



Coding with MedDRA



MedDRA was developed under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Board, which is composed of the six ICH parties (EU, EFPIA, MHLW, JPMA, FDA, PhRMA), 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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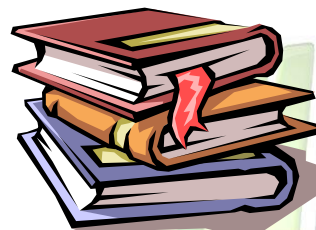


MedDRA Background



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

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

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 Board (industry, regulators, multi-national, other interested parties)

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MedDRA

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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Regulatory Status

- US FDA
 - Used in several databases including FAERS (drugs and biologics), VAERS (vaccines), and CAERS (foods, dietary supplements, cosmetics)
 - Recommended terminology for adverse event reporting in several Proposed Rules and Guidances
 - Effective June 2015, electronic submission required for postmarketing safety reports for drugs, biologics, and vaccines (relies upon ICH standards)
- Japanese Ministry of Health, Labour and Welfare
 - Mandatory use in electronic reporting

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Regulatory Status (cont)

- European Union
 - EudraVigilance database
 - Clinical trial SUSARs (Suspected Unexpected Serious Adverse Reactions)
 - Post-authorization Individual Case Safety Reports (ICSRs)
 - Requires current version of MedDRA or the one previous to it
 - Good pharmacovigilance practices (GVP) specifically mention MedDRA
 - Pharmacovigilance legislation covers suspected adverse reactions from:
 - Use inside **and outside** terms of marketing authorization
 - Overdose, misuse, abuse, and medication errors
 - Occupational exposures

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Regulatory Status (cont)

- European Union (cont)
 - Used in interface between EudraVigilance and EU Risk Management Plan
 - Used throughout Summary of Product Characteristics (labeling)
- ICH M4E Guideline on Common Technical Document
 - Recommended in adverse event summary tables
- Canada
 - Used in Canada Vigilance database
 - Recommended/preferred terminology for adverse reaction reporting and Product Monograph (labeling)
 - Electronic reporting via Gateway requires current version of MedDRA

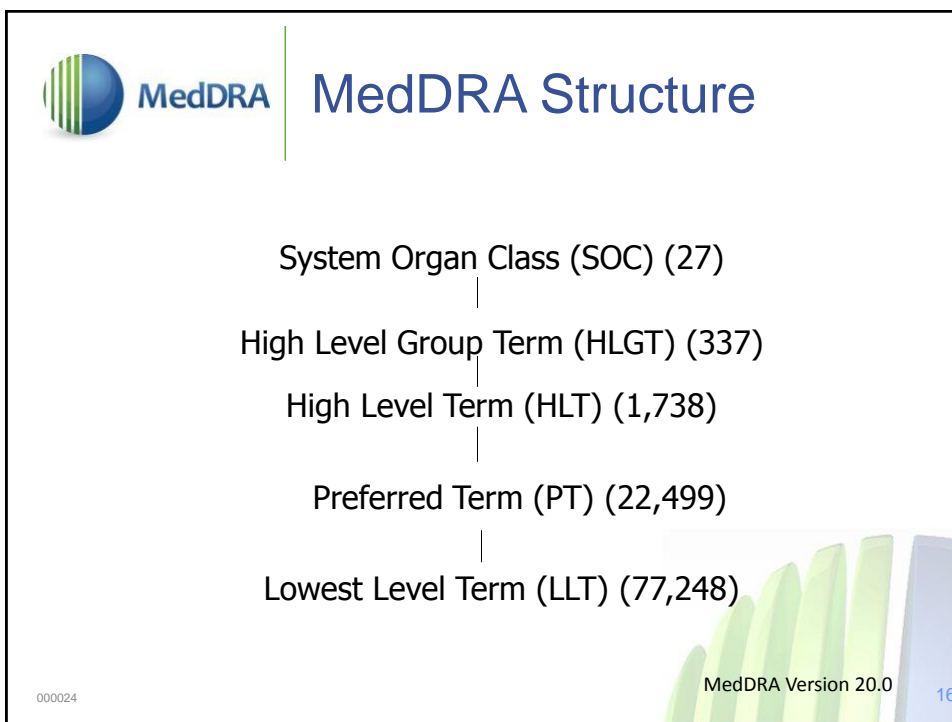
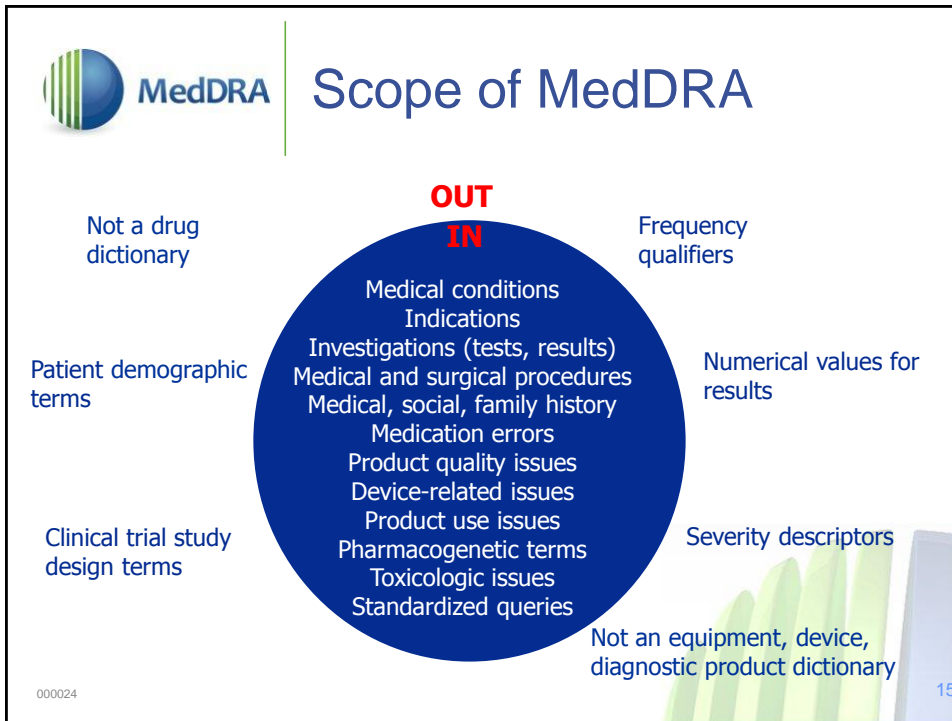
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MedDRA Overview





