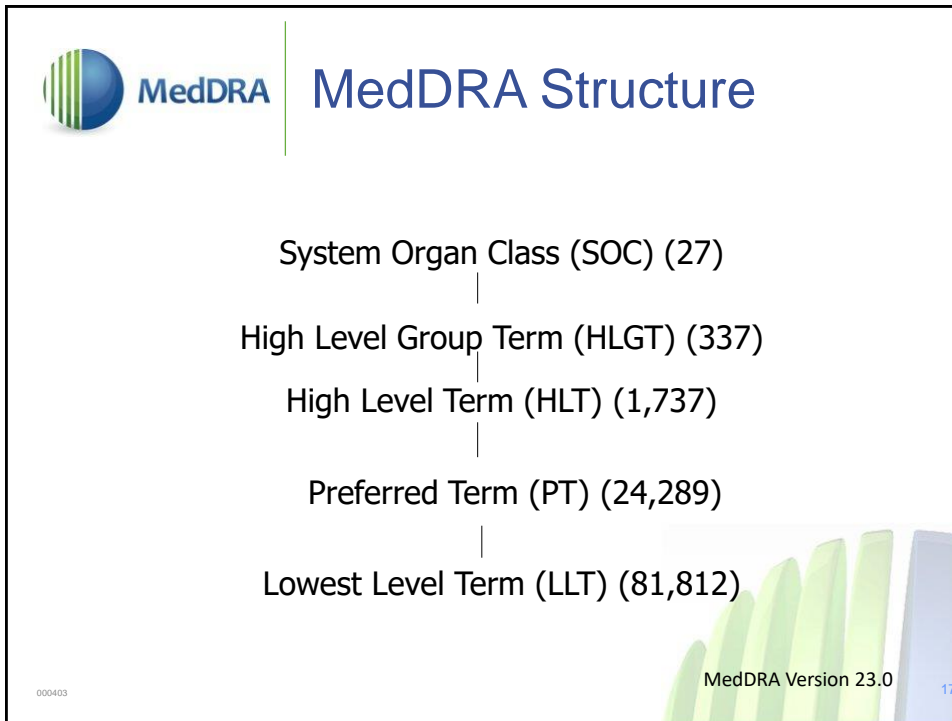
Severity descriptors

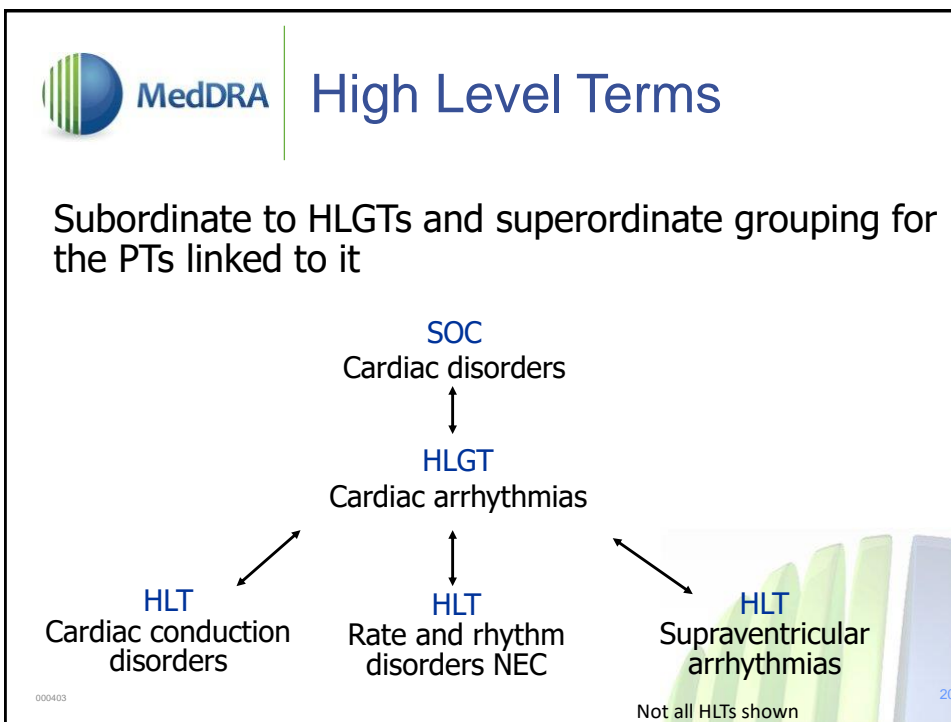