MedDRA

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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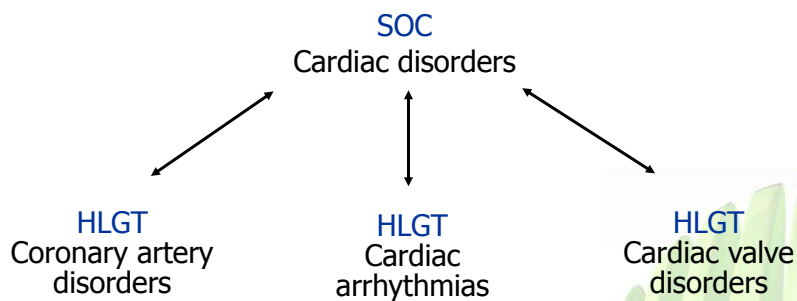
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High Level Group Terms

Subordinate only to SOCs and superordinate grouping for one or more HLTs



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Not all HLTs shown

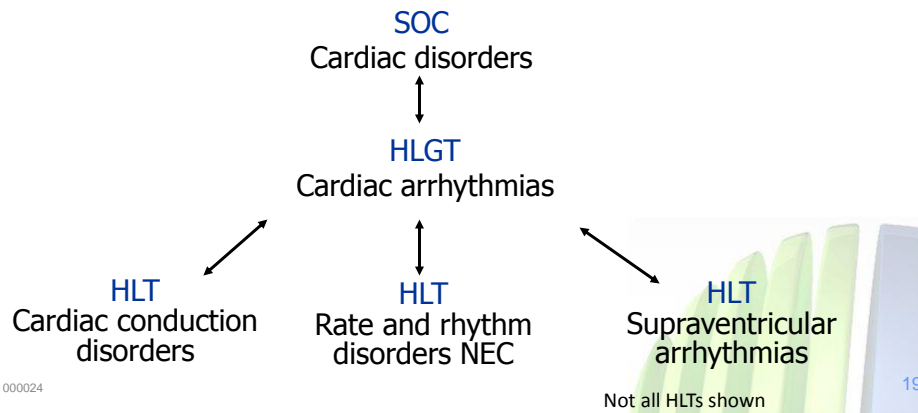
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High Level Terms