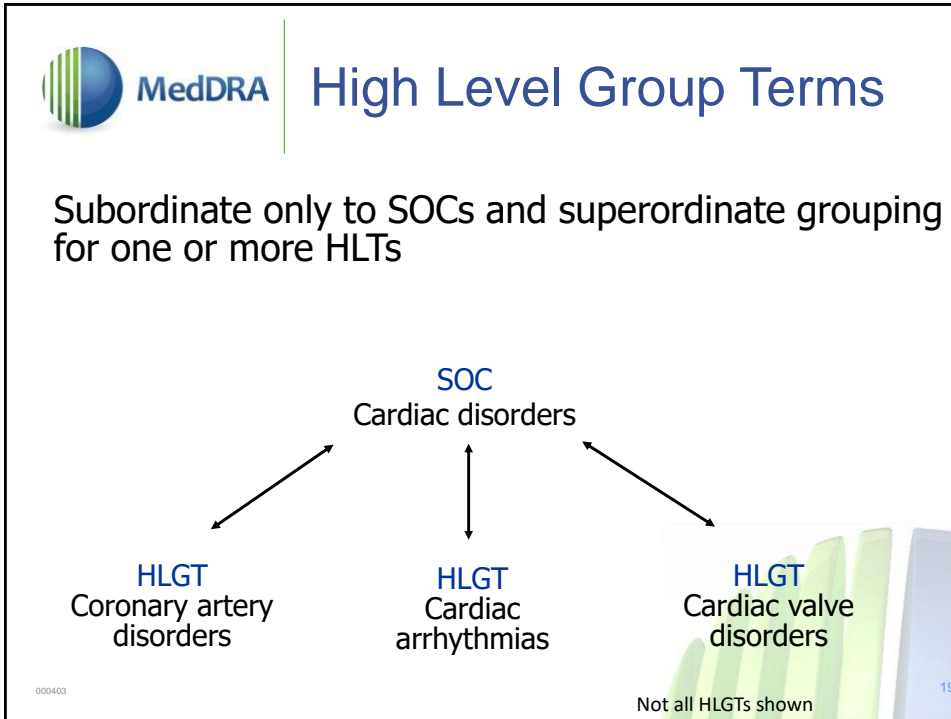
Not an equipment, device, diagnostic product dictionary

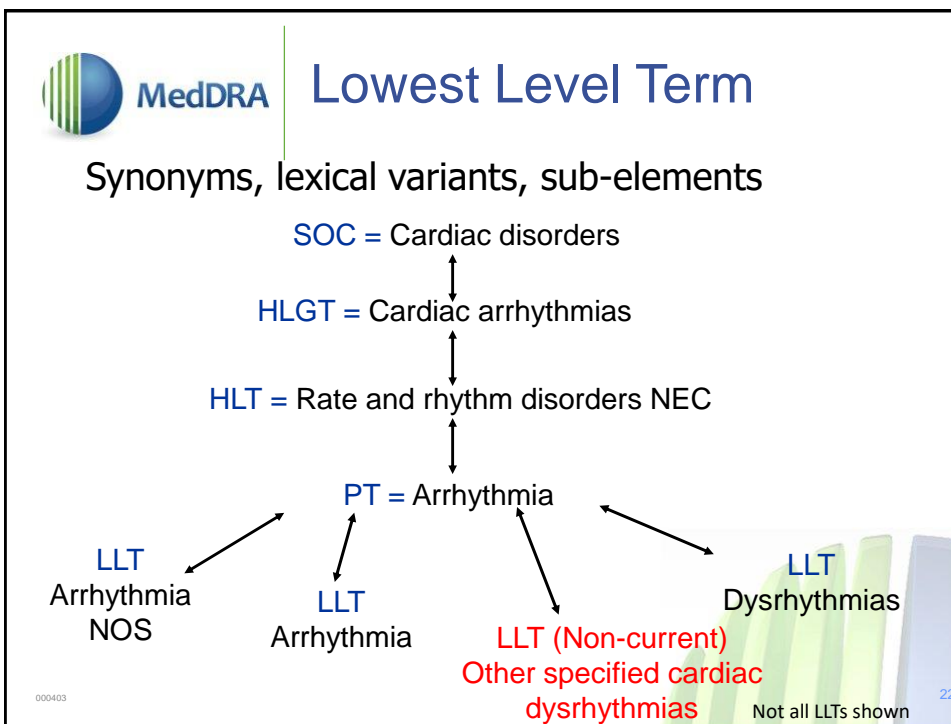
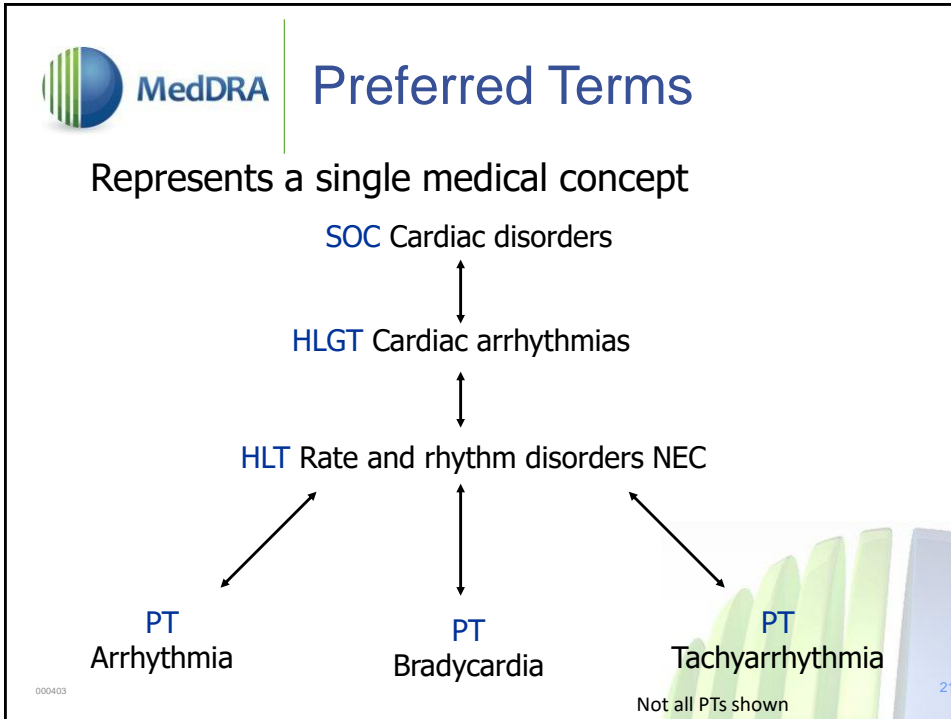
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## Non-Current Terms

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

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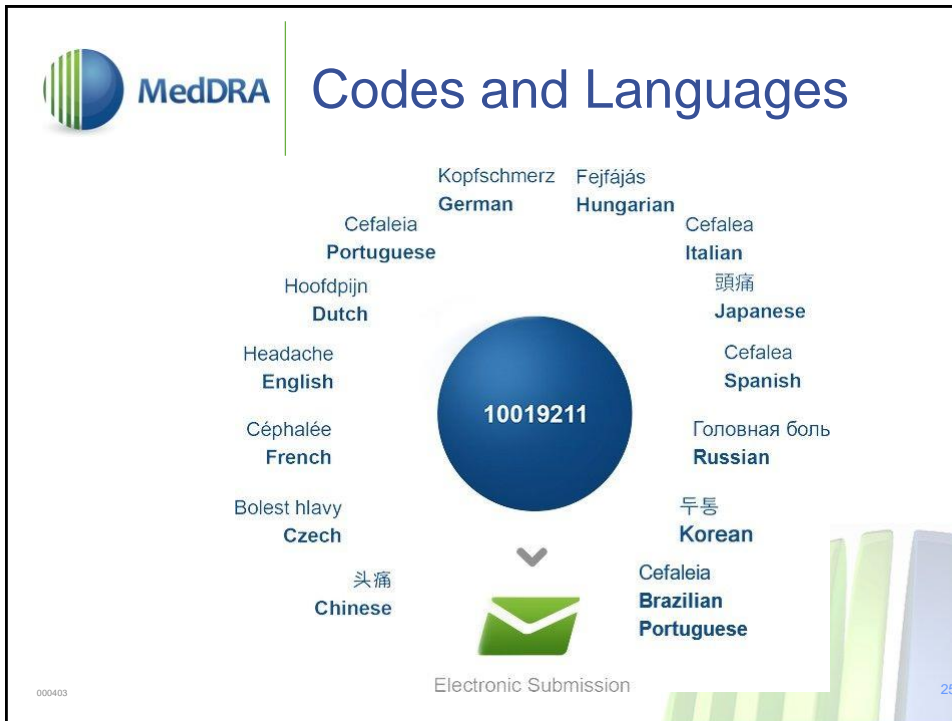
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## MedDRA Codes