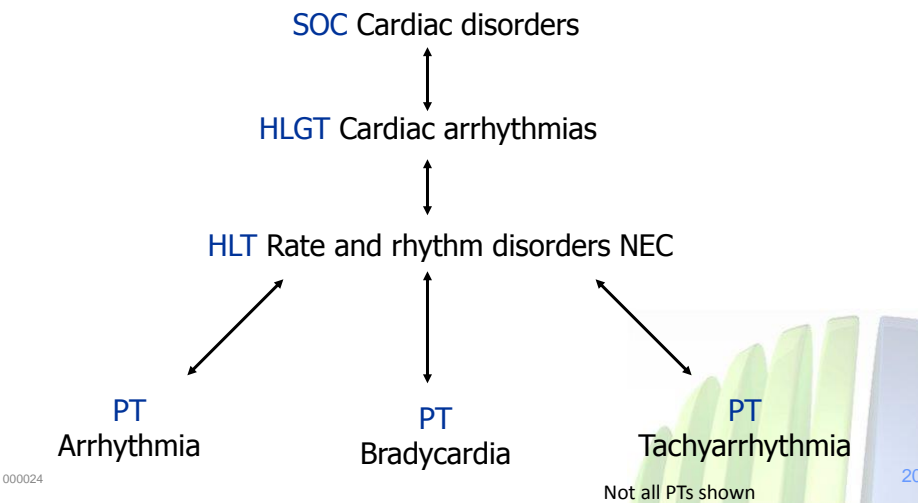
Subordinate to HLGTs and superordinate grouping for the PTs linked to it

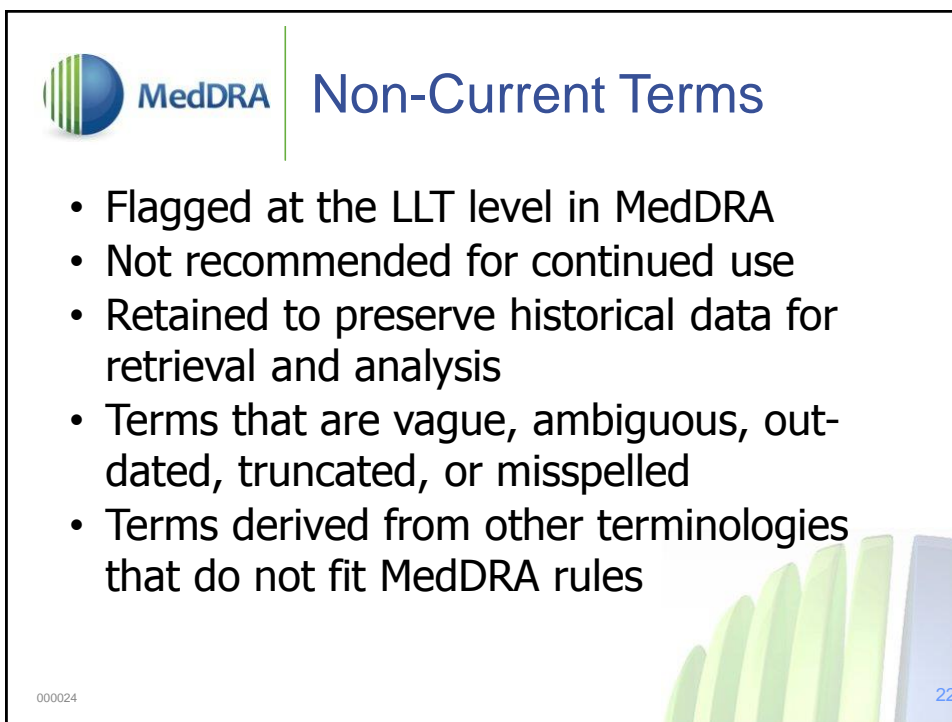
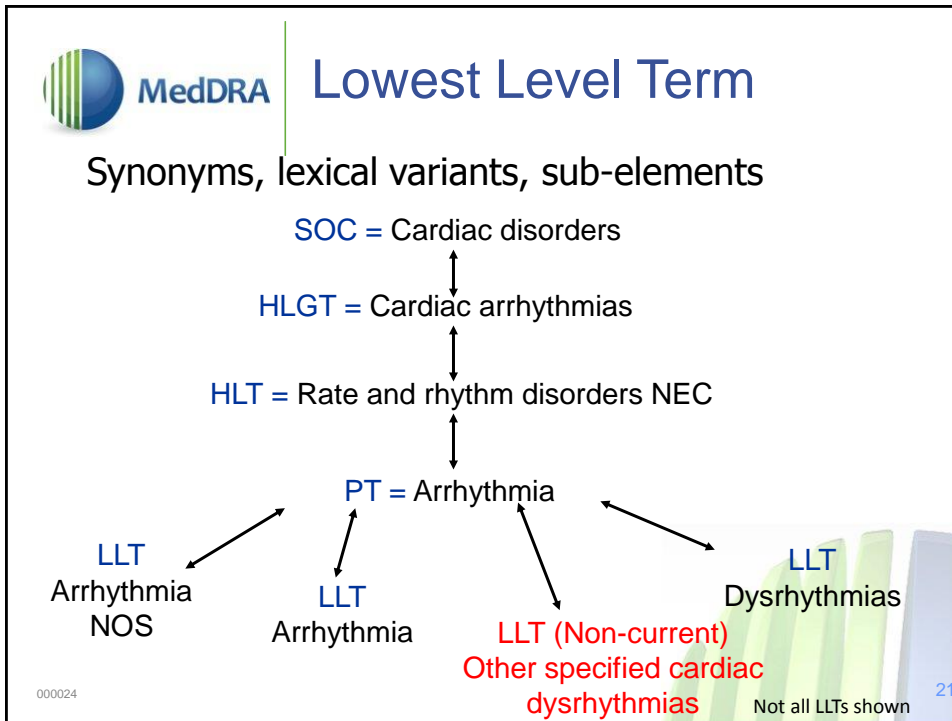


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Preferred Terms

Represents a single medical concept







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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

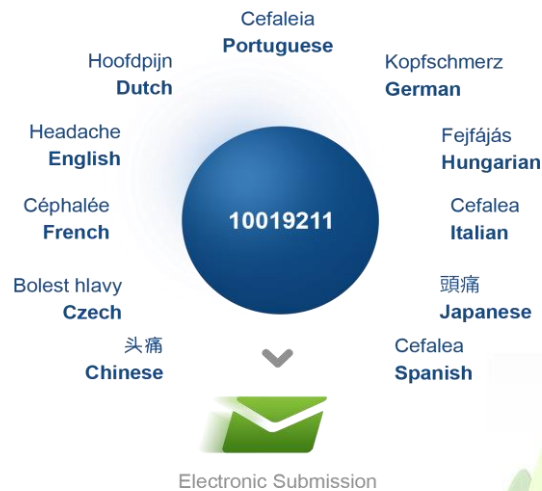
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Codes and Languages



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A Multi-Axial Terminology

- Multi-axial = the representation of a medical concept in multiple SOC
 - Allows grouping by different classifications
 - Allows retrieval and presentation via different data sets
- All PTs assigned a primary SOC
 - Determines which SOC will represent a PT during cumulative data outputs
 - Prevents “double counting”
 - Supports standardized data presentation
 - Pre-defined allocations should not be changed by users

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A Multi-Axial Terminology (cont)

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



HLGT = Respiratory tract infections



HLT = Viral upper respiratory tract infections



PT = Influenza

SOC = Infections and infestations
(Primary SOC)



HLGT = Viral infectious disorders



HLT = Influenza viral infections



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Rules for Primary SOC Allocation

- PTs represented in only one SOC are automatically assigned that SOC as primary
- PTs for diseases, signs and symptoms are assigned to prime manifestation site SOC
- Congenital and hereditary anomalies terms have SOC *Congenital, familial and genetic disorders* as Primary SOC
- Neoplasms terms have SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* as Primary SOC
 - **Exception:** Cysts and polyps have prime manifestation site SOC as Primary SOC
- Infections and infestations terms have SOC *Infections and infestations* as Primary SOC

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Primary SOC Priority

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

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

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A Multi-Axial Terminology (cont)

PTs in the following SOC **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



MedDRA Maintenance

- MedDRA is a user-responsive terminology
- Users may submit change requests (CRs) to the MSSO for consideration
 - Each organization: up to 100 CRs per month
 - For simple changes (PT and LLT levels), notification of final disposition within 7-10 working days
 - Complex changes above PT level received all year round. Posted for users' comments mid-year.
- Twice yearly official updates
 - 1 March X.0 release (Complex and simple changes)
 - 1 September X.1 release (Simple changes only)