- Each MedDRA term assigned an 8-digit numeric code starting with "1"
- The code is non-expressive
- Codes can fulfill a data field in various electronic submission types (e.g., E2B)
- New terms are assigned sequentially

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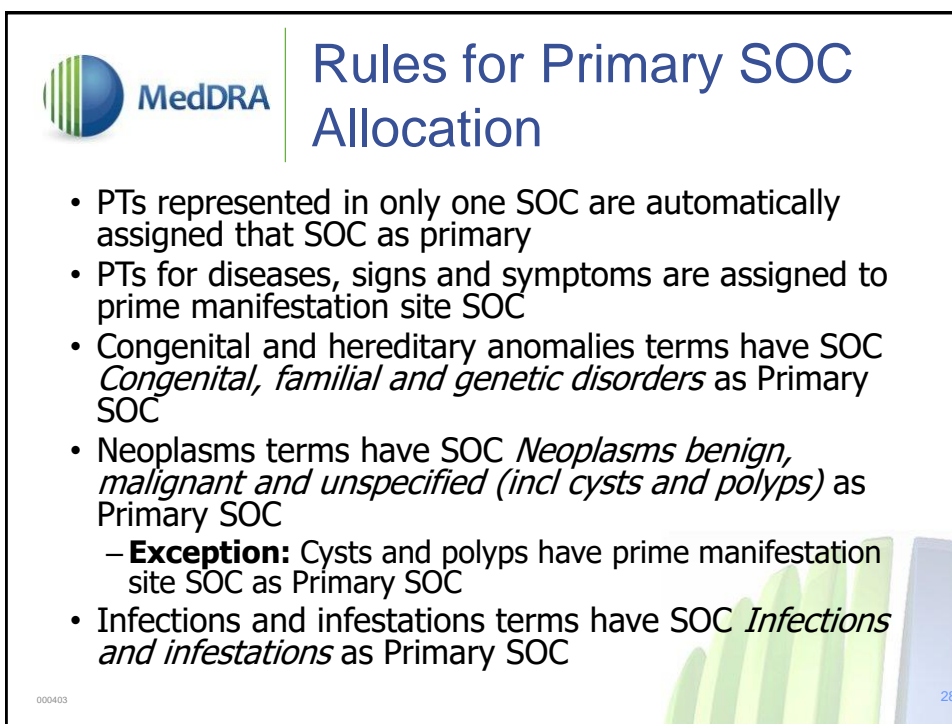
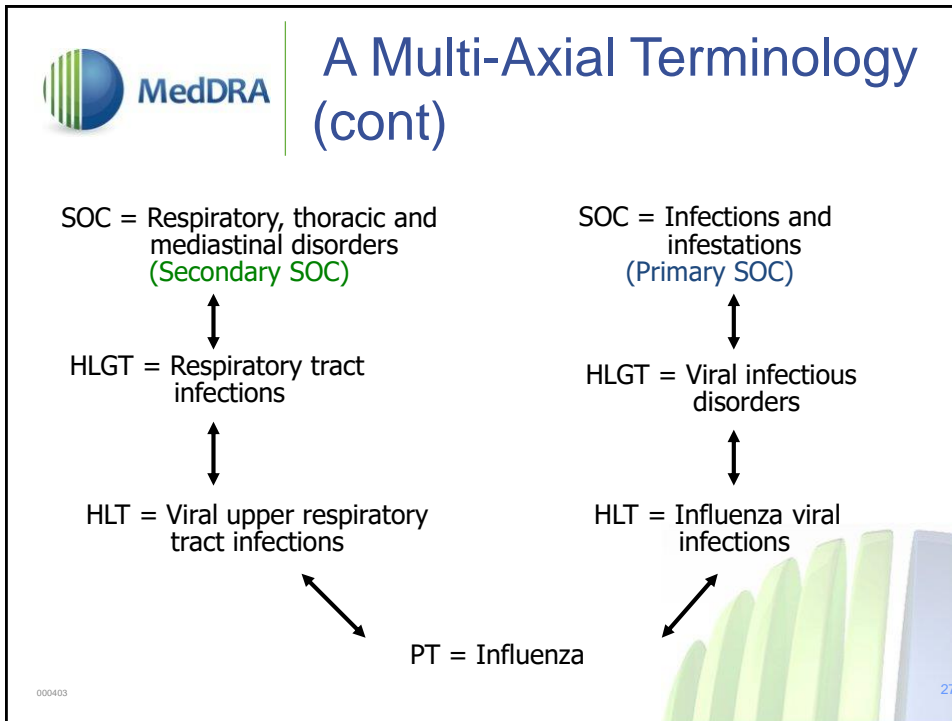


## A Multi-Axial Terminology

- 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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## 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<sup>st</sup>: Congenital, familial and genetic disorders*
- 2<sup>nd</sup>: Neoplasms benign, malignant and unspecified (incl cysts and polyps)*
- 3<sup>rd</sup>: 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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## 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 Maintenance





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## MedDRA Maintenance

- Users can send change requests (CRs) to MSSO for consideration
  - Organizations allowed 100 CRs/month
  - For simple changes (PT and LLT levels), response within 7-10 working days
  - Complex changes (above PT level) posted for comments mid-year
- Two MedDRA updates/year
  - 1 March X.0 (Complex release)
  - 1 September X.1 (Simple release)

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## WebCR


- Web-based tool for Change Requests (CR)
  - URL: <https://mssotools.com/webcr/>
  - Via the Change Request Information page
- Ability to submit CRs online
  - Requests must be in English
- Immediate confirmation
- Review unsubmitted CRs online
- Ability to query CR history back to v5.1

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# MedDRA Submitting Changes



**WebCR**  
MedDRA Change Request

[MedDRA Documentation](#)

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**Login to WebCR**

MedDRA ID:


Password:

Welcome to the MedDRA User Change Request Data Entry Web site.  
You may submit your MedDRA Change Request to the MSSO here.  
If you have problems logging in, please contact the MSSO Help Desk at:  
[MSSOHelp@meddra.org](mailto:MSSOHelp@meddra.org) or 1-877-256-8280

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- Online change request submission tool
- Guides the user to enter all needed information

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# MedDRA Submitting Changes (cont)

**Add a New PT**

**Proposed PT (Required)**

**Primary HLT (Optional)**

**Primary SOC (Optional)**

**Secondary HLT (Optional)**

**Secondary SOC (Optional)**

**Justification statement is required**


**Justification**  
Please consider including the gradation of chemical burns similar to the gradation of thermal burns under HLT Thermal burns to assist with coding and analysis.

**Attach supporting document (Optional)**

Attachment  
C:\Users\is804733\Desktop\Supportinginforma Browse...


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

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## MedDRA Submitting Changes (cont)

**Add a New PT**

**Proposed PT (Required)** 

Second degree chemical burns of skin

**Primary HLT (Optional)**

Chemical injuries

**Primary SOC (Optional)**

Injury, poisoning and procedural complications


**Secondary HLT (Optional)**

Dermatitis ascribed to specific agent

**Secondary SOC (Optional)**

Skin and subcutaneous tissue disorders

**Justification statement is required**

**Justification** 


Please consider including the gradation of chemical burns similar to the gradation of thermal burns under HLT Thermal burns to assist with coding and analysis.

**Attach supporting document (Optional)**

Attachment  
000403 C:\Users\is804733\Desktop\Supportinginforma Browse...