MedDRA WebCR

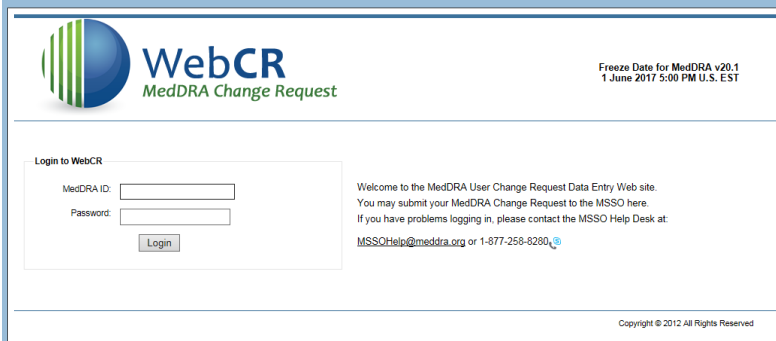
- Web-based tool for Change Requests (CR)
 - URL: <https://mssotools.com/webcr/>
 - Via the Change Request Information page
- Ability to submit CRs online
- Immediate confirmation
- Review unsubmitted CRs online
- Ability to query CR history back to v5.1

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MedDRA Submitting Changes




The screenshot shows the WebCR login interface. At the top left is the MedDRA logo and the text 'WebCR MedDRA Change Request'. At the top right, it says 'Freeze Date for MedDRA v20.1 1 June 2017 5:00 PM U.S. EST'. Below this is a 'Login to WebCR' section with two input fields: 'MedDRA ID:' and 'Password:', followed by a 'Login' button. To the right of the login fields is a welcome message: '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 or 1-877-258-8280.' At the bottom right of the page, it says 'Copyright © 2012 All Rights Reserved'.

- 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) 

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
000024 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

MedDRA Version Analysis Tool (MVAT)

- Web-based (<https://mssotools.com/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)
- User interface and report output available in all MedDRA languages

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MedDRA

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/>
- Features
 - Both 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

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MedDRA Browser Demonstration and Instruction



Coding Exercises





MedDRA

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”
- Use available resources for difficult verbatim terms (web search, medical dictionaries, colleagues)
- Become familiar with MedDRA Concept Descriptions

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MedDRA

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. The main content area displays 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.

ABCDEFGHIJKLMNOPQRSTUVWXYZ

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.

The interface also shows a sidebar with a list of SOC terms and a "Select SOCs to S" panel on the right.

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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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MedDRA

Exercise 4

A six year old boy was admitted for antipsychotic toxicity after accidentally ingesting the remaining 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

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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MedDRA

Quality of Serious Adverse Event (SAE) Reporting in Clinical Trials

- Study finds frequent errors in SAE reports to academic trial sponsors
 - Event verbatim inconsistent with report: 15%
 - Patient outcome not reported: 12.1%
 - Investigational product not identified: 11.2%
 - No causality assessment reported: 9.3%
 - Event seriousness unknown: 3.6%
- Study authors: Knowledge of MedDRA basics and coding practices key to data accuracy and completeness

Crepin S, Villeneuve C, Merle L. Quality of serious adverse events reporting to academic sponsors of clinical trials: far from optimal. Poster at 18th Annual Meeting of French Society of Pharmacology and Therapeutics; 2014 April 22-24, Poitiers, France.

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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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MedDRA

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 (verbatimims to coded terms; coded term to verbatimims; by SOC, etc.)

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MedDRA

QA Sample Report

SOC	HLT	PT	Verbatim	Count
Respiratory, thoracic and mediastinal disorders				
	Bronchospasm and obstruction			
		Wheezing		
			WHEEZING	18
			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 an unqualified test name term list
 - Example: PT *Blood glucose*
 - These terms should never be reported as AEs
 - Intended for use in E2B test name field only
- Standardised, complete list of test name terms is a useful tool for checking data quality
 - Identify inappropriate use of terms in data fields other than test name data element
 - Intended as recommendation only
 - Maintained by MSSO with each MedDRA release

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List Available for Download

Unqualified Test Name Term List / Support Documentation / How to Use

Description
Unqualified test name terms, e.g., PT Blood glucose, are intended for use only in the test name data element in data transmission standards and are not meant for use in other data fields capturing information such as adverse events/adverse reactions, medical history, or indications. The Unqualified Test Name Term List could be helpful to users in regulatory authorities and industry as a standardised query to check data quality by identifying the inappropriate use of unqualified test name terms in data fields other than the test name data element.