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

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## MedDRA 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 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)
  - Search Term Change (identifies changes to a single MedDRA term or code)

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## 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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## 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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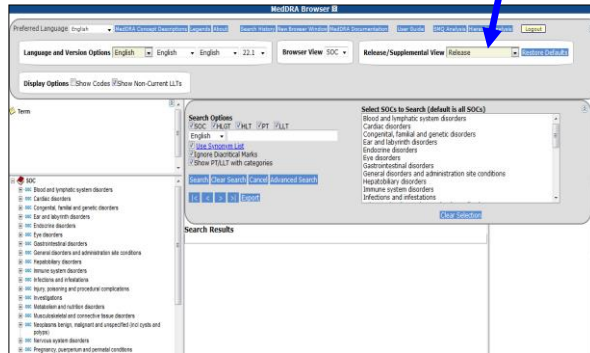
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## Data WBB Supplemental View

Change View to Supplementals

- Where will Change Requests I submitted appear in next release of MedDRA?
- What are the changes in an area of MedDRA in the next release?



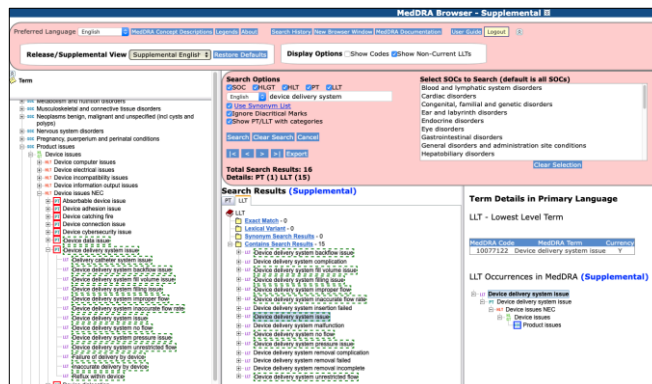
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## WBB Supplemental View (cont)

- Display changes color to pink
- Supplemental terms highlighted by broken green line
- Changes for the next release are displayed immediately after they are approved by the MSSO

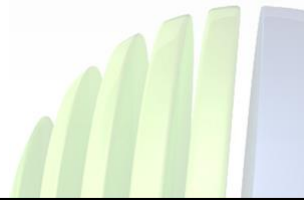


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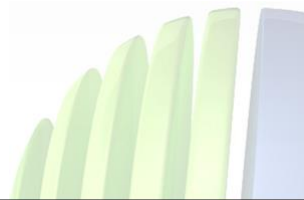
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## MedDRA Browser Demonstration and Instruction



## 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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## MedDRA Browsing Tips

- First, try using actual words from reporter
- Use “top-down” and “bottom-up” approaches
- Look at the “neighbors” and check the hierarchy
- Consider synonyms, e.g., “Liver” and “Hepatic”
- Use word stems, e.g., “Pancrea”

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## MedDRA Browsing Tips (cont)

- 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

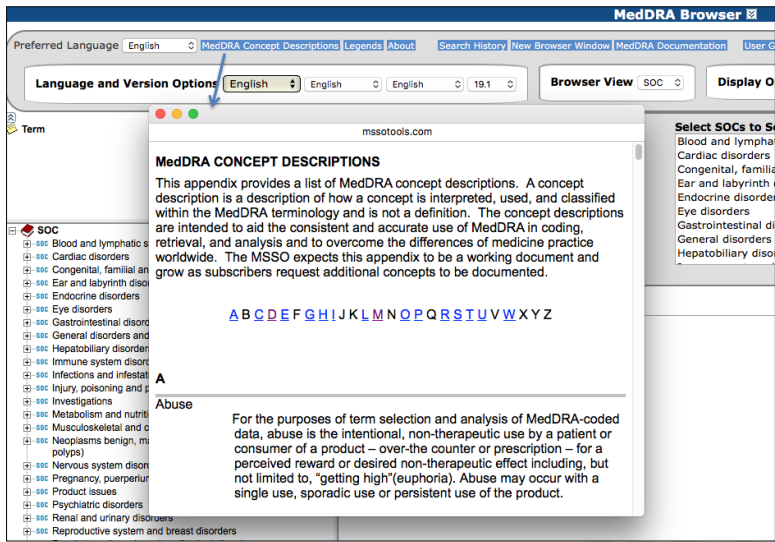
- Descriptions of how a concept is interpreted, used, and classified in MedDRA
- Not a definition
- Intended to aid accurate and consistent use of MedDRA in coding and retrieval
- Overcome differences in medical practice worldwide
  - Descriptions aim to be broadly consistent with definitions across different regulatory regions
- See Appendix B of MedDRA Introductory Guide
- Accessible in MSSO's Browsers

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# MedDRA Concept Descriptions (cont)



The screenshot shows the MedDRA Browser interface. A window titled 'MedDRA CONCEPT DESCRIPTIONS' is open, displaying the following text:

**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.

Below the text is an alphabetical index: **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**

The letter **A** is selected, and the following text is displayed:


**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.

On the left side of the browser, a list of SOC categories is visible, including: Blood and lymphatic disorders, Cardiac disorders, Congenital, familial and hereditary disorders, Ear and labyrinth disorders, Endocrine disorders, Eye disorders, Gastrointestinal disorders, General disorders and symptoms, Hepatobiliary disorders, Immune system disorders, Infections and infestations, Injury, poisoning and toxicology, Investigations, Metabolism and nutrition disorders, Musculoskeletal and connective tissue disorders, Neoplasms (benign, malignant and unspecified), Nervous system disorders, Pregnancy, puerperium and postnatal conditions, Product issues, Psychiatric disorders, Renal and urinary disorders, and Reproductive system and breast disorders.

On the right side, a 'Select SOCs to Show' panel lists: Blood and lymphatic disorders, Cardiac disorders, Congenital, familial and hereditary disorders, Ear and labyrinth disorders, Endocrine disorders, Eye disorders, Gastrointestinal disorders, General disorders and symptoms, Hepatobiliary disorders, Immune system disorders, Infections and infestations, Injury, poisoning and toxicology, Investigations, Metabolism and nutrition disorders, Musculoskeletal and connective tissue disorders, Neoplasms (benign, malignant and unspecified), Nervous system disorders, Pregnancy, puerperium and postnatal conditions, Product issues, Psychiatric disorders, Renal and urinary disorders, and Reproductive system and breast disorders.

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# MedDRA Exercise 1

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

\_\_\_\_\_ LLT → \_\_\_\_\_ PT

\_\_\_\_\_ LLT → \_\_\_\_\_ PT

\_\_\_\_\_ LLT → \_\_\_\_\_ PT

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## Exercise 2

Lab results indicate an increase in erythrocytes.

\_\_\_\_\_ LLT → \_\_\_\_\_ PT

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## 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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## Coding with MedDRA

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## What are Coding Conventions?

- Written guidelines for coding with MedDRA in your organization
- Support accuracy and consistency
- Common topics
  - Misspellings, abbreviations and acronyms
  - Combination terms and "due to" concepts
  - "Always query" terms, e.g., "Chest pain"
- Should be consistent with the MedDRA Term Selection: Points to Consider document

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## Why Do We Need Coding Conventions?

- Differences in medical aptitude of coders
- Consistency concerns (many more “choices” to manually code terms in MedDRA compared to older terminologies)
- Even with an autoencoder, 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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## Synonym Lists

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

Verbatim	LLT	Comment
Throbbing above temple Aching all over head Pulsing pain in head	Headache	
Muscular pain in legs	Myalgia of lower extremities	LLT <i>Myalgia of lower extremities</i> is a better choice than LLT <i>Muscular pain</i> 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 (verbatim to coded terms; coded term to verbatims; by SOC, etc.)