Supporting Documentation
Unqualified Test Name Term List (pdf)

Term List
Unqualified Test Name Term List (MedDRA Version 19.1) (xlsx)

- Link on Support Documentation page on MedDRA website
- Spreadsheet of LLT/PT names and codes from SOC *Investigations*
 - >3,600 terms in v19.1
- Explanatory document
 - Purpose, uses, development of list
- Also available in Japanese on JMO website

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List v20.0

◇	A	B	C
1	Term	Code	Level
2	17 ketosteroids urine	10000005	PT
3	17-hydroxycorticosteroid activity	10051618	LLT
4	2',5'-oligoadenylate synthetase test	10058945	PT
5	24 hour electrocardiogram	10073349	LLT
6	5-HIAA urine	10060014	LLT
7	5-hydroxyindolacetic acid	10050342	PT
8	5-hydroxyindolacetic acid in urine	10059972	PT
9	5'nucleotidase	10059898	PT
10	A/G ratio	10000037	LLT
11	Abdomen CT	10077423	LLT
12	Abdomen scan	10061936	PT
13	Abdominal CAT	10057791	LLT
14	Abdominal scan NOS	10000091	LLT
15	Abdominal wall biopsy	10000102	LLT
16	Abdominal X-ray	10061612	PT
17	Abdominal X-ray NOS	10050402	LLT
18	Absolute lymphocyte count	10073552	LLT
19	Absolute neutrophil count	10052033	LLT

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MedDRA

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

MedDRA® TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Release 4.13

Based on MedDRA Version 20.0

1 March 2017

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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



MedDRA

MedDRA Term Selection: PTC (cont)

- Developed by a working group of the ICH Steering Committee
 - Regulators and industry representatives from EU, Japan, and USA
 - Canadian and Korean regulatory authorities
 - WHO
 - MSSO and JMO
- Updated twice yearly with each MedDRA release
- Available on MedDRA and JMO websites
 - English and Japanese
 - Word (“clean” and “redlined”), PDF, HTML formats
 - “Redlined” document identifies changes made from previous to current release of document

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MedDRA

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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MedDRA

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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MedDRA

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

- 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)

Acknowledgement: Dr. Toni Piazza-Hepp, Office of Surveillance and Epidemiology, CDER, FDA

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

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Similar principles apply for multiple diagnoses

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Diagnoses and Provisional Diagnoses (cont)

- Always include signs/symptoms not associated with diagnosis

Reported	LLT Selected
Myocardial infarction, chest pain, dyspnoea, diaphoresis, ECG changes and jaundice	Myocardial infarction Jaundice (note that jaundice is not typically associated with myocardial infarction)

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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

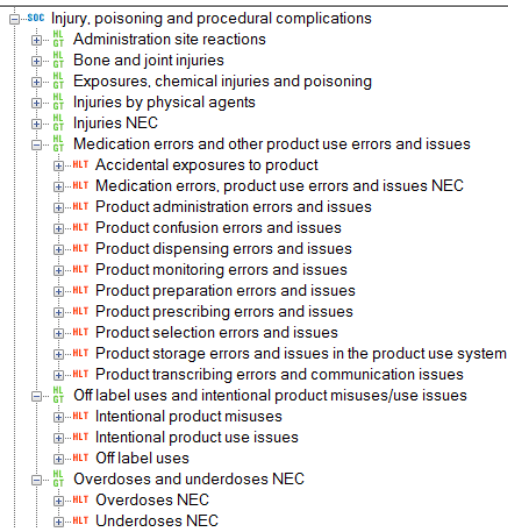
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New Medication Errors/Product Use Issues Hierarchy



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Advantages of New Hierarchy

- Avoids force-classification of medication errors vs. product use issues
- Classification by stage in the medication/product use process
 - Prescribing
 - Dispensing
 - Preparation for administration
 - Administration
 - Storage in product use system
- Intercepted medication errors under relevant stage HLTs
- Intentional concepts separated from errors/unspecified issues
- “Product” at HLT level covers medication and other product concepts such as device use/error terms

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What Terms to Select?

- Due to a prescribing error, the child was given drug X, which is labeled for use in adults only

Adult product administered to child

Accidental overdose

Drug prescribing error

Medication error

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Medication Errors (cont)

See Appendix B of MedDRA Introductory Guide or MedDRA Browser (both WBB and MDB) for Concept Descriptions

“Top-down” navigation in HLGT *Medication errors and other product use errors and issues* is best approach for term selection

- 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
 Therapeutic drug monitoring analysis incorrectly performed
 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
- Email
 - msohelp@meddra.org
- Frequently Asked Questions
 - www.meddra.org/faq

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