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### 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	1
			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 never be reported as AEs
  - 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*
  - > 3,900 terms in v23.0
- Explanatory document
  - Purpose, uses, development of list
- Also available in Japanese on JMO website

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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)

November 2017, Geneva, Switzerland

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## PtC Documents

PtC Category	PtC Document	Purpose	Languages	Release Cycle
<b>Term Selection</b>	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
<b>Data Retrieval and Presentation</b>	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
<b>General</b>	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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## 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 4.1 – Versioning (Appendix)
  - 4.1.1 Versioning methodologies
  - 4.1.2 Timing of version implementation

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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
- Selecting More than One Term
- Check the Hierarchy
- 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
- If terms are incorrectly placed, submit a change request to the MSSO

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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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## 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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## Selecting More than One Term Check the Hierarchy

- Can select more than one LLT to represent reported information. Document procedures.
  - Selecting one term may lead to loss of specificity
  - Selecting more than one term may lead to redundant counts
- Check the hierarchy above a selected LLT (PT, HLT, HLGT, SOC) to ensure placement accurately reflects meaning of reported term

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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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## 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*

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## Important Coding Errors (cont)

- “Soft Coding”
  - Selecting a term which is both less specific and less severe than another MedDRA term is “soft coding”
  - Example: “*Liver failure*” coded as hepatotoxicity or increased LFTs
  - Example: “*Aplastic anemia*” coded as unspecified anemia
  - Example: “*Rash subsequently diagnosed as Stevens Johnson syndrome*” coded as rash

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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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## 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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## 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>

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	Single provisional diagnosis with signs/symptoms
•Alternate: Diagnosis and 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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## What Terms 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 <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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## What Terms to Select?

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

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

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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

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## What Terms 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 <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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## What Terms 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
- Patient had features of aldosterone excess  
 Aldosterone increased  
 Aldosteronism  
 Blood aldosterone abnormal

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## Medication Errors

- See Appendix B of MedDRA Introductory Guide or MedDRA Browser (both WBB and MDB) for Concept Descriptions
- See Section 3 of MedDRA Points to Consider Companion Document for detailed examples, guidance and "Questions and Answers"
- "Top-down" navigation in HLGT *Medication errors and other product use errors and issues* is best approach for term selection

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## Medication Errors (cont)

- Medication error with clinical consequences

Reported	LLT Selected	Comment
Patient was administered wrong drug and experienced hypotension	Wrong drug administered Hypotension	
Insulin was given using the wrong syringe resulting in the administration of an overdose. The patient developed hypoglycaemia.	Drug administered in wrong device Accidental overdose Hypoglycaemia	If an overdose is reported in the context of a medication error, the more specific term <i>LLT Accidental overdose</i> can be selected

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## Medication Errors (cont)

- Medication error without clinical consequences

Reported	LLT Selected	Preferred Option
Medication was given intravenously instead of intramuscularly without any adverse effect	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 potential occurrence of medication error
- Unlikely to be reported as an adverse event but may need to be recorded in periodic safety reports

Reported	LLT Selected	Comment
Pharmacist notices that the names of two drugs are similar and is concerned that this may result in a medication error	Drug name confusion  Circumstance or information capable of leading to medication error	Note: this example is a potential medication error and LLT <i>Drug name confusion</i> provides additional information about the nature of the potential medication error

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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 to Select?

- The patient's renal function was measured every six months instead of on the monthly schedule recommended in the label for the drug
  - Medication monitoring error
  - Renal function test abnormal
  - Drug monitoring procedure incorrectly performed
- Unintentionally took more than maximum recommended dose due to dispensing error
  - Accidental overdose
  - Incorrect dose administered
  - Drug dispensing error

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## Misuse, Abuse and Addiction

Concept	Intentional?	By Whom?	Therapeutic Use?	Additional Sections in this Document
Misuse	Yes	Patient/consumer	Yes*	3.16.1
Abuse	Yes	Patient/consumer	No	3.16.2
Addiction	Yes	Patient/consumer	No	3.16.3
Medication error	No	Patient/consumer or healthcare provider	Yes	3.15
Off label use	Yes	Healthcare provider	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 (also record PT and primary SOC)

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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

- In this course, we covered:
  - A review of MedDRA's scope and structure, including primary SOC allocation rules
  - Coding conventions, synonym lists, and coding QA
  - Introduction to the MedDRA Term Selection: Points to Consider document
  - Coding exercises

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## MSSO Contacts

- Website
  - [www.meddra.org](http://www.meddra.org)
- Email
  - [msohelp@meddra.org](mailto:msohelp@meddra.org)
- Frequently Asked Questions
  - [www.meddra.org/faq](http://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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